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DRUGS AND CRIME PREVENTION COMMITTEE

# INQUIRY INTO MISUSE/ABUSE OF BENZODIAZEPINES AND OTHER PHARMACEUTICAL DRUGS

FINAL REPORT DECEMBER 2007







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**PARLIAMENT OF VICTORIA**  
**DRUGS AND CRIME PREVENTION COMMITTEE**

**INQUIRY INTO THE MISUSE/ABUSE OF  
BENZODIAZEPINES AND OTHER FORMS OF  
PHARMACEUTICAL DRUGS IN VICTORIA**

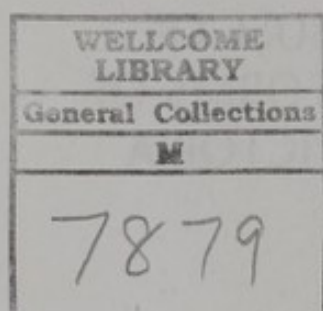
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Mr David Morris M.L.A., *Mornington* – Deputy Chairman  
Mr André Haermeyer M.L.A., *Kororoit* (from 21 June 2007)  
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## **Drugs and Crime Prevention Committee – 55th Parliament**

### ***Members***

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The Hon. Robin Cooper M.L.A., *Mornington* – Deputy Chairman  
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## Functions of the Drugs and Crime Prevention Committee

The Victorian Drugs and Crime Prevention Committee is constituted under the *Parliamentary Committees Act 2003* (Vic) as amended.

### Section 7

The functions of the Drugs and Crime Prevention Committee are, if so required or permitted under this Act, to inquire into, consider and report to the Parliament on any proposal, matter or thing concerned with:

- a. the use of drugs including the manufacture, supply or distribution of drugs;
- b. the level or causes of crime or violent behaviour.

## Terms of Reference

That under s 33 of the *Parliamentary Committees Act 2003* the following matter be referred to the Drugs and Crime Prevention Committee – for inquiry, consideration and report no later than 30 November 2007 on the misuse/abuse of benzodiazepines and other forms of pharmaceutical drugs in Victoria with particular regard to:

1. examining the nature, extent and culture of the misuse/abuse of benzodiazepines and other forms of pharmaceutical drugs;
2. examining the short and long-term consequences/harms of the abuse/misuse of benzodiazepines and other forms of pharmaceutical drugs;
3. examining the relationship between benzodiazepines and other forms of pharmaceutical drugs and other forms of licit and illicit substance use;
4. reviewing the adequacy of existing strategies for dealing with benzodiazepines and other forms of pharmaceutical drugs misuse/abuse;
5. recommending best practice strategies to address the issue of benzodiazepines and other forms of pharmaceutical drugs, including regulatory, law enforcement, education and treatment responses; and
6. examining national and international legislation, reports and materials relevant to the issue.

Dated: 1 March 2007

## Acknowledgements

The Committee wishes to acknowledge the valuable contribution of Professor Steve Allsop, Associate Professor Simon Lenton, Dr Susan Carruthers and Mr James Fetherston of the National Drug Research Institute, Curtin University of Technology as consultants to the *Interim Report*. Where relevant this work has been incorporated into the *Final Report*. The Committee also recognises Dr Nicole Lee and Ms Suzi Nielsen from Turning Point Alcohol and Drug Centre for their assistance in drafting Chapter 7.1 and 7.2.

The Committee also wishes to thank Mignon Turpin for her editing work, Matt Clare of Mono Design for the cover design and Mary Silvestro and Chris Watson for laying out the report.

## Chair's Foreword

It is with pleasure I present the Final Report into the Misuse and Abuse of Benzodiazapines and Opioid Analgesics.

Firstly I would like to thank Johan Scheffer and the members of the Drugs and Crime Prevention Committee of the 55th Parliament for their initial work on this Inquiry.

The most telling part of our investigations was the realisation that many people within the community do not perceive prescription drug abuse to be a form of drug abuse. Consequently, they are unaware of the harms that are associated with the misuse and abuse of prescription medications. The Committee has also been concerned by the lack of research information available on the legal and illegal use of benzodiazapines and opioid analgesics in the community, both locally and overseas. Much of the information the Committee received was anecdotal.

However there was general agreement amongst health professionals and those people that have abused these medications that these drugs can be dependency inducing and that some people can become dependent in a short period of time. The Committee received evidence that benzodiazepines should not be prescribed for periods longer than two weeks, without good reason as dependency can quickly ensue.

These drugs are widely prescribed in our community and yet they do have significant side effects. During our investigations a number of areas of concern were raised about the effects of these drugs both on the individual and the community in general.

Evidence overseas does show however that the illegal procurement of these drugs and their subsequent abuse can be significantly decreased by the introduction of a centralised real-time online prescription recording service, and many people in Victoria believe that this would be a step forward in Australia in combating illegal access, in particular the phenomenon of 'doctor shopping'.

Finally I would like to thank the excellent parliamentary staff at the Drugs and Crime Prevention Committee, Sandy Cook, Pete Johnston, Chantel Churchus, Michelle Summerhill and Dominique Comber-Sticca for their dedication and hard work in the preparation of this report.

**Judy Maddigan**

Chair





# Recommendations

The Drugs and Crime Prevention Committee recommends that the Victorian Government undertake actions in the following areas:

## Education

### Community

1. Develop a state-wide comprehensive public education campaign on benzodiazepines and opioid analgesics, along the lines of the QUIT, TAC or WorkCover campaigns that is based on best practice. This campaign should include information on the:
  - ♦ Risks and harms associated with misuse
  - ♦ Questions to ask your doctor and pharmacist
  - ♦ Negative effects of sharing medication
  - ♦ Appropriate storage of medicines, use-by dates and appropriate disposal
  - ♦ Treatment options and support services.
  - ♦ The harms associated with poly drug use.
2. The information presented in the campaign should also be tailored to particular demographic groups such as specific age groups, culturally and linguistically diverse communities, people with mental illness, Indigenous groups, those suffering with chronic pain, intravenous drug users and drivers of motor vehicles who are concurrently taking prescription or pharmaceutical medications. The information should be tailored to meet their specific needs.
3. Investigate appropriate methods of delivering information and education to targeted groups within the community such as mainstream media, community radio, community newspapers, the workplace, community leaders and via modern technologies such as SMS and the Internet.

### Doctors

4. Work with professional bodies and university medical faculties to develop and deliver undergraduate, professional and mandatory ongoing education and training for Victorian doctors on best practice benzodiazepine and opioid analgesic prescribing and management. Such training should be updated regularly and provided on an ongoing basis to provide a level of competency standards required of doctors and other prescribing health professionals to practise in Victoria. Such training could include:
  - ♦ Risks associated with long-term use of benzodiazepines and analgesic opioids
  - ♦ Importance of regular reviews of benzodiazepine dosing
  - ♦ Alternatives to pharmacological treatments for patients suffering from pain, anxiety or sleep disorders
  - ♦ Appropriate management of benzodiazepine and opioid analgesic withdrawal (including tapering)
  - ♦ Identifying signs of dependence in patients and making referrals to a service that can appropriately manage that person's misuse or abuse
  - ♦ Importance of liaison and communication between doctors and pharmacists at a local level.
5. The Medical Practitioners Board of Victoria be responsible for developing appropriate prescribing standards and distributing authoritative information to doctors in relation to safe prescribing of benzodiazepines and opioid analgesics.



### *Nurses, allied health professionals and medical centre staff*

6. Recommend to relevant professional bodies and universities that they develop and deliver undergraduate and ongoing education and training to nurses and allied health professionals on best practice benzodiazepine and opioid analgesic prescribing and pain and sleep disorder management.
7. Recommend to relevant professional bodies and tertiary institutions that they develop and deliver education and training to drug and alcohol workers and non-professional medical centre staff on best practice benzodiazepine and opioid analgesic prescribing, and pain and sleep disorder management.
8. The Nurses Board of Victoria be responsible for developing appropriate dispensing standards and distributing authoritative information to nurses in relation to safe dispensing of benzodiazepines and opioid analgesics.

### *Pharmacists*

9. Recommend to relevant professional bodies and universities that they develop and deliver undergraduate education and training and postgraduate and ongoing professional development on:
  - ◆ Best practice benzodiazepine and opioid analgesic dispensing and pain and sleep disorder management
  - ◆ Pharmacists duty of care to patients/clients
  - ◆ Customer education
  - ◆ Alternatives to pharmacological treatments for patients suffering from pain, anxiety or sleep disorders.
10. Recommend to pharmacy organisations that they encourage their members wherever practicable to provide counselling rooms/private space for detailed consultation and advice. This might include information on medications and pharmacotherapy dispensing.
11. The Pharmacy Board of Victoria be responsible for developing appropriate dispensing standards and distributing authoritative information to pharmacists in relation to safe dispensing of benzodiazepines and opioid analgesics.

### *Patient information*

12. The Health Minister propose, at the next Health Ministers' Conference, that the Australian Pharmaceutical Advisory Council and/or the Therapeutic Goods Administration review the presentation and marketing of prescription and other pharmaceutical medicines to consumers. Such a review should include but not be restricted to:
  - ◆ Increasing the amount of information available to consumers on medication labels and the form in which this is presented (for example size of lettering, community languages)
  - ◆ A general review of the requirements currently mandatory on Consumer Medical Information to ascertain whether they could be improved and strengthened.

### *Harm Reduction*

13. Provide resources for Victorian Needle and Syringe Programmes to deliver ongoing health education programmes for injecting drug users, which include specific information on benzodiazepines and opioid analgesics.

### **Research**

14. Establish a research strategy to address the knowledge gaps apparent in relation to the misuse and abuse of prescription drugs. The research strategy should prioritise the

research issues that have been identified in the academic literature and evidence given before this Committee. This should include research into:

- ◆ The long-term effects of benzodiazepines, in particular the impact of long-term use on cognitive functioning
  - ◆ The long-term efficacy and therapeutic value of benzodiazepines and any problems associated with withdrawal from these drugs
  - ◆ The development by the pharmaceutical industry of 'tamper proof' prescription drugs
  - ◆ The extent to which prescription drugs can be purchased, accessed or traded on illegal Internet sites
  - ◆ The issue of 'doctor shopping' in Victoria and Australia. Such research should not only address the extent to which 'doctor shopping' occurs in Australia but also the cost of this practice to the economy
  - ◆ Current and emerging treatments for benzodiazepine abuse and their effectiveness
  - ◆ The extent of misuse and abuse of prescription medication in particular populations such as those living in rural and regional Victoria, culturally and linguistically diverse communities, Indigenous communities and young people
  - ◆ The extent of misuse and abuse of prescription medication in the workplace
  - ◆ Possible locations where problematic prescribing and dispensing is occurring
  - ◆ The effect of benzodiazepine and opioid analgesic consumption on driving performance
  - ◆ The extent to which prescription drugs are obtained to sell as a means of financing the purchase of illicit drugs
  - ◆ The provision of local level data and research in metropolitan and rural communities.
15. The Health Minister propose, at the next Health Ministers' Conference, that Medicare Australia make available ongoing and timely statistics relating to the Doctor Shopping Programme for research and policy development purposes.

### **Prescription recording service**

16. Develop in consultation with the Pharmacy Board of Victoria, Royal Australian College of General Practitioners, Health Commissioner of Victoria and other relevant health and medical stakeholders an electronic 'real time' prescription recording service that would be available to medical practitioners and pharmacists in Victoria.
17. The Health Minister propose, at the next Australian Health Ministers' Conference, that consideration be given to the rolling out of the prescription recording service at a national level.

### **Prescribing and packaging practices**

18. Consider the development of an electronic prescription system on a state-wide basis with a view to the Health Minister proposing to the Australian Health Ministers' Conference that such a system should be implemented at a national level.
19. In conjunction with relevant pharmacy and medical bodies, consideration of the suitability and efficacy of current packaging arrangements for prescription drugs. In particular, whether packaging of smaller amounts of prescription drugs is feasible and cost effective.
20. In consultation with relevant medical and pharmacy bodies, conduct a review of the current prescription drugs permit system and drug controls. Such a review should include but not be restricted to:



- ◆ Whether benzodiazepines as a general class of drug be considered for rescheduling to Schedule 8 by the National Drugs and Poisons Schedule Committee
- ◆ Whether there should be consideration of revised regulations and guidelines for the prescribing of benzodiazepines. In particular, consideration should be given to the period for which benzodiazepines are permitted to be prescribed (including the prescribing of repeats)
- ◆ Request the Victorian Minister for Health propose at the next Australian Health Ministers' Conference that the Commonwealth Government advocate through the World Health Organization and/or United Nations for an international convention on unauthorised Internet access to prescription drugs.

## **Treatment and management approaches**

### **Alternative treatment models**

21. Investigate emerging treatment models as alternatives to prescribing for anxiety, sleep disorders and pain management. These alternatives would include non-pharmacological treatments such as cognitive behavioural therapy, light therapy.
22. Investigate emerging treatment models including non-pharmacological treatments for benzodiazepine and opioid analgesic dependency and withdrawal.
23. Provide resources to establish additional specialised treatment services for pain management.
24. Consider using existing facilities such as Community Health Centres as appropriate locations for developing services for treatment and management of anxiety, sleep disorders and pain, including outreach services, which address patient needs in a holistic manner.

### **Specific treatment centres**

25. Establish benzodiazepine-specific treatment services, including in-patient withdrawal.

### **Self-help groups**

26. Facilitate and provide grants to develop a network of Self-Help Groups within metropolitan and rural and regional Victoria for people misusing and abusing prescription medications.

### **Services**

27. Provide additional funding to withdrawal and treatment services to develop specialised programmes for those wishing to withdraw and/or seek treatment from prescription drug dependency and abuse.
28. Extend the current length-of-stay for patients withdrawing from benzodiazepines and provide additional support to outpatients.
29. Provide further resources to drug treatment agencies in rural and regional Victoria to allow services to meet the needs of the rural communities.

### **Extension of consulting times**

30. Request the Victorian Minister for Health to propose at the next Australian Health Ministers' Conference that the Commonwealth Government through Medicare Australia develop extended consultation times and Medicare billing allocation codes which allow doctors to adequately discuss anxiety, sleeping disorder and pain management with their patients.

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# List of Abbreviations

ACC	Australian Crime Commission
ADCA	Alcohol and other Drugs Council of Australia
ADEC	Australian Drug Evaluation Committee
ADF	Australian Drug Foundation
ADHD	Attention Deficit Hyperactivity Disorder
ADIN	Australian Drug Information Network
ADIS	Alcohol and Drug Information System
ADRAC	Adverse Drug Reactions Advisory Committee
AHMAC	Australian Health Ministers' Advisory Council
AIC	Australian Institute of Criminology
AIHW	Australian Institute of Health and Welfare
AMA	Australian Medical Association
AMA (Vic)	Australian Medical Association – Victoria
ANCD	Australian National Council on Drugs
ANF	Australian Nursing Federation
APAC	Australian Pharmaceutical Advisory Council
APhA	American Pharmacists Association
ARCOS	Automation of Reports and Consolidated Orders System
ARGOM	Australian Regulatory Guidelines for Over The Counter Medicines
ARGPM	Australian Regulatory Guidelines for Prescription Medicines
ARTG	Australian Register of Therapeutic Goods
ASIPP	American Society of Interventional Pain Physicians
ASSAD	Australian Secondary Students' Alcohol and Drug survey
AUSTFA	Australia–United States Free Trade Agreement
BC	British Columbia
BCS	British Crime Survey
BJA	Bureau of Justice Assistance (U.S.)
CA	Certification Authority
CASA	Center on Addiction and Substance Abuse (U.S.)
CEP	Continuing education programmes
CMC	Case Management Committee
CMEC	Complementary Medicines Evaluation Committee
CMI	Consumer Medicine Information
CREDIT	Court Referral and Evaluation for Drug Intervention and Treatment Program
CSA	Controlled Substances Act 1984 (SA)
CSA (U.S.)	Controlled Substances Act (U.S.)

CSAPR	Controlled Substances Act (Poisons) Regulations 1996 (SA)
CURES	Controlled Substances Utilisation Review and Evaluation System
DAPIS	Drugs and Poisons Information System
DEA	Drug Enforcement Administration (U.S.)
DHHS (U.S.)	Department of Health and Human Services (U.S.)
DHHS	Department of Health and Human Services (Tas)
DHS	Department of Human Services
DoHA	Department of Health and Ageing (Commonwealth)
DPCS	Drugs, Poisons and Controlled Substances (Regulations)
DPCSA	Drugs, Poisons and Controlled Substances Act
DPRG	Drugs and Poisons Regulation Group
DPU	Drugs and Poisons Unit (Department of Human Services Victoria)
DSM	Diagnostic and Statistical Manual
DUMA	Drug Use Monitoring in Australia
DUSC	Drug Utilisation Sub-Committee
DVA	Department of Veterans Affairs
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
EPCS	Electronic Prescriptions for Controlled Substances (U.S.)
ERDS	Ecstasy and Related Drugs Reporting System
FCLC	Federation of Community Legal Centres
FDA	Food and Drug Administration (U.S.)
FSMB	Federation of State Medical Boards (U.S.)
GABA	gamma-aminobutyric acid
GAO	General Accounting Office (U.S.)
GMiA	Generic Medicines Industry Association
GMP	Good Manufacturing Practice
HCRRRA	Health Consumers of Rural and Remote Australia
HHS	Health and Human Services (U.S.)
HIC	Health Insurance Commission
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IDRS	Illicit Drug Reporting System
IFCs	Internet Facilitation Centers (U.S.)
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
INCB	International Narcotics Control Board
IHRA	International Harm Reduction Association
KASPER	Kentucky All Schedule Prescription Electronic Reporting
KBI	Kentucky Bureau of Investigation
MBS	Medical Benefits Scheme



MCDS	Ministerial Council on Drug Strategy
MDMA	Methylenedioxy-methylamphetamine
MEC	Medicines Evaluation Committee
MMT	Methadone Maintenance Treatment
MPBV	Medical Practitioners Board of Victoria
MSC	Medicines Scheduling Committee
MTF	Monitoring the Future
NABP	National Association of Boards of Pharmacy (U.S.)
NAMSDL	National Alliance for Model State Drug Laws (U.S.)
NBV	Nurses Board of Victoria
NCCTG	National Coordinating Committee on Therapeutic Goods
NCETA	National Centre for Education and Training on Addiction
NCIP	National Clearinghouse on Internet Prescribing (U.S.)
NDARC	National Drug and Alcohol Research Centre
NDIC	National Drug Intelligence Centre (U.S.)
NIDA	National Institute on Drug Abuse
NDLERF	National Drug Law Enforcement Research Fund
NDPSC	National Drugs and Poisons Schedule Committee
NDRI	National Drug Research Institute
NDS	National Drug-control System
NDSHS	National Drug Strategy Household Survey
NETA	National e-Health Transition Authority
NHS	National Health Service
NMP	National Medicines Policy
NPA	National Prescription Audit
NPS	National Prescribing Service
NSDUH	National Survey on Drug Use and Health
NSP	Needle and Syringe Programs
ODC	Office of Diversion Control (U.S.)
OHS	Occupational Health and Safety
PADS	Prescription Abuse Data Synthesis
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PDI	Party Drugs Initiative
PDMP	Prescription Drug Monitoring Program
PGA	Pharmacy Guild of Australia
PIN	Patient Identifier Number
PPA	Prescription Pricing Authority
PSA	Pharmaceutical Society of Australia
PSB	Pharmaceutical Services Branch (Tas)

PSC	Poisons Scheduling Committee
PSR	Professional Services Review scheme
PTD	Psychotherapeutic drugs
QCPP	Quality Care Pharmacy Program
QUM	Quality Use of Medicines
RACGP	Royal Australian College of General Practitioners
RADARS	Researched Abuse, Diversion and Addiction-Related Surveillance
RPBS	Repatriation Pharmaceutical Benefit Scheme
RUM	Return of Unwanted Medicines
SAMHSA	Substance Abuse and Mental Health Services Administration
SSRIs	Selective Serotonin Reuptake Inhibitors
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
TAC	Transport Accident Commission
TGA	Therapeutic Goods Administration
TGAC	Therapeutic Goods Advertising Code
TGO	Therapeutic Goods Order
TGVA	Therapeutic Goods (Victoria) Act
TRANX	Tranquilliser Recovery and New Existence
UNIDCP	United Nations International Drug Control Program
UNODC	United Nations Office of Drugs and Crime
UNODCCP	United Nations Office for Drug Control and Crime Prevention
USGAO	United States General Accounting Office
VAADA	Victorian Alcohol And Drug Association
VDHP	Victorian Doctors Health Program
VIFM	Victorian Institute of Forensic Medicine
VIPPS	Verified Internet Pharmacy Practice Sites (U.S.)
VMA	Victorian Metropolitan Alliance
VNHP	Victorian Nurses Health Program
VYADS	Victorian Youth Alcohol and Drugs Survey
WHO	World Health Organization
YSAS	Youth Substance Abuse Service



## **PART A:**

# **Contextualising Misuse of Prescription Drugs**

## **Section One: Background**

### **1.1 Introduction and Background to the Inquiry**

In the United States the abuse of prescription drugs including pain killers, stimulants, sedatives and tranquillisers has gone beyond the abuse levels of practically all illicit drugs, with the exception of cannabis. The abuse rate is higher than that of such drugs as MDMA (ecstasy), cocaine, methamphetamine and heroin. The number of Americans who abuse controlled prescription drugs nearly doubled from 7.8 million to 15.1 million from 1992 to 2003...

The demand for these drugs is so high, that it has given rise to a new problem – that of counterfeit products...The demand of the illicit market in North America for Oxycontin® has lead to distribution of counterfeit products containing illicitly manufactured fentanyl.

An equally serious consequence is that abuse of prescription drugs can have lethal effects. An increasing number of deaths related to abuse of narcotic [analgesics] including fentanyl and oxycodone have been recorded in North America and Europe (International Narcotics Control Board 2007, p.1).

The above quote is taken from the most recent Annual Report of the International Narcotics Control Board. Although the observations quoted relate to North America, the Report stresses that abuse of prescription drugs is increasing to alarming proportions in many countries of the world and it requests:

All governments alert their law enforcement and health authorities as to the rising trafficking and abuse of pharmaceutical products containing controlled substances. The Board also recommends providing adequate information to law enforcement and health authorities as well as to the general public on the risks and possible consequences of their abuse so as to ensure a realistic risk perception (International Narcotics Control Board 2007, p.2).

Despite such concern at both international and local level, one of the most concerning findings of this Inquiry has been the discovery that many people perceive benzodiazepines and opioid analgesics as benign and safe. Consequently, prescription drugs are somehow not viewed as 'drugs of abuse'. Indeed, one of the most difficult challenges posed by this Inquiry is countering this perception. Challenging the culture of drug use and abuse and contesting ideas as to what does or does not count as a 'drug' is a very difficult task.

Evidence provided to this Inquiry demonstrates that many people in the broad community including those who use (and misuse) benzodiazepines and opioid analgesics are ignorant of, or underestimate, the risks. Whilst there is limited understanding of the appropriate uses for benzodiazepines and opioid analgesics, there appears to be variable knowledge about the risks and harms associated with misuse of these drugs. As one Canadian observer has remarked to this Inquiry:

'...when people think of drug problems, they think heroin, cocaine, they really don't put prescriptions drugs into the mix.'<sup>1</sup>

Other experts with whom the Committee has met throughout this Inquiry have also expressed concern about the prevailing community attitude and belief that prescription medications are essentially safe because they have been provided by a healthcare professional. Mr Gino Vumbaca, Executive Officer of the Australian National Council on Drugs, the peak drug advisory body to the federal government, observed in this regard:

...it is a lack of awareness people have about the impact of a prescribed pill, because they think if you go to a doctor and get a script...it's safe. The doctor wouldn't give you something that causes grief.<sup>2</sup>

Discussions with representatives from Victoria's culturally and linguistically diverse communities also painted a clear picture of this lack of awareness:

It is also not uncommon for some people from an ethnic background, especially elderly people, to keep...medication at home. They store it at home just in case something happens. Some could be off-the-shelf medication, but some could be prescribed drugs that they have left over from some other illness that they used to have, and because of the lack of understanding this means they might start sharing medication. If people have similar symptoms, they start sharing the medication among the community.<sup>3</sup>

Official data from the most recent National Drug Strategy Household Survey supports the evidence presented in the discussion above. When respondents were asked to name the drug they thought of when people talked about a drug 'problem', only a total of 0.5 per cent of Australians aged 14 years and older nominated the non-medical use of tranquillisers/sleeping tablets as the drug most associated with a drug 'problem'.<sup>4</sup>

This failure to perceive prescription drugs as potential drugs of abuse can be seen in the following quotes taken from evidence to this Inquiry by courageous women who have struggled for many years with problems associated with prescription drug dependency:

At work I am Mary Smith the pathology nurse and I get along well with my colleagues. Going home can be a nightmare. I immediately think of medication, the minute I start driving home. I have to push myself not to look at doctors' surgeries. In the tram on the way down here, to be honest, I see medical clinics. Most people see milk bars or lollies. No, I see

1 Ms Janet Currie, Psychiatric Medicines Awareness Group (PMAG), Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, in conversation with the Drugs and Crime Prevention Committee, Teleconference, 24 July 2007.

2 Mr Gino Vumbaca, Executive Officer, Australian National Council on Drugs, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, in conversation with the Drugs and Crime Prevention Committee, 17 May 2007.

3 Ms Wesa Chau, Multicultural Network Coordinator for North-West CALD partnership, Action on Disability within Ethnic Communities, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Forum with people from Culturally and Linguistically Diverse Communities, Melbourne, 9 July 2007.

4 Respondents to the survey were allowed to nominate up to two drugs (Australian Institute of Health and Welfare 2005a).



medical clinics. It is something that is so frighteningly there, right in my face. You are almost counting medical clinics along the street. It is very frightening.<sup>5</sup>

My life revolved around getting Panadeine Forte and pethidine, and that was all that mattered. I had come to the point where I never left the house unless it was to go and see my doctor or go to a hospital to get pethidine. That is all it was. It had been like that for about four years. I had not been to my local shopping strip for four years. I had not seen my neighbours for four years, and I was terrified. I would make sure that whenever I left the house there would be nobody around so I would not have to see anybody.<sup>6</sup>

The harm that is associated with benzodiazepines and other pharmaceutical drugs has, to some extent, been long neglected. Indeed, many people would not consider such drugs to be an important focus of any attempt to prevent and respond to 'drug problems'.

As one woman speaking to the Committee explained:

I went and had a haircut last Friday and there were not too many people in my hairdresser's, so I mentioned that I was coming here today. They said, 'Drugs and crime. What's all that about?' So I just let it slip and we had a discussion. They said, 'Yes, but that's not you'. I said, 'Yes. I'm a recovering drug addict'. 'Really?' I said, 'Yes'. 'Yes, but not you'. I said, 'Yes'. They said, 'But what did you take?' I said, 'Narcotics: codeine, pethidine, benzodiazepine, Valium'. 'Yes, but that's not really drugs.' I said, 'Yes, it is'. They said, 'But that's not really – you wouldn't call that a drug addict'. I said, 'Well, what do you mean by a drug addict' Again, it came straight back to somebody with a needle hanging out of their arm, somebody who is addicted to cocaine, marijuana, somebody who is a street person, somebody who is dirty and unclean; that is a drug addict. Drug addicts do not look like me or you.<sup>7</sup>

This perception is not restricted to those who have little experience with drug-related issues. It is also indicative of how some people who are well informed about the issues surrounding illegal drug use often underestimate the risks associated with the misuse of pharmaceutical drugs:

People who inject drugs are reasonably well informed of key risks associated with heroin use. Amongst our service users, benzodiazepines are perceived to be less harmful and safer than heroin use. There is a lack of awareness of how easy it is to develop a dependency on benzodiazepines, and how serious this dependency can be. Some education has been undertaken to increase users' awareness of overdose, however in general there is still a lack of understanding regarding a drug's length of action (the half life) and interactions between opiates and benzodiazepines.<sup>8</sup>

Just as prescription drugs may not be conceptualised as drugs of abuse by some members of the community, people may similarly tend to minimise the pain and trauma for family members and friends of someone affected by prescription drug addiction or abuse. The distress that prescription drug abuse has caused to the families and friends of those affected by such drug use was evident in a number of submissions and statements made to the Inquiry. For example, when the Committee was in Bendigo in May 2007 it met with Mr and Mrs Brown,<sup>9</sup> parents whose lives had been severely disrupted due to their son's long-term and debilitating addiction to prescription painkillers and other drugs.

5 'Mary', Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 20 June 2006. The name of the person who gave evidence has been changed to protect her anonymity.

6 'Anne', Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 20 June 2006. The name of the person who gave evidence has been changed to protect her anonymity.

7 'Anne', Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 20 June 2006. The name of the person who gave evidence has been changed to protect her anonymity.

8 Submission made by Western Region Health Centre to the Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

9 The names of the witnesses have been changed to protect their anonymity.



An account of this family's 'journey through hell' is worth quoting at length if for no other reason than reinforcing the fact that it is not only the families of heroin or amphetamine users who have to face the secondary consequences of drug addiction:

Members of the committee, in August 1994 family life as we knew it disappeared forever when our 18-year-old son Tony<sup>10</sup> was involved in a single-car accident on a local country road.

The severity of Tony's injuries led to him being flown to Melbourne, where he remained for the next six months. His injuries included a fractured pelvis, a badly broken ankle, a severely damaged foot, three broken fingers, a damaged valve to his heart, a fractured vertebra and multiple cuts and abrasions. Two days after being in Melbourne, Tony began to suffer renal failure and was admitted to the ICU, where he remained on the brink of death for eight days.

Little did we know that the pain relief being administered to Tony in those early days would lead to a life of unmanageable addictive behaviour that would spiral in and out of control for the next 13 years, and possibly for the rest of Tony's life. Sadly, it was not only Tony who was affected by this tragic accident but all of his family.

Even in the early days after the accident, Tony demanded more and more painkillers, which were freely administered on request. In the end, I think it was given simply to shut him up. There were times when I even intervened and fought for more on his behalf, as it is not easy as a mother to sit by your son's bed as he cries in pain. Was it addiction and craving, even at that early time? We will never know. But as time marched by, we became more and more suspicious. Perhaps it was addiction beginning to manifest itself in him...

Tony had several operations....He was finding the pain in his foot continually hard to bear and lived on a variety of painkillers to help him through the day. From memory, at this stage they were mainly Panadeine Forte and similar. There was always a box on hand. He consumed them like Smarties.

...We hoped for a miracle, but it was short-lived. The demands for pain-relieving medication drove the doctors and nurses insane. Things became so bad after one particular operation that a nurse rang to inform me that Tony had a drug problem – newsflash! – and we were summoned to Melbourne to meet his doctors to work out a plan of attack.

We had lost our first round in our efforts to break the cycle and demonstrate to the doctors that Tony had a serious problem. We came home disgusted. When he was finally discharged from the hospital, he was given a show bag of goodies to see him on his way, much of which was consumed on his way home. These included a variety of substances, including benzos and opiates. He was to have further operations on his foot, none of which gave much improvement but certainly added to his addiction being a more serious problem than ever, as he was taking painkillers daily at this stage.

The behaviour pattern went from bad to worse. We did deals with him and took control of his daily medication, which rocked from oxies to benzos, all mind-altering stuff. He knew it but was unable to stop. The amounts he could tolerate were unbelievable. Doctors were still prescribing boxes of Serepax that would last one or two days. He even cut a deal with a chemist once: a bottle of red for some benzos. We were powerless.

In summarising, we must all be aware that pharmaceuticals are more dangerous and insidious than street drugs. This disease is not selective as it occurs in rich and poor families, the educated and the uneducated. It is believed there is a predisposition to substance abuse and also evidence that suggests it may be hereditary. Tony is a beautiful, soft, gentle-natured person. He is currently waiting to do a detox program, as he has been for the last five months. He lives in a backpackers' [hostel] in Ballarat, as we could no longer manage him at home.<sup>11</sup>

10 Tony is a pseudonym used to protect the identity of the son.

11 'Mr and Mrs Brown', Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Bendigo, 29 May 2007.

Just as a son's prescription drug dependence may have a devastating affect on his parents, so too can a parent's addiction mean family disruption and breakdown for children and siblings. The Committee also received evidence from a woman with a longstanding addiction to benzodiazepines, an addiction she is still struggling with to this day. The effect on her children has also been traumatic:

I have a 16-year-old daughter who is currently finding it very difficult to come to terms with a mother that has had an addiction. She left me a note near the kettle the night before last – it was rather sad really – saying that she has had to lie to people to cover up things that I have done in the past. I have tried very hard to make amends with Jane. I am finding a lot of difficulty talking to her at the moment – (a) that she is 16; (b) I cannot justify the lies in the past. All I have done is to try to be up-front with her, and talk about the addiction and the dependency. But at the moment she is a very angry 16-year-old. I currently have a broken sliding door at the back. She is a very angry young girl.

I would like her to get help somewhere but at the moment it is all me. She sees herself as a reflection of me. I find the whole thing at the moment is very confronting. That is why I am having a lot of difficulty staying away from, or trying to keep away from, medication. It is so tempting to go back and block out that whole emotional thing that I can feel now occurring. My only outlet at the moment is work.<sup>12</sup>

The Drugs and Crime Prevention Committee recognises the significant health benefits that arise from safe and effective prescription and use of benzodiazepines and other pharmaceutical drugs. However, substantial concern has been expressed by members of the community and individual professionals and professional organisations regarding the significant harms that can arise from misuse of these medicines. Various coronial inquiries have noted that benzodiazepines and other pharmaceuticals have been identified in a significant proportion of drug-related deaths.<sup>13</sup>

Medical services have reported their concerns about vascular and other damage that arises from injecting pharmaceuticals not manufactured for that purpose, often resulting in severe damage to extremities, sometimes resulting in amputation. Damage to other organs can occur and cerebral strokes are also a risk (see Chapter 2.2). Recent examinations of drug-related deaths indicate a need to review strategies to prevent such misuse.<sup>14</sup> Police, doctors, pharmacists and statutory bodies invest much time in deterring and detecting fraudulent behaviour associated with acquiring pharmaceuticals for misuse. Pharmaceutical misuse can impact on the wellbeing of the broad community and governments can have a role in preventing and responding to related problems.

These are challenges and problems that are experienced in most Australian states and territories, and indeed in many other countries in the world (for example, see National Center on Addiction and Substance Abuse at Columbia University (CASA) 2005).

## Putting prescription drug misuse in context

Modern medicine relies on an increasing array of drugs or medications. Many of these are controlled, either through limited access by prescription from a medical practitioner or dentist and/or being limited to supply by a pharmacist. Others are more freely available through a variety of outlets.

The availability of medicines is controlled because in addition to the intended benefits there are sometimes unintended adverse consequences. These consequences can arise if the medication is used outside guidelines for safe and effective use (for example, if overused or

12 'Mary', Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 20 June 2006. The name of the person who gave evidence has been changed to protect her anonymity.

13 See Chapter 4.4.

14 See *Heroin-related overdose project*, Inquests into the deaths of David Borg, David Eberhardt, Sally Jessup, Clinton McLeod, Baskel Summut and Matthew Try, State Coroner's Office, Victoria, April 2000.



underused); used in conjunction with other drugs (polydrug use can reduce the effectiveness of specific drugs, thus interfering with treatment and increasing the risks of adverse consequences); or used by people who could be at elevated risk of harm because of individual characteristics (for example, some people are allergic to certain medicines, or health conditions render a particular course of drug use dangerous).

Many drugs have psychoactive properties, defined by the World Health Organization (WHO) as follows: 'A psychoactive substance is one that, when ingested, alters mental process – that is thinking or emotion' (WHO 1994, p.53). Drugs with psychoactive properties include alcohol, marijuana, heroin and cocaine and a range of medications. Examples of the latter include benzodiazepines (eg. prescribed for anxiety or sleep disorders), antidepressants (eg. prescribed for severe mood disorders), opioids (eg. prescribed for pain management) and amphetamines (eg. prescribed for the management of Attention Deficit Hyperactivity Disorder (ADHD)).

The Youth Substance Abuse Service (YSAS) stated in its submission to this Inquiry, 'Context is an important precursor to understanding and assessing possible harms associated with problematic drug use'.<sup>15</sup> This is particularly the case with regard to prescription drugs as the nature of the drug, the reason the drug is taken and the culture surrounding the use of that drug can be markedly different between various groups of drug misusers see Zinberg (1984). Such differences are important not only in themselves but also in terms of the strategies employed to address prescription drug misuse. Dr Alex Wodak and Ms Mary Osborn from the Drug and Alcohol Service at St Vincent's Hospital Sydney stated in a submission to this Committee that:

It is important to separate out the very different problems arising in different age groups and populations in terms of developing effective interventions. Very different problems arise in quite different settings [such as] young poly drug users; middle aged people with severe chronic illnesses; and the elderly...Most of the problems with benzodiazepines in particular are seen in the first and third groups.<sup>16</sup>

The main division between prescription drug misusers can be characterised as between those who have developed dependence after having been prescribed the medications for genuine illness, those using the drugs recreationally and those who may use the drugs as an addition to or substitution for an illicit drug such as heroin. Patients who have been prescribed such drugs as a legitimate component of their treatment can develop tolerance and dependence, requiring larger doses to bring about the intended or desired effect and continued doses to avoid the discomfort of withdrawal. As a consequence, some patients originally prescribed these drugs might eventually seek out these drugs for illegitimate purposes. However, there are other reasons why people might seek to illegitimately access and use prescription drugs. These include:

- ♦ **Iatrogenic dependence:** that is, they have become psychologically and/or physiologically dependent as a consequence of their treatment, which has now been completed;
- ♦ **Self-medication:** this could be self-medication of a medical condition without formal skilled medical intervention. Sometimes people can use drugs in an attempt to endure otherwise intolerable circumstances. For example, people may use central nervous system depressants such as opioids or benzodiazepines in an attempt to dull emotional pain related to past trauma and/or current circumstances. Such use can nevertheless be very risky;

<sup>15</sup> Submission of Youth Substance Abuse Service (YSAS) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2007.

<sup>16</sup> Submission of Dr Alex Wodak, Director, and Ms Mary Osborn, Senior Policy Officer, Drug and Alcohol Service, St Vincent's Hospital Sydney, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.



- ♦ **Dealing with withdrawal symptoms:** pharmaceutical medications may be used illicitly to self-medicate adverse consequences of other drug use (for example, central nervous system depressants may be used to try to alleviate withdrawal or 'crash' symptoms that arise from heavy amphetamine use);
- ♦ **Drug substitution:** for example, if there is a shortage in the supply of one drug in the market, a drug user may substitute with another that has the same or similar effect. Thus, the recent heroin shortage has been associated with an increase in diversion and misuse of drugs such as benzodiazepines and prescribed opioids;
- ♦ **Enhancement of other drug use:** for example, some individuals will take a controlled medication in combination with another drug to enhance or extend the overall desired effects. This can substantially increase the risk of adverse outcomes, as indicated by the significant proportion of fatal heroin overdoses where benzodiazepines have been detected;
- ♦ **Performance enhancement:** for example, some stimulants are used to enhance performance in social and employment situations;
- ♦ **Use by sexual predators:** for example, flunitrazepam (a benzodiazepine) has been added to drinks (drink spiking) or otherwise administered to an unsuspecting individual to assist in sexual assault; and
- ♦ **Use as a street currency:** pharmaceutical drugs are sold on the black market, thereby creating direct or indirect currency for the person who has obtained them.<sup>17</sup>

An individual may obtain pharmaceuticals for misuse through a number of ways including:

- ♦ Stealing, forging or altering prescriptions, which are then used to unlawfully obtain the drugs;
- ♦ Burglary of surgeries and pharmacies;
- ♦ Through 'doctor shopping' (presenting to several doctors and obtaining prescriptions for imaginary or exaggerated symptoms);
- ♦ Poor prescribing practices, such as prescribing larger quantities than are needed for managing the patient's conditions, providing an opportunity for the patient to sell the excess to others;
- ♦ Purchasing on the black market;
- ♦ Purchasing over the Internet;
- ♦ Health workers self-prescribing or otherwise misappropriating through work; and
- ♦ Opportunistic means (for example, from family members or friends who have been legitimately prescribed these medications).

These methods are discussed to varying degrees throughout this Report.

The variety of ways in which these drugs are obtained indicates that preventing pharmaceutical misuse will require responses at several levels, including engaging national and state statutory bodies, professional boards and organisations, and implementing responses through law enforcement, health and community services.

## Why the concern?

The misuse of pharmaceuticals is a concern for several reasons. Many of the drugs that are misused are subsidised by the Australian government through the Pharmaceutical Benefits Scheme (PBS), so widespread misuse can add a direct and substantial burden to the health budget, for no legitimate purpose or benefit. Use of these drugs outside of quality medical management can also result in a variety of adverse physical and mental health outcomes. Sometimes the drugs are used in doses or in a manner that creates significant risks to the individual. For example, many of these drugs are injected, even though this is not the use

<sup>17</sup> These reasons for use are discussed at greater length in Chapter 2.3 of this Report.

they are designed for, causing substantial problems such as vascular damage. They may also be used in conjunction with other (often illegal) drugs, significantly increasing the risk of fatal and non-fatal overdose. Maintenance of dependence through pharmaceutical misuse can create substantial harm and distress for individuals, families and the whole community, who sometimes mistakenly believe that a medicine is relatively low risk, as revealed by the following contribution to the Australian Drug Foundation website 'Somazone'.

...the thing is you think that just because a drug isn't from the street or isn't illegal it is fine to take. I thought because a doctor gave me the tablets I couldn't become addicted or harmed but that isn't the truth. It's far from the truth; I thought I was safe taking those drugs but I was so wrong.<sup>18</sup>

Misuse of benzodiazepines, especially when combined with alcohol, can create an increased risk of aggression and violence. This in turn creates risks for police and treatment service providers who assist those who abuse these drugs. A submission sent to this Inquiry from the mother of a son who struggled with benzodiazepine dependence eloquently pointed out that the problems facing both the person misusing the drugs and their families go beyond the physical or medical consequences of their addiction:

Benzos combined with alcohol or heroin are a dangerous mix both physically to the body but also affect the ability to make decisions, to discern danger and to discern actions...many actions in crime are made under this influence and are made spontaneously as drug combination appears to take away inhibitions and impulse control. These drugs long term and in large quantities also appear to take away memory both short term and long term.

Getting free of these drugs has been harder than getting free of heroin for my son. Being 'pilled out' has caused more legal problems for my son and his friends.<sup>19</sup>

On the other hand, any attempt to prevent pharmaceutical misuse must consider the tension that exists between their legitimate and illegitimate use. A discussion on prescription drugs must take into consideration that when these drugs are used as intended as part of quality medical care, they can make a positive contribution to the wellbeing and health of many community members who are legitimately prescribed them and take them as indicated. Quigley (2001) sums up this challenge neatly, and whilst his comments are focused specifically on benzodiazepines they are pertinent also to concerns about all types of pharmaceutical drug misuse:

Benzodiazepine regulation is a highly challenging task, obliging us to come to grips with the determinants of community mental health, the role of general practitioners, the logic of the pharmaceutical industry and the dynamics of illicit drug markets. Sedative drugs play a range of roles in society, and display varying degrees of safety and legitimacy, depending on source, mode of utilization, social context and many other factors...

Any simplistic attempt to restrict availability of a compound is liable to have negative therapeutic implications for legitimate patients, while the effect of regulation on street drug cultures cannot be predicted in advance (Quigley 2001, p.333).

## An overlooked problem

Despite the concerns expressed in the last section with regard to the dangers of misused or abused prescription drugs, it can hardly be said that this area is one that is in fact conceptualised as a drug problem when compared to illicit drugs such as heroin or amphetamine or even licit drugs such as alcohol. Such indifference or lack of knowledge may even extend to the health professions and particularly general practitioners (GPs).<sup>20</sup>

18 Submission from the Australian Drug Foundation to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

19 Submission from Ms Margaret Quon to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

20 For a discussion of the need to provide better education and training for general practitioners in the area of prescription drug abuse, see Chapter 6.2.



Dr Mike Tedeschi, a drug and alcohol clinician with whom the Committee met at the Canberra Hospital, explained this as follows:

I don't think there's any great push from any one area, saying do something this is an urgent problem. If you have on the whole a happy patient, a willing prescriber, a subsidised PBS, you haven't got a problem. So we [drug and alcohol workers] might think there's a problem or say there's a potential problem but if you haven't got a great push from any one area saying there's a problem, it makes it very hard.<sup>21</sup>

The submission to the Committee from Dr Wodak and Ms Mary Osborn outlines a number of factors that have led to poor outcomes and indifference in this area. These include:

- ◆ Lack of interest
- ◆ Poor data
- ◆ Obstruction by the pharmaceutical industry<sup>22</sup>
- ◆ Lack of ownership by the relevant medical professional organisations such as the Royal College of General Practice, the Australian and New Zealand College of Psychiatrists and the Australian Medical Association<sup>23</sup>
- ◆ It is hard using [inadequate] existing guidelines for state and territory Departments of Health to separate honourable doctors doing their best under difficult circumstances from less well motivated doctors
- ◆ Part of this problem is also the failure of States and the Commonwealth to provide adequate funding and support for alcohol and drug treatment in Australia.<sup>24</sup>

### The current Inquiry

On 17 January 2006, the Governor in Council requested that the Drugs and Crime Prevention Committee of Parliament inquire into and report to Parliament on the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria. In particular, the Committee was required to:

1. Examine the nature, extent and culture of the misuse/abuse of benzodiazepines and other forms of pharmaceutical drugs;
2. Examine the short and long-term consequences/harms of the abuse/misuse of benzodiazepines and other forms of pharmaceutical drugs;
3. Examine the relationship between benzodiazepines and other forms of pharmaceutical drugs and other forms of licit and illicit substance use;
4. Review the adequacy of existing strategies for dealing with benzodiazepines and other forms of pharmaceutical drugs misuse/abuse;
5. Recommend best practice strategies to address the issue of benzodiazepines and other forms of pharmaceutical drugs, including regulatory, law enforcement, education and treatment responses;
6. Examine national and international legislation, reports and materials relevant to the issue.

21 Dr Mike Tedeschi, ANU Medical School, Canberra Hospital, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Canberra, 16 May 2007.

22 For a discussion of the role of the pharmaceutical industry with regard to prescription drug misuse see Chapter 5.1.

23 The Committee approached most major health and medical organisations for a response by way of submission or to give evidence to the Committee addressing the Terms of Reference. As can be seen in Appendices 1 and 2 many organisations did so. The Committee repeatedly approached important organisations such as the National Prescribing Service to have involvement with this Inquiry. Unfortunately, they continually refused to do so on the basis that it did not fall within their remit or priorities.

24 Submission of Dr Alex Wodak, Director and Ms Mary Osborn, Senior Policy Officer, Drug and Alcohol Service, St Vincent's Hospital Sydney to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.



### ***The work of the Drugs and Crime Prevention Committee of the 55th Parliament***

At the outset the Committee engaged the National Drug Research Institute (NDRI), Curtin University of Technology, as the consultant to the project.

With the invaluable assistance of NDRI the Committee embarked upon preliminary research in order to canvass the issues and receive input and information from the many individuals, agencies and organisations that have a stake or interest in the issues raised in the Terms of Reference.

After calling for and receiving written submissions<sup>25</sup> the Committee conducted public hearings in Melbourne on 19 and 20 June 2006 and 13 July 2006. In total, the Committee received formal oral evidence from 20 witnesses.<sup>26</sup> In addition, Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, Department of Human Services (DHS) Victoria, provided the Committee with an extensive briefing on 29 May 2006 and supplied a vast array of government and academic publications.

On 24 August 2006 the Committee tabled an Interim Report for the Inquiry in the Parliament. The purpose of this Interim Report was primarily to highlight the scope and complexity of the issues to be addressed. It also aimed to provide an overview of the academic and non-academic literature, outline the major legal and regulatory frameworks governing drugs and medicines control, and review some of the policies and programmes currently addressing the misuse/abuse of benzodiazepines and other pharmaceutical drugs in Victoria and other Australian jurisdictions. In particular the Interim Report raised specific questions and issues that required further consideration before the Committee could conclude its deliberations and recommended that the Drugs and Crime Prevention Committee of the 56th Parliament should complete the Inquiry.

On 31 October 2006 the 55th Parliament was prorogued, causing the Inquiry to lapse. On 1 March 2007 the Legislative Assembly referred the same terms of reference to the Drugs and Crime Prevention Committee of the 56th Parliament with a requirement to report to Parliament by 30 November 2007.

### ***The work of the Drugs and Crime Prevention Committee of the 56th Parliament***

The Committee embarked upon an extensive research process in order to canvass the issues and receive input and information from as many individuals, agencies and organisations with a stake or interest in the issues raised in the Terms of Reference. This process is detailed below.

#### **Call for further written submissions**

Calls for written submissions, particularly addressing the questions and issues raised in the *Interim Report* and also by the Terms of Reference, were published on 14 April 2007 in *The Age* and *Herald Sun*. Letters inviting submissions to the Inquiry were sent to all local councils and shires in Victoria and key government and non-government agencies in Victoria and interstate. The Committee received 30 written submissions.<sup>27</sup>

#### **Review of the literature**

In conducting the Inquiry, the Committee has also undertaken a comprehensive review of the literature on the misuse and abuse of benzodiazepines and opioid analgesics in Australia and overseas. The review included published, unpublished and web-based literature. The process involved using search engines such as Medline, Austlii, Lawlink, APAIS, CINCH Health and Medical Complete, ProQuest Social Science and Google Scholar Science Direct MedLine. Key references identified by those who made submissions to the Inquiry were also accessed if they had not already been identified in the formal search

25 For a list of submissions received by the Committee of the 55th and 56th Parliament see Appendix 1.

26 For a list of witnesses who gave evidence to the Committee of the 55th and 56th Parliament at public hearings see Appendix 2.

27 For a list of submissions received by the Committee of the 55th and 56th Parliament see Appendix 1.

process. In addition, the websites of key national and state statutory bodies (for example, Medicare Australia, the Therapeutic Goods Administration, DHS Victoria) and professional organisations (for example, Royal Australian College of General Practitioners, Pharmaceutical Society of Australia) were reviewed for any literature, regulations and clinical and practice guidelines on drugs under consideration in this Inquiry.

### **Interstate and overseas visits**

During the Inquiry the Committee travelled both overseas and interstate to gain information.

#### Interstate travel

The Committee held meetings with key government and non-government agencies in Canberra and Adelaide to discuss approaches to 'doctor shopping' and treatment and education to address the misuse and abuse of benzodiazepines and opioid analgesics.<sup>28</sup>

#### Overseas travel

The Committee's research revealed that the misuse/abuse of benzodiazepines and other pharmaceutical drugs has been identified for some time as being a serious problem in Canada and the United States. As a consequence these countries have developed a range of regulatory regimes, law enforcement projects and educational, prevention and treatment strategies at both national and state/provincial levels. In comparison, as with most drug issues, Australia has tended to experience problems associated with various forms of drug abuse, including prescription drug abuse, long after they have been identified in North America or Europe.

Members of the Committee travelled to Canada and the United States of America from 20 July 2007 to 4 August 2007 investigating the issues relating to this Inquiry.<sup>29</sup> In all, the Committee met with 102 people from 35 organisations and departments. The Committee was therefore in a position not only to observe valuable best practice strategies and programmes developed in North America but also to learn from mistakes made and the experience gained to date by those working in the field.

### **Public hearings**

The Committee conducted public hearings in Melbourne on 4, 25 and 26 June 2007, 9 July 2007 and 20 August 2007. In total, the Committee received formal oral evidence from 36 witnesses.<sup>30</sup>

### **Additional witnesses**

In order to gain expert opinion and complement the information and testimony received from witnesses at the public hearings, visits to various facilities and information gained from submissions, the Committee periodically invited expert witnesses to address it regarding a range of pertinent matters and issues.<sup>31</sup>

### **Forums and roundtables**

During the Inquiry the Committee held six forums/roundtables to collect evidence.

#### Roundtable with representatives from culturally and linguistically diverse communities

During its deliberations for the Inquiry the Committee was keen to establish whether the misuse/abuse of pharmaceutical drugs (particularly sleeping tablets and pain relief medications) is a problem for Victorians from culturally and linguistically diverse

28 For a list of interstate meetings and site visits see Appendix 4.

29 For a list of international meetings attended see Appendix 3. The Committee's 'Report on Overseas Evidence Seeking Trip 2007' is to be tabled in Parliament in December 2007.

30 For a list of witnesses who gave oral evidence to the Committee at public hearings see Appendix 2.

31 For a list of expert witnesses invited to speak to the Committee of the 55th and 56th Parliament see Appendix 5.



communities and the challenges that this might pose for these communities. With the assistance of the Ethnic Communities Council of Victoria (ECCV), the Committee therefore held a roundtable discussion with people from culturally and linguistically diverse communities on Monday 9 July 2007<sup>32</sup> at Parliament House. Invitations were sent to the ECCV's 170 members' organisations and the Committee also invited a range of other organisations including local migrant resource centres, local community health centres and organisations with a particular interest in health issues within culturally and linguistically diverse communities.

Given the limited evidence available with regard to prescription drug use and abuse among culturally and linguistically diverse communities, this forum provided an excellent opportunity to obtain valuable information from a small, but enthusiastic sample of Melbourne's various culturally and linguistically diverse groups.

#### Roundtable with pharmaceutical industry representatives

The Committee believed it was essential to canvass the views of representatives from the pharmaceutical industry and considered a roundtable discussion would provide the best opportunity to gain greater insight into the range of issues confronting the Industry. With the assistance of Medicines Australia, the national association representing more than 90 per cent of the medicines and pharmaceuticals industries in Australia, and the Generic Medicines Industry Association the Committee invited all the member organisations of these Associations to attend a roundtable on Monday 16 July 2007. Committee members found the issues that were raised during that discussion most informative. However the Committee was disappointed that only four companies sought to appear.<sup>33</sup>

#### Roundtable to canvass the views of Indigenous Victorian drug and alcohol workers

Members of the Committee recognised that it is important to thoroughly canvass the views of Victorian Indigenous people. The Committee therefore decided to hold a roundtable on 20 August 2007. Prior to the roundtable all Indigenous drug and alcohol workers in the state were invited to attend and were provided with a list of questions the Committee wished to seek their views on. The forum was extremely insightful and, in addition to providing views and information, will hopefully also result in Indigenous community input for strategies to reduce the misuse/abuse of benzodiazepines and opioid analgesics.<sup>34</sup>

#### Forums conducted in regional and rural Victoria

Throughout the course of its investigation the Committee became aware of the relative paucity of research and lack of attention given to prescription drug use, and misuse, in rural and regional Victoria. In the *Interim Report* for the current Inquiry, the Committee called for more information about the nature and extent of the misuse and abuse of benzodiazepines and opioid analgesics within specific populations in the wider community, including rural and regional communities and Indigenous Victorians.

The Committee held three forums in rural and regional Victoria to seek the views of key groups including drug and alcohol workers, outreach workers, doctors, pharmacists, nurses, academics and other interested parties. It also organised a phone hook-up with representatives from rural health consumer organisations around Australia.

#### *Forums*

The first was conducted on 29 May 2007 in Warrnambool with the assistance of the Western Region Drug and Alcohol Centre.<sup>35</sup> The second was held in Ballarat on the same day with the assistance of the Alcohol and Drug Centre, Ballarat Community Health Centre, and the third forum took place in Bendigo on 30 May 2007 with the assistance of Alcohol and Drug Services, Bendigo Community Health Services.

32 For a list of those who attended the roundtable see Appendix 6.

33 For a list of those who attended the roundtable see Appendix 6.

34 For a list of those who attended the forums see Appendix 6.

35 For a list of those who attended the forum see Appendix 6.



### *Teleconference*

The Committee was concerned that the views of health consumers, particularly in rural and regional Victoria and Australia, were also heard. To this end the Committee invited members of the Health Consumers of Rural and Remote Australia Association (HCRRA) to participate in a teleconference on 4 June 2007. The HCRRA is a not-for-profit organisation working to improve rural health outcomes by involving consumers in the planning, implementation, management and evaluation of health services throughout rural and remote Australia. The Committee spoke with representatives from the Northern Territory, Western Australia, Queensland and Victoria.<sup>36</sup>

The perspectives, research directives, opinions and evidence that were received from these individuals, organisations, Shire and City councils and members of various communities who attended the forums or participated in the teleconference have been invaluable in providing the Committee with a greater understanding of pharmaceutical drug misuse and abuse confronting rural and regional communities.

### **Meetings with those affected by benzodiazepines and opioid analgesic abuse**

During the course of the Inquiry the Committee met with many people who came forward to share their personal or family experiences of the struggle with the terrible effects that these pharmaceuticals drugs can have. Their personal insights provided unique and important perspectives on the issues surrounding prescription drug misuse.

The Committee is most appreciative of the time, effort and valuable contribution that all the individuals and organisations have made during the progress of this Inquiry. The submissions, visits, public hearings and research projects have provided insights into the excellent work of various community and government organisations and valuable knowledge about what has turned out to be an extremely complex issue.

The publication of this Report marks the conclusion of this Inquiry.

### **Which drugs to include?**

The Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria has been a complex undertaking. The Terms of Reference have required the Committee to examine a wide range of multi-layered issues and each reference could easily have been an inquiry in its own right.

In Australia, the most commonly misused pharmaceuticals are painkillers/analgesics, benzodiazepines, narcotic analgesics, the stimulants methylphenidate (Ritalin) and dexamphetamine, and performance-enhancing drugs such as steroids (Australian Institute of Health and Welfare 2005a).

Given the enormity of this area, some parameters have had to be drawn as to exactly what this Inquiry could realistically cover and still comprehensively meet the Terms of Reference. This Inquiry therefore will focus only on the prescribed drugs that are captured under the broad headings of benzodiazepines and the narcotic analgesics (opioids). The reasons for so doing are as follows.

First these drugs and medicines, when used inappropriately or misused, not only result in serious physical damage and medical problems, they may also cause grave legal and social problems for the individual, their families and the broad community.

Second, given the enormous body of literature and research that has been produced with regard to *both* benzodiazepines and narcotic analgesics, it is certainly appropriate that this Report should be limited to covering these groups of drugs only.

36 For a list of those who participated in the teleconference see Appendix 7.

Third, these are the drugs that have been noted as major areas of concern by the experts with whom the Committee has met in Victoria, interstate or during its visits in North America.

### *The nature of drugs covered in this Report*

Although covered in more detail in Chapter 2.2, it is worthwhile considering briefly the nature of the drugs covered in this Report:

- ◆ Benzodiazepines are a group of depressant drugs, referred to as hypnotic sedatives or tranquillisers, initially developed as a safer alternative to barbiturates. They are most commonly used to treat stress, anxiety and panic disorders and sleeping disorders. They are sometimes used in the treatment of alcohol dependence. The following are examples of the wide variety of benzodiazepines that are available, with examples of the more familiar trade names in brackets: temazepam (Normison, Temtabs); triazolam (Hacion); bromazepam (Lexotan); oxazepam (Serepax); alprazolam (Xanax); nitrazepam (Mogadon); flunitrazepam (Rohypnol). Benzodiazepines, when used in legitimate treatment, are generally taken orally or injected, depending on the form in which they are prescribed.
- ◆ Narcotic analgesics are depressant drugs used in pain management and sometimes in the treatment of opioid dependence (for example, to assist in drug withdrawal or as part of drug maintenance treatment). The following are examples of narcotic analgesics: morphine, codeine phosphate, oxycodone, methadone, buprenorphine and pethidine. Narcotic analgesics, when used in formal treatment, are most commonly taken orally or injected, depending on the form in which they are prescribed.

### **Delimiting the Inquiry**

The other groups of drugs that may be loosely grouped under the Inquiry's Terms of Reference and the broad rubric of *pharmaceutical drugs* are not appropriate to consider at this stage for two main reasons. First, they may have been exhaustively examined by this Committee in other contexts, for example the illicit use of pseudoephedrine to manufacture amphetamines was examined in the extensive report on amphetamines completed by the Drugs and Crime Prevention Committee in 2004 and thus will not be covered here.

The second reason is that other groups of pharmaceutical drugs may warrant more extensive consideration than the time available for this Report permits. The pharmaceutical drug groups that could fall into this category include:

- ◆ The prescription and use of Ritalin and dexamphetamines for the treatment of ADHD;
- ◆ Over-the-counter drugs (for example, some pain and cold remedies and analgesics);
- ◆ Other central nervous system depressants such as ketamine and the barbiturates;
- ◆ The misuse of antidepressants, including both tricyclics and Selective Serotonin Reuptake Inhibitors and antipsychotics and neuroleptic drugs such as chlorpromazine;
- ◆ Drugs used in sport, including some anabolic steroids;
- ◆ Drugs used by elderly people; and
- ◆ Drugs used by prisoners and those in custody.

Limiting the groups of drugs the Committee will be covering in this Report by no means suggests that the issues raised by the misuse of the drugs in the above list are unimportant. On the contrary, the misuse of such drugs is an emerging issue and is something that may best be covered through other dedicated reviews or inquiries.



## A note on terminology

A number of terms have been used in this Report. Many of these have highly technical and internationally recognised meanings and most of these are included in the Demand Reduction Glossary of Terms (United Nations International Drug Control Program (UNDCP) 2000). These definitions and terms, in addition to those drawn from other international glossaries, are attached in Appendix 8 of this Report. It is essential, however, that two of the key terms that form the subject matter of this Inquiry – *abuse* and *misuse* of pharmaceutical drugs – are clearly defined at the outset.

Drug abuse has been stated to be 'A term in wide use but of varying meaning' (United Nations International Drug Control Program 2000, p.1). In international drug control conventions, "Abuse" refers to any consumption of a controlled substance no matter how infrequent'. The American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, defining abuse in the context of psychoactive substances, states that it will usually result in 'a maladaptive pattern of substance use leading to clinically significant impairment or distress' (DSM-IV American Psychiatric Association 1994 cited in United Nations International Drug Control Program 2000, p.1). The way in which such maladaptive behaviour is manifested giving rise to a pattern of drug abuse is expanded in the definition contained in the glossary in Appendix 8 of this Report.

Drug misuse, on the other hand, is usually characterised in the sense that a drug, usually a licit drug, is not used appropriately or for the purposes for which it was developed. The UNDCP Glossary defines misuse as: 'The use of a substance for a purpose not consistent with legal or medical guidelines, as in the non medical use of prescription medications. The term is preferred by some to abuse in the belief that it is less judgemental' (UNDCP 2000, p.45).

## Overview of the Final Report

Examining an issue as wide ranging as pharmaceutical drug abuse is a complex task. To facilitate the discussion of this problem, this Report is divided into Sections, each of which covers a significant area for consideration in this examination of the misuse and abuse of certain pharmaceutical drugs. Chapters within a Section pertain to specific aspects of that area of discussion.

Section One begins with a brief summary of the issues relevant to the misuse of prescription drugs and the criteria used to determine which drugs should be the focus of the Report. It then describes the nature, characteristics and properties of those drugs, benzodiazepines and opioid analgesics, including their therapeutic effects.

A statistical analysis of the extent of use and misuse of benzodiazepines and opioid analgesics opens Section Two. Information on the sources of this data is also provided, and the limitations of these are discussed. This Section then looks at the adverse consequences of misusing and abusing prescription drugs, which can result from medical as well as non-medical use. The effects of specific prescription drugs are described, as are the effects of injecting prescription drugs intended to be taken orally. Discussion also explores the profiles of people who misuse or abuse prescription drugs and their reasons for doing so. Access to non-medically prescribed pharmaceutical drugs is the final topic of this Section, which covers 'doctor shopping', diversion through prescription pad fraud and alteration, theft, Internet access and obtaining medically prescribed supplies from family and friends. Access by health professionals for their own use is also examined.

Section Three examines the federal and state legislative and regulatory frameworks for overseeing clinically prescribed medications and minimising misuse of prescription drugs. Discussion then moves from regulatory concerns to an examination of criminal and other laws pertaining to illegal possession, manufacture and trafficking of drugs of dependence, with specific focus on offences that pertain to prescription drugs. Attention is also given to



the recent law applying to drug driving and the possibility of a criminal law for 'doctor shopping'.

Systems monitoring the use and misuse of prescription drugs are examined in detail in Section Four, beginning with the various models in place in North America. Particular attention is paid to PharmaNet, an online 'real time' monitoring system operating in British Columbia, Canada. Discussion then turns to the Australian federal control systems of Medicare Australia and the Pharmaceutical Benefits Scheme, as well as looking closely at the most developed state approaches to monitoring such as those implemented in South Australia and Tasmania. This Section concludes with an exploration of the arguments for and against introducing an online/real-time centralised prescription drug monitoring programme in Victoria.

Section Five examines the prescribing practices that aim to prevent the abuse or misuse of prescription medicines. It begins by discussing the major federal and state government programmes that provide the cornerstone of safe and effective prescribing and by examining the role played by professional boards and bodies in developing standards of practice, clinical guidelines, and training programmes. It then looks specifically at electronic prescribing and the technology that supports it. Current electronic prescribing systems in North America and safeguards to protect their integrity and consumers' privacy are investigated as a background for discussing the possible establishment of an electronic prescribing regime in Australia. The final discussion in this Section explores the positives and negatives of accessing prescription drugs on the Internet. Although Internet access to prescription medicines is seen to benefit patients in remote areas, there are risks and dangers associated with illegal importation, fraud and the production of counterfeit drugs. Such problems have already been experienced in the United States. This Section concludes with a discussion of strategies to counter the negative aspects of Internet pharmacies and ensure safe prescribing practices in Australia.

A most concerning finding of this Inquiry has been the lack of knowledge many people have about the risks associated with misusing benzodiazepines and opioid analgesics, in part due to the limited information and education available about these prescription drugs. Discussion in Section Six begins by ascertaining what type of information is currently available and how a systematic approach for disseminating information among the community can be developed. The need for specific education and training for healthcare professionals, particularly general practitioners, is then explored. This discussion canvasses views about perceived gaps in the training and education of healthcare professionals with regard to addiction medicine. The need to provide information and education for other specific groups in the community and deliver it appropriately is also discussed. The last part of this Section investigates the role harm reduction strategies can play in minimising dangers posed by misusing and abusing benzodiazepines and opioid analgesics, with particular focus on injecting drug users.

Section Seven focuses on treatment for people who misuse and abuse benzodiazepines and opioid analgesics. It begins by outlining the principles of drug treatment and examining the kinds of treatment interventions appropriate for misuse and abuse of these prescription drugs. Types and availability of specialist services able to respond to prescription drug misuse are investigated, as well as alternative non-drug treatments. The second part of this Section looks at existing and potential challenges and barriers to effective treatment and how these may be addressed.

The final Section specifies areas in which more research is required to further understand and reduce the misuse and abuse of prescription drugs. The Report concludes with the Committee's findings resulting from this Inquiry.

## 1.2 The Therapeutic Use of Benzodiazepines and Other Forms of Pharmaceutical Drugs

Whilst the focus of this report is on the misuse or abuse of pharmaceutical drugs such as the benzodiazepines and opioid analgesics, it is undoubtedly true that these drugs have positive therapeutic aspects for conditions such as anxiety, insomnia and pain management, as well as side effects and negative aspects. Whether the ingestion of these drugs results in therapeutic or negative effects of course will depend on how they are used and other factors. It is therefore important to understand the pharmacology of these drugs and both the therapeutic and side effects that result from their use.<sup>37</sup>

### Benzodiazepines

#### *Background and history*

Benzodiazepines are a class of drug commonly used as sedative/hypnotics (to assist relaxation and sleep) and anxiolytics (to relieve anxiety). They are also used in anaesthesia and in epilepsy medication.

Some benzodiazepines are prescribed by doctors to relieve stress and anxiety and to help people sleep. They are also used to treat epilepsy (sometimes), to relax muscles, to help people withdraw from alcohol, or as an anaesthetic before surgery.<sup>38</sup>

When they were first introduced (in the 1960s) they were seen as a valuable alternative to the barbiturates, which had been used for similar purposes but were associated with dependence and implicated in cases of intentional and unintentional overdose (Richards 2005). It was found that restriction of the availability of barbiturates in the early 1970s reduced deaths due to suicide as a result of barbiturate overdose. This was at a time when benzodiazepines were introduced as an alternative drug for the treatment of insomnia (Oliver & Hetzel 1972).

Ms Susan Alexander of the pharmaceutical company Roche Australia explained to the Committee the efficacy of benzodiazepines compared to barbiturates:

Benzodiazepines as a class commenced with the Roche discovery of chlordiazepoxide (Librium) in 1957...The benzodiazepines have come to play an essential role in modern clinical practice, not only in the treatment of sleep and anxiety disorders but in a wide variety of psychiatric and medical uses. Benzodiazepines are considered to be remarkably safe compared to other medicines used for these indications. As a class, they are safer than the family of drugs that they have largely replaced, which is the barbiturates, and are considered one of the safest options available today for the medical treatment of these disorders.<sup>39</sup>

37 Further information on the side effects or negative aspects of these drugs when misused is found in Chapter 2.2.

38 The Australian Drug Foundation (ADF) website (Accessed at, <http://druginfo.adf.org.au/article.asp?ContentID=benzodiazepines>).

39 Ms Susan Alexander, Head of Regulatory Affairs and Head of Operations, Roche Products on behalf of Medicines Australia, in conversation with the Drugs and Crime Prevention Committee (via telephone), 20 June 2006. It should be noted that Ms Alexander was speaking primarily in her role as a representative of Medicines Australia, the peak industry body for pharmaceutical companies in Australia.



Dr Mike McDonough also expanded on the background to the development of benzodiazepines:

Pre the 1960s what the medical profession was prescribing here, in the US and in Europe as tranquillisers and sleeping tablets were drugs known as the bromides, the barbiturates and chloral hydrate...from a public health perspective, one would have to reflect on the greater and significant mortality – that is, overdose mortality – [resulting from these drugs]. Most of the movie stars that died from overdose...took barbiturates. Marilyn Monroe for example, was thought to have taken barbiturates...<sup>40</sup>

Benzodiazepines, when first introduced on the market, were conversely viewed as a much safer drug: Although as explained further in Chapter 2.2 some of the risks associated with benzodiazepine use were not foreseen at the time of their introduction.<sup>41</sup>

It should be added that in addition to the positive attributes of the benzodiazepine class of drugs already referred to, it was initially also thought that the benzodiazepines were free of 'addictive' properties, although as discussed later in this chapter by the 1970s it had become clear that these drugs could produce withdrawal symptoms consistent with the development of dependence (de las Cuevas et al 2003).<sup>42</sup>

### Prescribing benzodiazepines

Since their introduction, the benzodiazepines have become one of the most widely used groups of medications around the world, second only to drugs prescribed for heart and circulatory problems (World Health Organization (WHO) 1996). General practitioners prescribe around 80 per cent of all benzodiazepines, and an average of 10 per cent of the world's population use benzodiazepines as tranquillisers or hypnotics (WHO 1996). In

Table 1.2a: Benzodiazepines frequently used in Australia – active ingredient, brand name, company, schedule, indications, form and access

Drug Name	Proprietary Name	Company	Schedule	Indication	Form	Restricted
alprazolam	Alprax	Arrow	S4	Anxiety including anxious patients with some symptoms of depression (short-term); panic disorder	T	yes <sup>a</sup>
	Alprazolam-DP	Genepharm	S4	Anxiety including anxious patients with some symptoms of depression (short-term); panic disorder	T	yes <sup>a</sup>
	Zamhexal	Hexal Aust	S4	Anxiety including anxious patients with symptoms of depression (short-term); panic disorder	T	yes <sup>a</sup>
	Xanax	Pfizer	S4	Anxiety including anxious patients with symptoms of depression (short-term); panic disorder	T	yes <sup>a</sup>
	Kalma	Alphapharm	S4	Anxiety including anxious patients with some symptoms of depression (short-term); panic disorder	T	yes <sup>a</sup>
	GenRx Alprazolam	GenRx	S4	Anxiety including anxious patients with some symptoms of depression (short-term); panic disorder	T	yes <sup>a</sup>
bromazepam	Lexotan	Roche	S4	Tension, anxiety, agitation	T	yes <sup>b</sup>
clonazepam	Frisium	Aventis	S4	Acute anxiety and sleep disturbances associate with anxiety	T	no
	Rivotril	Roche	S4	Partial and generalised epilepsy in adults and children; Status epilepticus	T, L, I	yes <sup>c,d,e,g</sup>
	Paxam	Alphapharm	S4	Partial and generalised epilepsy in adults and children	T	yes <sup>c,d,e</sup>

40 Dr Mike McDonough, Medical Director Drug and Alcohol Services, Western Hospital, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 20 June 2006.

41 Dr Mike McDonough, Medical Director Drug and Alcohol Services, Western Hospital, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 20 June 2006.

42 Problems of dependence are discussed in Chapter 2.2. Also, see Appendix 8 for a definition of dependence.

Table 1.2a: cont'd

Drug Name	Proprietary Name	Company	Schedule	Indication	Form	Restricted
diazepam	Antenex	Alphapharm	S4	Anxiety disorders or short-term relief of anxiety; acute alcohol withdrawal; muscle spasm	T	for more than 50x2mg tablets <sup>f,j</sup>
	Valpam	Arrow	S4	Anxiety disorders or short-term relief of anxiety; acute alcohol withdrawal; muscle spasm; spasticity	T	for more than 50x2mg tablets <sup>f,j</sup>
	Valium	Roche	S4	Anxiety disorders or short-term relief of anxiety; acute alcohol withdrawal; muscle spasm; spasticity; status epilepticus; tetanus	T, I	for more than 50x2mg tablets <sup>f,j</sup>
	Diazepam GenRx	GenRx	S4	Anxiety disorders or short-term relief of anxiety; acute alcohol withdrawal; muscle spasm; spasticity in cerebral palsy; paraplegia; athetosis; stiff man syndrome	T	no
	Ducene	Sauter Laboratories	S4	Anxiety disorders or short-term relief of symptoms of anxiety; acute alcohol withdrawal; muscle spasm	T	yes <sup>h,i</sup>
	Diazepam-DP	Genepharm	S4	Management, short-term relief of anxiety disorders; acute alcohol withdrawal; muscle spasm	T	yes <sup>f,j</sup>
	Diazepam Injection (DBL)	Mayne Pharma	S4	Anxiety disorders or short-term relief of anxiety; acute alcohol withdrawal; muscle spasm; spasticity in cerebral palsy; paraplegia; athetosis; stiff man syndrome; pre-op medication	I	no
	Diazepam Elixir (10mg/10ml)	Orion Laboratories	S4	Anxiety; muscle spasm; cerebral spasticity; acute alcohol withdrawal	L	no
flunitrazepam	Hypnodorm	Alphapharm	S8	Severe insomnia	T	yes <sup>o,p</sup>
lorazepam	Ativan	Sigma Pharmaceuticals	S4	Anxiety disorders or short-term relief of symptoms; anxiety associated with depressive symptoms; pre-op medication	T	no
midazolam	Hypnovel	Roche	S4	Short-acting sleep inducing agent for conscious sedation for short procedures and the induction of anaesthesia; sedation in ICU; pre-op medication	I	no
	Midazolam Injection and Midazolam Injection BP Midazolam Sandoz	Pfizer Mayne Pharma Sandoz	S4 S4 S4	Short-acting sleep inducing agent for conscious sedation for short procedures and the induction of anaesthesia; sedation in ICU; pre-op medication	I	no
nitrazepam	Mogadon	Valeant	S4	Insomnia	T	yes <sup>k,u</sup>
	Alodorm	Alphapharm	S4	Insomnia	T	yes <sup>k,u,m</sup>
oxazepam	Serepax	Sigma	S4	Anxiety disorders or short-term relief of symptoms; anxiety associated with depressive symptoms; alcohol withdrawal	T	yes <sup>k,u</sup>
	Murelax	Fawns & McAllen	S4	Anxiety disorders or short-term relief of symptoms; anxiety associated with depressive symptoms; alcohol withdrawal	T	yes <sup>k,u</sup>
	Aleparm	Alphapharm	S4	Anxiety disorders or short-term relief of symptoms; anxiety associated with depressive symptoms; alcohol withdrawal	T	yes <sup>k,u</sup>
temazepam	Normison	Sigma	S4	Adjunctive therapy in the short-term management of insomnia in adults	T	yes <sup>l,m,n</sup>
	Temaze	Alphapharm	S4	Adjunctive therapy in the short-term management of insomnia in adults	T	yes <sup>l,m,n</sup>
	Temtabs	Sigma	S4	Adjunctive therapy in the short-term management of insomnia in adults	T	yes <sup>l,m,n</sup>
triazolam	Halcion	Pfizer	S4	Short-acting hypnotic, insomnia (short-term treatment)	T	no

**Notes:**

1. Indication for authority for restricted use: a) Panic disorder where other treatments have failed or are inappropriate; b) Patients with terminal illness; refractory phobic or anxiety states; c) Tablets continuing supply for palliative care patients for the prevention of epilepsy; d) Continuing supply for palliative care patients for the prevention of epilepsy where consultation with a specialist has occurred; e) Neurologically proven epilepsy; f) Liquid neurologically proven epilepsy; g) Injection continuing supply for palliative care patients for the prevention of epilepsy; h) Continuing supply for palliative care where anxiety is a problem; i) Continuing supply for palliative care where anxiety is a problem where consultation with a specialist has occurred; j) Continuing supply for palliative care where anxiety is a problem; k) Continuing supply for palliative care where anxiety is a problem where consultation with a specialist has occurred; l) Malignant neoplasia; m) Continuing supply for palliative care where insomnia is a problem; n) Continuing supply for palliative care where insomnia is a problem where consultation with a specialist has occurred; o) Patients with terminal disease; p) Patients with refractory phobic or anxiety states.

2. Key for 'Form': T – Tablet; L – liquid, oral solution; I – injection

Source: MIMS Online 2007.



Australia and New Zealand it is estimated that around 4 per cent of all prescriptions from general practitioners are for the benzodiazepines (Hulse, White & Cape 2002).<sup>43</sup>

In Australia there are currently 11 widely used benzodiazepine formulations. Table 1.2a describes the many common benzodiazepines and their brand names, the scheduling of the drugs,<sup>44</sup> the form in which they are available (tablet, capsule etc.) and the purpose of the prescription/treatment (the indication).

### *The effects of benzodiazepines*

Benzodiazepines depress the activity of the central nervous system and slow down the messages travelling to and from the brain. They affect physical, mental and emotional responses. Some effects are the intended therapeutic effects (for example, reduced anxiety) and others are unwanted side effects. Both intended and side effects can be divided into short-term effects and long-term effects, and have been summarised by the Australian Drug Foundation (ADF) as follows:

#### **Immediate effects**

##### Low to moderate doses

Short-term use (less than two weeks) of benzodiazepines may have the following effects: relaxation; calmness; and relief from tension and anxiety.

Other effects can include drowsiness, tiredness, lethargy, dizziness, vertigo, blurred or double vision, slurred speech, stuttering, mild impairment of thought processes and memory, feelings of isolation and emotional depression.

##### Higher doses

The most probable effects of higher doses are: drowsiness; over-sedation; sleep.

Before the person falls asleep, or if they do not sleep, higher doses may produce an effect similar to alcohol intoxication. Effects could be confused, slurred speech; poor coordination; impaired judgement; difficulty thinking clearly; loss of memory; blurred or double vision; and/or dizziness. Mood swings and aggressive outbursts may also occur. The symptoms intensify as the dose increases. Feelings of jitteriness and excitability often become evident as the effects of large doses wear off.

Very high doses of benzodiazepines can cause unconsciousness or coma. Death rarely occurs from overdose of benzodiazepines alone, but some deaths have occurred when large doses were combined with alcohol or other drugs. Deaths have occurred due to the inhalation of mucus or vomit whilst the person has been unconscious.

#### **Long-term effects**

The use of benzodiazepines over a long period of time (more than two to three weeks) is not recommended.

Benzodiazepines can help to relieve anxiety in the short term. However, they do not solve the problem that caused the anxiety in the first place – they treat the symptoms but not the cause.

Long-term use of benzodiazepines may cause: drowsiness; lack of motivation; difficulty thinking clearly; memory loss; personality change; changes in emotional responses; anxiety; irritability; aggression; difficulty sleeping; disturbing dreams; nausea; headaches; skin rash; menstrual problems; sexual problems; greater appetite; weight gain; increased risk of accidents; increased risk of falling over (older people).

<sup>43</sup> Chapter 2.1 describes in detail the rates of use and misuse of benzodiazepines.

<sup>44</sup> Pharmaceutical drugs are scheduled from S2 to S9. This affects their availability (eg. lower schedule drugs are more easily available, higher schedule drugs are more strictly controlled). See Chapter 3.1 for a detailed explanation.

Very high doses of benzodiazepines over a long period of time may cause confusion, lack of coordination, depression and slurred speech, and may lead to increased aggressiveness. It is ironic that the long-term effects include anxiety and sleeplessness, when these are the very problems that benzodiazepines are supposed to relieve.<sup>45</sup>

### **The half-life of benzodiazepines**

Among other factors, the choice of which drug is prescribed for a particular condition is affected by how quickly they take effect and how long they last.<sup>46</sup> This is related to their half-life, described as follows:

The term [half-life] refers to the time needed for the blood level of a particular drug to decline to half of the maximum level (peak). After absorption, the various drugs are transported to the various sites of action through the blood stream. During this transportation and distribution process, the drugs already in the blood or in the various organs are gradually transformed into various metabolites, and either deposited or excreted from the body...Half-life is a generally accepted...indication of the relative duration of a drug's effects. Heroin, for example, has a short half-life, while morphine has a longer one. The various benzodiazepines and barbiturates also have greatly varying half-lives (United Nations International Drug Control Program (UNIDCP) 2000, p.30).<sup>47</sup>

The 'half-life' of a drug is important because it has implications for the duration of drug effects and, if a person becomes dependent, for withdrawal management.<sup>48</sup> Therefore different benzodiazepines will be prescribed for different purposes. The WHO (1996) classifies benzodiazepines into three broad groups according to their elimination half-life:

- ◆ Long-acting benzodiazepines have half-lives which generally exceed 24 hours;
- ◆ Intermediate and short-acting benzodiazepines have half-lives which range from five to 25 hours; and
- ◆ Ultra short-acting benzodiazepines have half-life values of less than five hours.

### **Speed of onset of drug effect and abuse liability**

There is good evidence that the reinforcing effects of drugs, and the likelihood that their use will lead to drug dependence and addiction or be sought for abuse, depends on the speed at which the drug enters the brain and causes an effect, and how quickly the drug is removed. This is determined by the pharmacokinetics (absorption, metabolism, distribution and elimination) of the drug. In addition, solubility in lipids (lipophilicity) is also important, because drugs soluble in lipids cross the barrier between the blood stream and the brain (the blood-brain barrier) more rapidly. Drug formulations or routes of administration (such as intravenous injection or snorting) that enable rapid entry of the drug into the brain increase the potential for addiction and dependence (Gossop et al 1992).

Early evidence suggests that rapid-acting and short-lived barbiturates had greater abuse potential than slower onset long-acting barbiturates (Jaffe 1990). Additionally, researchers have found that rapidly administered drugs tend to be those that produce subjective pleasurable effects (Abreu et al 2001). Much of the research on speed of onset and its effects on abuse liability has been done on the benzodiazepine drugs. Research comparing slower onset benzodiazepines with more rapid onset benzodiazepines suggests that the former have substantially lower abuse potential (Griffiths et al 1984; Busto & Sellers 1986). Another study suggested that the subjective effects produced by diazepam were greater than those produced by oxazepam, a difference attributed to the greater lipid solubility of diazepam, a difference that would contribute to a more rapid onset of effect (Bliding

45 ADF website. (Accessed at: <http://druginfo.adf.org.au/article.asp?ContentID=benzodiazepines>).

46 ADF website. (Accessed at: <http://druginfo.adf.org.au/article.asp?ContentID=benzodiazepines>).

47 See Appendix 8 for a fuller definition.

48 See Chapter 7.1 for a discussion in the context of treatment and Appendix 8 for a definition of 'half-life'.



1974). In addition, a rapid decrease in drug concentration is associated with a termination of the 'high' and a resumption of drug-seeking behaviour (O'Brien 2001).

### Side effects

As already indicated, there are some side effects or unwanted effects to the use of benzodiazepines. One of the most common short-term adverse effects of benzodiazepines is drowsiness, which occurs in 10 to 15 per cent of those taking therapeutic doses, although this common side effect usually diminishes after a few days of treatment (due to the development of tolerance) (Barker et al 2003). This consequence of drowsiness clearly has repercussions for driving impairment, an issue discussed further in Chapters 2.2 and 8.1. Most of the acute side effects of the benzodiazepines, however, are related to the central nervous system effect of the drug and include fatigue, ataxia (difficulty in coordinating movement), confusion and weakness.

The use of benzodiazepines in the elderly may be a risk factor for falls, hip fracture, and cognitive impairment. Long-acting benzodiazepines may be associated with a higher risk than short-acting benzodiazepines (Ray, Thapa & Gideon 2000). Also, studies in patients and healthy volunteers have shown that benzodiazepines impair anterograde memory (memory from the time the drug is taken, and for the period when there are sufficient levels detectable in the blood) in a dose-dependent manner, without affecting long-term memory (Taylor & Tinklenberg 1987). Table 1.2b below lists the reported side effects of benzodiazepines.

**Table 1.2b: Side effects associated with benzodiazepines**

Side effects		
Aggression	Agitation	Anorexia
Anterograde amnesia	Auditory hallucinations	Bitter or metallic taste
Bizarre behaviour	Constipation	Delirium
Depression	Dry mouth	Dysathria (slurred speech, difficulty pronouncing words)
Failure to ovulate	Falls in the elderly	Flushing
Gastro-intestinal complaints	Genitor-urinary complaints	Headache
Hiccups	Increased or decreased libido	Increased appetite
Increased salivation	Joint pain	Menstrual irregularities
Muscle cramps	Nausea	Palpitations
Panic	Paranoid ideation	Shortness of breath
Swollen tongue	Tachycardia	Visual disturbances
Vivid dreams	Weight loss	

Source: Adapted from Barker et al 2003, p.204.

Most side effects are dose-dependent – the higher the dose the higher the risk of side effects. Such side effects may be more likely to occur among the elderly who are more susceptible, due to factors such as an impaired ability to metabolise and excrete a drug (WHO 1996; Longo & Johnson 2000).

There are also some long-term consequences, although these cannot be identified with as much confidence because there are various methodological difficulties in the studies (Barker et al 2003; Curran 1991 cited in Barker et al 2003). One common and problematic long-term effect of benzodiazepine use is dependence. This can occur even at therapeutic doses, a risk that has prompted the following prescribing information and advice from MIMS Online:

In general, benzodiazepines should be prescribed for short periods only (e.g two to four weeks). Continuous long-term use is not recommended. There is evidence that tolerance develops to the sedative side effects of benzodiazepines. After as little as one week of

therapy, withdrawal symptoms can appear following the cessation of recommended doses (MIMS Online 2003).

Thus, even with therapeutic doses, tolerance and dependence can develop reasonably quickly and some people can become dependent within a few days.

...the thing to remember is that these medications are usually prescribed on what is believed to be a short-term basis. They almost invariably are started for sleeping difficulties that present around a particular issue, whether that be a grief issue or an illness that is considered to be time limited. Often the problem then becomes that, after a week or so of using the medications, it can be quite hard to stop them. Then the cycle of dependence can begin. I think there are two issues there: are they being prescribed in the recommended way for limited periods of time and are other issues being looked at, which I think is quite difficult in a community medical setting where there is a lot of time pressure.

...Most people would become dependent after two weeks – within that period – but most people would have some degree of dependence after a week. In hospital, we use these medications sometimes for alcohol withdrawal, and we are very careful to make sure people are not on them for more than five days because after five days we have to bring down the doses very slowly, rather than just stopping them – so dependence develops very quickly.<sup>49</sup>

...Different ones come on quickly and wear off quickly so we have found that with the ones that come on and wear off quickly such as alprazolam or Xanax the severity of dependence seems to come on a bit quicker and a bit more. So the ones that dribble out of your system slowly do not seem to be as nasty when you cease them suddenly. Alprazolam, for example, because it goes away quickly, people tend to very quickly start to get very agitated and even occasionally have seizures. But generally, yes, about a week; they cause dependence quite quickly.<sup>50</sup>

Finally, as already indicated, benzodiazepines are depressant drugs (in terms of their action on the central nervous system). In combination with other depressant drugs, the effects of both can be exacerbated:

Combining benzodiazepines with alcohol, barbiturates, antihistamines, antidepressants, cannabis, or heroin can greatly increase the effects of the drugs taken. This can be very dangerous, especially if the person intends to drive. Some combinations can be life threatening.

Taking benzodiazepines with alcohol greatly reduces alertness and judgment of time, space, and distance. When large amounts of alcohol and benzodiazepines are taken together, it can result in death.

Combining benzodiazepines with other sedatives, antihistamines (cough, cold and allergy remedies), barbiturates or sleeping pills increases the effects on the brain, resulting in unconsciousness and failure to breathe, which can lead to death.

The combination of heroin and benzodiazepines can be deadly. With benzodiazepines in the system, it takes less heroin to overdose.<sup>51</sup>

These adverse consequences are addressed in more detail in Chapter 2.2.

### *The efficacy of benzodiazepines*

Benzodiazepines are widely used in treatment for a range of medical conditions and without doubt can be effective therapies. For example, Ms Susan Alexander stated:

From the Roche position, preclinical, clinical and epidemiological studies have demonstrated that benzodiazepines have a relatively low potential for abuse. There is little evidence that

49 Dependence is further discussed in Chapter 2.2 and, in relation to treatment, in Section Seven. Also, see Appendix 8 for a definition of dependence.

50 Dr Matthew Frei, Interhospital Liaison Group, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 19 June 2006.

51 ADF website. (Accessed at: <http://druginfo.adf.org.au/article.asp?ContentID=benzodiazepines>).



patients prescribed them for legitimate reasons abuse them. There is a great body of evidence to show that benzodiazepines are abused by those already misusing and abusing other largely illegal drugs. There is little compelling evidence to show that different benzodiazepines differ in abuse potential. Roche has sponsored numerous epidemiology studies to better establish the nature of benzodiazepine use and abuse in the US, the Netherlands, Germany and France. National studies of drug abuse show that polydrug addicts may use benzodiazepines to help overcome the withdrawal symptoms of heroin addiction, which is nervousness and sleep problems, and to dampen the depressive effects of cocaine addiction.<sup>52</sup>

Notwithstanding that many medical professionals, researchers and scientists do recognise the general efficacy of benzodiazepines and realise the costs associated with their use are less than from the drugs they replace such as barbiturates, such costs 'are still appreciable and could be reduced'.<sup>53</sup> For example, whilst Dr Alex Wodak and Ms Mary Osborn of Alcohol and Drug Services at St Vincent's Hospital, Sydney acknowledged the therapeutic uses of benzodiazepines, they also pointed out that:

- The fact that benzodiazepines usually contribute to harms in younger persons rather than causing harms on their own has resulted in too little attention being paid to effective interventions;
- Although the numbers of deaths involved are relatively few, the person years of life lost is far from insignificant;
- Benzodiazepine consumption in younger people is often a marker of severe antecedent factors and severe health and social costs. For example, benzodiazepine consumption is often an indicator of severe mental illness and is also an indicator of poor prognosis including increased risk of fatal and non fatal overdose, high HIV risk behaviour and crime.<sup>54</sup>

With regard to the last point, however, the Youth Substance Abuse Service (YSAS) states in its submission to this Inquiry that benzodiazepines can have a positive role to play in addressing anxiety and related conditions in young people:

[This Committee's] Interim Report noted that 'Benzodiazepines can help relieve anxiety in the short term. However, they do not solve the problem that caused the anxiety in the first place – they treat the symptoms but not the cause'. In YSAS view this is an assumption that does not enjoy universal agreement.

Endogenous anxiety related to developmental difficulties, traumatic childhoods, GABA [gamma-aminobutyric acid] system dysfunction etc may not be entirely resolvable through psychodynamic means. A parallel can be found in depression and the prescribing of SSRIs [Selective Serotonin Reuptake Inhibitors] which while they do not 'solve the problem that caused the depression in the first place' can be seen as a useful and effective...<sup>55</sup>

Whatever disagreement there may be with regard to the exact extent of benefits or harms attributable to their ingestion, it is undoubtedly true that in most circumstances the use of benzodiazepines is an improvement upon the barbiturate drugs of an earlier period.

However, as the above discussion has indicated, there are also various side effects, some of which can be quite unpleasant. Side effects are influenced by dose and individual

52 Ms Susan Alexander, Head of Regulatory Affairs and Head of Operations, Roche Products on behalf of Medicines Australia, in conversation with the Drugs and Crime Prevention Committee (via telephone), 20 June 2006. It should be noted that Ms Alexander was speaking primarily in her role as a representative of Medicines Australia, the peak industry body for pharmaceutical companies in Australia.

53 Submission of Dr Alex Wodak, Director and Ms Mary Osborn, Senior Policy Officer, Alcohol and Drug Service, St Vincent's Hospital Sydney, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

54 Submission of Dr Alex Wodak, Director, and Ms Mary Osborn, Senior Policy Officer, Alcohol and Drug Service, St Vincent's Hospital Sydney, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

55 Submission of Youth Substance Abuse Service (YSAS) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2007.

characteristics. In addition, both the short- and long-term effects of benzodiazepine use can have serious consequences. Tolerance and dependence to benzodiazepines can occur quickly and the drug effects, and negative consequences, can be exacerbated if combined with other central nervous system depressants.

### **Narcotic analgesics (opioids)**

'Opioid' is a general term which includes drugs containing natural opiates derived from the opium poppy and a range of synthetic and semi-synthetic substances which have morphine-like effects. Opioids, or narcotic analgesics, are commonly:

...taken to relieve pain, the most common complaint that physicians hear from their patients. Opioids are prescribed for three types of pain: acute or short-lived pain, chronic malignant (cancer) pain and chronic non-malignant pain...Opioids attach to opioid receptors in the brain, block the transmission of pain signals to the brain and, like illicit opioids (e.g. heroin), produce a sense of heightened pleasure. The use of opioids is an important component of pain management (National Center on Addiction and Substance Abuse (CASA) 2005, p.13).

Opioid use has a long history, as the following quote from the National Centre for Epidemiology and Population Health reveals:

The opioids have been used both medically and recreationally for centuries. A tincture of opium called laudanum has been widely used since the 16th century as a remedy for 'nerves' or to depress coughing or stop diarrhoea. By the early 19th century, morphine had been extracted in a pure form suitable for solutions, and with the introduction of the hypodermic needle in the mid-19th century, injection of the solution became the common method of administration. Heroin (diacetylmorphine) was first marketed in 1898 for general medical use and was heralded firstly as a cough suppressant, then in 1900 as a remedy for morphine addiction. Of the 20 alkaloids contained in opium, only codeine and morphine are still in widespread clinical use today. In this century, many synthetic drugs have been developed which have essentially the same effects as the natural opium alkaloids.

The opioid-related synthetic drugs, such as pethidine and methadone, were developed to provide an analgesic without dependence-producing properties. Unfortunately, however, all the opioids and their synthetic derivatives which are effective as analgesics are also dependence producing. Modern research has led to the development of another family of drugs called narcotic antagonists (eg naloxone hydrochloride). These drugs are not used as painkillers, but to reverse the effects of opioid overdose.<sup>56</sup>

### ***Effects of opioid drugs***

The effects of opioids are influenced by how much is used, how it is ingested and individual factors.

#### **Immediate effects**

The immediate effects of opioids relate to analgesia (relief of pain) and euphoria (a feeling of wellbeing). The latter effect may also be directly associated with the analgesic effect. Other short-term and immediate consequences as described by the National Centre for Epidemiology and Population Health include:

Production of nausea and vomiting. Depression of respiration – the cause of death from overdose. Reduction of movements of the bowel (intensive constipation). Miosis (constriction of the pupils of the eyes).

The main therapeutic application of the narcotics is for the relief of severe pain. The drug effect is not on the perception of pain but rather upon its interpretation by the brain. Typically, the patient is aware that the pain is still present, but it is no longer interpreted as

<sup>56</sup> National Centre for Epidemiology and Population Health, Australian National University, cited from <http://nceph.anu.edu.au/Publications/Opioids/stage1vol2b.pdf>.



being painful or disturbing. The euphoric and dependence-producing capacity of these drugs is probably directly associated with this action. Other therapeutic applications are for cough suppression and treatment of diarrhoea. Synthetic and semi-synthetic derivatives have been made and selected for their specificity for these actions with a minimum of dependence producing capability.

Narcotics briefly stimulate the higher centres of the brain, then depress the activity of the central nervous system. Immediately after injection the user feels a surge of pleasure ('a rush') which gives way to a state of gratification into which hunger, pain and sexual urges usually do not intrude. The dose required to produce this effect may initially cause restlessness, nausea and vomiting. The effects of a usual dose in a therapeutic setting lasts approximately 3 to 4 hours.

With moderately high doses the body feels warm, the extremities heavy and the mouth dry. The user goes 'on the nod', an alternately wakeful and drowsy state during which the world is forgotten. As the dose is increased, breathing becomes progressively more depressed. With very large doses the person cannot be roused, the pupils are contracted to pinpoints, the skin is cold, moist and bluish, and profound respiratory depression resulting in death may occur.<sup>57</sup>

### Effects of prolonged use

The major longer-term hazards associated with opioid analgesics are respiratory depression and, to a lesser degree, circulatory depression. There are, however, a wide range of common and uncommon side effects associated with opioids affecting the cardiovascular system, the nervous system, the skin, the gastro-intestinal tract, the excretory system, the liver and gall bladder and the endocrine system. In normal doses, the most common side effects of opioid analgesics are nausea, vomiting, constipation, drowsiness and confusion. Larger doses produce respiratory depression and hypotension with circulatory failure and deepening coma (MIMS Online 2003).

The amount required to produce life-threatening respiratory depression varies considerably with the individual, and regular users may tolerate large doses. In long-term use, physical dependence and tolerance may develop. Commenting on the dangers associated with long-term use of analgesic opioids, the National Centre for Epidemiology and Population Health states:

The narcotic analgesics, in pure form and administered cleanly, are non-toxic to body tissue. If not administered cleanly in pure form, chronic opioid users may develop endocarditis, an infection of the heart lining and valves by organisms introduced into the body during injection of the drug...The main problem associated with the prolonged usage of narcotics is the development of tolerance and a withdrawal syndrome. In the therapeutic situation, these problems can be avoided or minimised by carefully regulating the interval between doses.<sup>58</sup>

The following withdrawal symptoms may be observed after narcotics are discontinued: body aches, diarrhoea, gooseflesh, loss of appetite, nervousness, restlessness, runny nose, sneezing, tremors or shivering, stomach cramps, nausea, trouble with sleeping, unusual increase in sweating and yawning, weakness, tachycardia and unexplained fever. With appropriate medical use of narcotics and gradual withdrawal from the drug these symptoms are usually mild (MIMS Online 2003).

Table 1.2c indicates many of the opioid drugs available on prescription in Australia.<sup>59</sup> This table provides information on their common name, the major therapeutic purpose for each drug and the form in which it is prescribed.

57 National Centre for Epidemiology and Population Health, Australian National University, cited from <http://nceph.anu.edu.au/Publications/Opioids/stage1vol2b.pdf>.

58 National Centre for Epidemiology and Population Health, Australian National University, cited from <http://nceph.anu.edu.au/Publications/Opioids/stage1vol2b.pdf>.

59 MIMS Online 2003.

**Table 1.2c: Narcotic analgesics used in Australia – active ingredient, brand name, company, schedule, indications, form and access**

Drug Name	Proprietary Name	Company	Schedule	Indication	Form	Restricted
Morphine HCl	Ordine	Mundipharma	S8	severe pain	L	yes <sup>b</sup>
Morphine Tartrate	Morphine Tartrate (inj)	Mayne	S8	severe intractable pain in cancer patients	I	no
Morphine Sulphate	Kapanol	GlaxoSmithKline	S8	chronic pain unresponsive to non-narcotic analgesia	C	yes <sup>b</sup>
	Anamorph	Fawcett & McAllen	S8	severe pain with inadequate response to other measures	T	yes <sup>b</sup>
	MS Mono	Mundipharma	S8	chronic severe pain of cancer	C	yes <sup>a</sup>
	MS Injection	Mayne	S8	moderate to severe pain unresponsive to non-opioids, pre-operative medication, analgesic adjunct in general anaesthetic	I	no
	Sevredol	Mundipharma	S8	chronic severe pain of cancer	T	yes <sup>b</sup>
Oxycodone HCl	Oxycontin	Mundipharma	S8	moderate to severe pain unresponsive to non-opioids, pre-operative medication, analgesic adjunct in general anaesthetic	T (CR)	yes <sup>a</sup>
	Oxynorm	Mundipharma	S8	moderate to severe pain	C, L, I	yes <sup>b</sup>
	MS Contin	Mundipharma	S8	opioid responsive, chronic severe pain	CRT, CRS	yes <sup>a</sup>
	Endone	Sigma	S8	moderate to severe pain	T	yes <sup>b</sup>
Oxycodone pectinate	Prolozone	Pharmalab	S8	pain, especially post-op and in carcinoma	S	yes <sup>b</sup>
Hydromorphone	Dilaudid	Abbott	S8	opioid analgesia, moderate to severe pain	T, L, I	yes <sup>b</sup>
Fentanyl	Durogesic	Janssen-Cilag	S8	opioid analgesic, management of chronic pain	P	yes <sup>a</sup>
	Sublimaze	Janssen-Cilag	S8	short-duration analgesia perioperatively and as a supplement in general and regional anaesthesia; premedication/ induction with a neuroleptic	Z	no
	Fentanyl Injection DBL	Mayne Pharma	S8	analgesia in anaesthesia and peri-operatively, with a neuroleptic, anaesthesia induction, maintenance	I	no
	Naropin	AstraZeneca	S8	analgesia in anaesthesia	I	no
	Actiq	Orphan	S8	opioid tolerant cancer breakthrough pain	Z	no
Alfentanil hydrochloride	Rapizen	AstraZeneca	S8	analgesia in anaesthesia, induction agent	I	no
Dextro-propoxyphene napsylate	Doloxene	Aspen Pharmacare	S4	mild to moderate pain	T	no
Pethidine	Pethidine Injection	Mayne Pharma	S8	moderate to severe pain (short-term) anaesthetic adjunct, obstetric analgesia	I	no
	Pethidine hydrochloride	Sigma	S8	moderate to severe pain, pre-op medication, analgesia adjunct in general anaesthetic, obstetrics	I	no
	Pethidine Injection BP	AstraZeneca	S8	moderate to severe pain, pre-op medication, analgesia adjunct in general anaesthetic, obstetrics	I	no
Methadone HCl	Physeptone	GlaxoSmithKline	S8	pain, treatment of opiate dependence	L, T	yes <sup>c</sup>
	Biodone Forte	National Sales	S8	treatment of opiate dependence	L	yes <sup>c</sup>
	Methadone Syrup	GlaxoSmithKline	S8	treatment of opiate dependence	L	yes <sup>c</sup>
Buprenorphine	Subutex	Reckitt Benckiser	S8	opiate dependence (maintenance and detoxification)	SLT	yes <sup>c</sup>
	Temgesic	Reckitt Benckiser	S8	opioid agonist; acute, moderate to severe pain (short-term use less than or equal to 1 week)	L, SLT	no
Norspan	Mundipharma		S8	moderate to severe pain	P	no
Buprenorphine and naloxone	Suboxone	Reckitt Benckiser	S8	opiate dependence in conjunction with medical, social and psychological treatment	SLT	yes <sup>c</sup>

**Notes:**

1. Indication for restricted use: a) Chronic severe disabling pain not responding to non-narcotic analgesic; b) Severe disabling pain not responding to non-narcotic analgesics; c) Opioid management.
2. T - Tablet; L - liquid, oral solution; I - injection; C - capsule; P - patch; SLT - sublingual tablet; S - suppositor CRT-controlled release tablet; CRS-controlled release suspension.

Source: MIMS Online 2003.



As indicated in Table 1.2c, there is a range of different narcotic analgesic drugs, some of which are discussed briefly in the list below. Most are S8 drugs (prescription only, with strict controls) but some are more widely available.<sup>60</sup> The following information is drawn from that published in MIMS Online (2003) medicine database.<sup>61</sup>

- ◆ **Morphine:** Morphine is derived from opium. It affects the central nervous system and smooth muscle. The analgesia induced by morphine is a result of increases in both the pain threshold and pain tolerance: patients remain aware of the existence of the pain but are less distressed by it. Morphine relieves most types of pain but is more effective against dull constant pain and is recommended for use in the chronic severe pain of cancer. Morphine drugs used in Australia include Sevredol®, Anamorph®, Kapanol®, MS Contin® and MS Mono®.
- ◆ **Hydromorphone:** Hydromorphone is derived from morphine but is approximately eight times more potent. It is used for moderate to severe pain. It is available as a tablet, oral liquid and in solution for injection. A high potency injection for use in opioid dependent patients is also available. In Australia, hydromorphone is available as Dilaudid®.
- ◆ **Fentanyl:** Fentanyl is a synthetic opioid analgesic. It has similar properties to morphine. It differs from morphine in that it has a rapid onset and short duration of action. It is used as a short acting analgesic during periods of anaesthesia, as a pre-operative medication, and as an analgesic immediately following surgery. In Australia, fentanyl is available as: Actiq® (in the form of a lozenge); as Sublimaze® and Fentanyl® injections for post-operative use; Durogesic® as a transdermal patch; and Naropin® with fentanyl as an epidural infusion. Actiq® is a high potency fentanyl preparation only for use with patients who have developed a tolerance to other opioid analgesia and are experiencing breakthrough pain.<sup>62</sup>
- ◆ **Pethidine:** Pethidine is a synthetic opioid analgesic with actions similar to those of morphine. It is primarily used as an analgesic, as a pre-operative medication, as an obstetric analgesic and as an adjunct in anaesthesia. Prolonged use of pethidine is associated with a number of severe side effects (it is neurotoxic) and use is not recommended for periods longer than 24 to 36 hours.
- ◆ **Oxycodone:** Oxycodone is a semi-synthetic narcotic analgesic available in Australia as Endone®, OxyNorm®, OxyContin® and Proladone®. It is used for analgesia and is recommended for use in cases of moderate to severe pain.
- ◆ **Codeine Phosphate:** Codeine is derived from opium. It modifies the perception of, as well as the emotional response to, pain. It is easily absorbed. Codeine has three functions as a pharmaceutical: as a cough suppressant, as a mild analgesic with sedative effects for the relief of mild to moderate pain (eg. period pain, tension headache or migraine, pain associated with dental or surgical procedures and neuralgia) and as an anti-diarrhoeal drug (MIMS Online 2003). Codeine has about one-sixth the analgesic activity of morphine. In doses up to 12.8mg, codeine, in combination with other mild analgesics (eg. paracetamol, aspirin), is classified as S3 or S2 and is available in pharmacy-only preparations such as Panadeine® and Nurophen Plus® without a prescription. Products containing greater than 15mg of codeine alone, or in compound products, are classified as Schedule 4 drugs for which a prescription is required.

60 There are various schedules for drugs. This affects their availability (eg. lower schedule drugs are more easily available, higher schedule drugs are more strictly controlled). See Chapter 3.1 for a detailed explanation.

61 The MIMS Online medicine database is compiled using the Australian Therapeutic Goods Administration (TGA) Approved Product Information that originates from the manufacturer/distributor and is standardised using MIMS Online editorial guidelines. (Accessed at: <http://MIMSOnline.hcn.net.au.dbgw.lis.curtin.edu.au/ifmx-nsapi/MIMSOnline-data>).

62 Breakthrough pain is a term meaning that pain breaks through normal pain management (or is felt over and above normal pain management) to require a narcotic analgesic.



- ◆ **Dextropropoxyphene napsylate:** Dextropropoxyphene napsylate is a synthetic opioid analgesic with a chemical structure similar to that of methadone and a potency of between two-thirds to equal that of codeine. It is available as Doloxene®, with Dextropropoxyphene napsylate as the only active ingredient and as Capadex® or Digesic® in which it is combined with paracetamol. Dextropropoxyphene napsylate preparations are recommended for mild to moderate pain.

In summary, narcotic analgesics are available in a variety of forms. They may be used for more minor health problems such as coughs, but are the mainstay of pain management. There are a variety of side effects, and tolerance and dependence can readily develop with continued use. As central nervous system depressants, their effects and associated risks are exacerbated when combined with other such depressants.

### *The use of opioids to treat pain*

There has been much debate and controversy as to whether one has seen the emergence of a 'pain culture' in recent years in which medication, including opioid use, is increasingly seen as the first and only treatment modality. Debates have also centred generally on the extent to which opioids should be used in pain management and treatment. This has been particularly true for the newer opioid analgesics such as OxyContin®. These debates and broader issues pertaining to pain management through the use of opioids and alternative methods are fully canvassed in Section Seven of this Report. Nonetheless, it should be noted here that, as with benzodiazepines, many observers including medical scientists, practitioners and academics have exhorted the Committee not to ignore the positive benefits these medications can have in alleviating pain and distress, particularly in the treatment of cancer or other acute syndromes. For example, Dr John Whitlam, Director of Medical Affairs for pharmaceutical conglomerate Mundipharma told the Committee:

I think there is no dispute, there is no controversy that opioids have an incontrovertible place in the management of acute pain and cancer pain...Frequently patients who suffer acute pain may be given immediate release opiates to manage that pain. A more complex area is chronic pain, in particular, chronic non-cancer pain. There is a deal of discussion in the literature about the utility of opioids in chronic non-cancer pain. The literature strongly suggests that there is a case for opioids in chronic non-cancer pain but a cautious stepwise approach to the treatment of that pain is really required.

On the balance of evidence there is a place for opioids. There are patients with non-cancer pain – osteoarthritis and other chronic severe, crippling pains where they need daily doses of opioids...All in all there is a lot of support for the use of opioids in non-cancer pain but they [guidelines] all stress the need for caution. They stress the need for GP education. They stress the need for a stepwise approach, according to what is called the World Health Organization analgesic ladder. You do not start with opioids, you start with aspirin, you start with paracetamol;...you may eventually end up on a partial agonist or a full mu agonist like oxycodone and morphine. There are a lot of patients out there who need opioids. They should really go through that analgesic ladder for treatment, as well as being assessed for all the other psychological co-morbidities that usually are associated with these sorts of patients.<sup>63</sup>

Mundipharma clearly recognises the potential for abuse of opioid drugs. In a written submission to this Inquiry it balanced both the positive aspects of the drugs and the problems associated with their ingestion when misused or abused:

Mundipharma has always recognised the potential for abuse and diversion of its morphine and oxycodone containing products and, indeed, all opioid containing pharmaceutical products distributed by various pharmaceutical companies in Australia. Moreover, Mundipharma is cognizant of its responsibilities to the community to do all it can to act

<sup>63</sup> Dr John Whitlam, Director of Medical Affairs, Mundipharma, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Pharmaceutical Industry Forum, Parliament House, Melbourne, 16 July 2007.



ethically, responsibly and to ensure appropriate and safe use of its products throughout Australia, including Victoria.

For example, we actively reinforce the message to prescribing doctors that for non-cancer pain, opioid treatment should be restricted to situations where:

- all other conservative methods of analgesia have been tried and have failed;
- the pain is having a significant impact on the patient's quality of life;
- there is no psychological contraindication, drug seeking behaviour or history of drug misuse.

Counterbalancing this, however, is the vast improvement in the effective treatment throughout Australia of countless thousands of patients suffering severe, unremitting and seriously debilitating pain through innovative pain management modalities, both non-pharmacologic (eg. cognitive behavioural therapy) and pharmacologic. Palliative care patients are no longer required to die in pain. Driving this important, and necessary, improvement in chronic pain management is an increasingly greater understanding of the complexities of pain mechanisms and ways to interrupt these, and the recognition of the interactions between these and the psychological and environmental factors that influence the perception of pain and the success of treatments.

The challenge for regulators is, therefore, to define and implement effective strategies that prevent the abuse and diversion of prescription medicines, including opioids, and that do not pose unreasonable and insurmountable barriers to genuine patients in genuine need of opioid pharmacotherapeutics to alleviate their intractable, and often crippling, pain.<sup>64</sup>

Striking the balance between the therapeutic need for and application of these drugs and their potential for abuse and the appropriateness of opioids for pain relief is discussed at length throughout this Report.

## Conclusion

The information given above is not exhaustive. It is designed to provide a brief introduction to pertinent medical and pharmaceutical information about the drugs that are the subject of this Inquiry – benzodiazepines and opioid analgesics. There are many medical textbooks available that can supplement this information for the interested reader who requires more in-depth and sophisticated technical knowledge in this area.<sup>65</sup>

64 Submission of Mundipharma to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

65 See for example, Rang, Dale & Ritter 2003, *Pharmacology*, 5th edn, Churchill Livingstone, Sydney.

## Section Two:

# The Nature and Extent of Use and Misuse of Benzodiazepines and Narcotic Analgesics

## 2.1 The Extent of Licit and Illicit Use of Benzodiazepines and Opioid Analgesics

### Introduction

The extent of benzodiazepine and other pharmaceutical drug use and misuse can be demonstrated in part by reviewing a range of available data sources. The purpose of this chapter is twofold. The first is to provide information on the size of the problem of pharmaceutical drug misuse. The second is to provide an overview of the various sources of information available that can inform the shape and conduct of further inquiry into this important issue.

As such, the approach taken is not to provide an exhaustive collection of tables and data. Rather, the chapter is very much a scoping piece. It includes a snapshot of data, from the United States as an example of the kind of information and data collection systems available overseas. This information not only puts the Australian and Victorian data in context but also provides a basis for seeing how our local systems could be improved, or not, as appropriate.

Importantly, as has already been noted, the prescription pharmaceutical drugs most prone to misuse are also used legitimately for the appropriate treatment of recognised medical conditions. Thus, understanding misuse of these drugs needs to include consideration of the extent of legitimate use. Furthermore, as the pharmaceutical drugs which are misused are diverted from the chain of legitimate manufacture, supply, prescription, dispensing, and finally use, it is important to have an understanding of the data on the size of the licit pharmaceutical supply and use market as a starting point for any consideration of data pertaining to illicit pharmaceutical access and use. Consequently this chapter begins with a brief summary of data on prescription drug supply as well as the number of prescriptions written for these drugs. Data is provided from the United States and Australia.

The next section of the chapter focuses on illicit use. Illicit drug use, like other illegal behaviour, is by its very nature a hidden activity. Users of illicit drugs are understandably wary of who gets to find out about their behaviour. Therefore it is not possible to get a totally accurate picture of illicit drug misuse. Different research strategies are used to collect data at a population level and in more targeted studies of populations known to be at risk.



In the final analysis, what emerges is a patchwork of often overlapping, but different, data sources that nevertheless provide the best available understanding of the nature and extent of illicit pharmaceutical misuse. This patchwork is most valuable when data from different sources converges to a similar finding.

The chapter includes data from primary use sources; that is, those surveys and other sources that directly measure use of the drugs, or prescriptions for use in the case of legitimate supply. However, sources that could be considered secondary indicators of use, such as ambulance call-out rates and hospital attendances, are more directly indicators of harm and so are included in Chapter 2.2.

## **Data sources and their limitations**

### *Data sources on licit availability and use of pharmaceutical drugs*

#### **Global data sources**

Global data on the manufacture and supply of the drugs of interest to this Inquiry are not readily available. However, some countries routinely collect data on pharmaceutical drug supply. The United States is one such example.

#### **United States data sources**

In the United States, analysis by the National Centre on Addiction and Substance Abuse (CASA 2005) was conducted on data from two main sources of pharmaceutical drug supply: (i) data from the Automation of Reports and Consolidated Orders System (ARCOS), which is managed by the Drug Enforcement Agency; and (ii) data from the National Prescription Audit Plus. The ARCOS system covers only 1,100 distributors and manufacturers, which CASA notes is a small fraction of the more than one million distributors and manufacturers registered with the Drug Enforcement Agency. Furthermore, as ARCOS only includes Schedule 3 and 4 drugs,<sup>66</sup> benzodiazepine supply data is not included. Data from this system is not included in this Report. National Prescription Audit Plus lists the top 200 drugs dispensed to patients from retail pharmacies based on a nationwide survey of 22,000 retail pharmacies and covering some 36 million filled prescriptions. This sample accounts for more than half of all retail pharmacies in the United States (CASA 2005).

#### **Australian data sources**

##### *Australian Statistics on Medicines 2006*

In Australia, pharmaceutical prescription data was accessed from publications of the Drug Utilisation Sub-Committee (DUSC) of the Australian Pharmaceutical Benefits Advisory Committee. The DUSC, part of the Australian Government Department of Health and Ageing (DoHA), provides annual estimates of the aggregate community use of prescription medicines in Australia in their Australian Statistics on Medicines series (DUSC 2003, 2004, 2005, 2006). These publications, and the data set on which they are based, provide a potentially very valuable source of statistics on legal availability of the range of prescription drugs, including those of most interest to the current Inquiry. The data set can be accessed to produce data at the national and state level. It provides information on the aggregate number of prescriptions written for each specific drug preparation and the aggregate cost to the Pharmaceutical Benefits Scheme (PBS). As an example, Table 2.1a provides a small extract from the publication Australian Statistics on Medicines 2006, which deals with the class of 'drugs used as hypnotics and sedatives' and the class opioids used for pain relief. It also comprises estimates based on prescriptions submitted for payment of a subsidy under the PBS and Repatriation Pharmaceutical Benefits Scheme (RPBS), along with data from a representative sample of community pharmacies, in order to estimate the non-subsidised

66 For the most part this is equivalent to Schedule 2 and 3 and some Schedule 4 drugs in Australia (see Chapter 3.1 of this for further discussion of drug scheduling).

use of prescription medicines in the community. Information from these sources is combined into one database to provide an estimate of prescriptions for subsidised and non-subsidised medicines in Australia (DUSC 2007).

The problems with this source of information are threefold: First, it does not include drugs prescribed in public hospitals, and second, and more significantly, the data is currently published in a raw form. Whilst Australian pharmaceutical prescription and supply data has been subject to unpublished analysis that addresses questions of relevance to the current Inquiry (eg. Dobbin 2006, unpublished), there has not been a publicly available comprehensive analysis of this data, such as that produced in the United States (CASA 2005). This is needed to inform consideration of pharmaceutical drug misuse and responses to it. Finally, the available data is rarely disaggregated to give 'snapshots' of prescription drug abuse in particular groups, for example among Indigenous or culturally and linguistically diverse communities, for people living in rural and regional areas or among prison populations. Such specialised data should be collected if, as anecdotal evidence strongly suggests, there may be problems of abuse in these groups.<sup>67</sup>

67 For example, a submission to this Inquiry by Darebin City Council stated that with regard to their own research into prescription drug abuse in the Darebin municipality (North East Melbourne):

'Anecdotal evidence from a number of Aboriginal agencies indicated that medication misuse – in particular medication mismanagement – was impacting significantly on Indigenous residents due to the high level of medications many Indigenous people are prescribed.'

It is their view, however, that there is a significant gap in the research (including the collection of extent of use data) that is being done with regard to prescription drug use in Indigenous communities (Submission of Darebin City Council to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006).

Such concerns were apparent among most of the groups who attended the Committee's various forums. These included attendees at the Indigenous forum the Committee held in August 2007 who called for further research of this nature; participants in forums the Committee conducted during May 2007 in Ballarat and Warrnambool who voiced the need for specialised data collection to identify the extent of the problem in rural and regional communities; and participants at the Committee's July 2007 Forum for Culturally and Linguistically Diverse Communities who also drew attention to the current lack of research into misuse and abuse of prescription drugs among their members.



Table 2.1a: Sample data from Australian Statistics on Medicines, 2005

ATC	Code	Form And Strength	DDD	Units	Scripts	Cost(\$)
<b>Drugs used as Hypnotics and Sedatives</b>						
Benzodiazepine Derivatives						
	N05CD03	Flunitrazepam 4216 Tablet 1 mg 30	1.00	MG	60,130	979,536
	N05CD02	Nitrazepam 2723 Tablet 5 mg	5.00	MG	686,340	4,595,088
		2732 Tablet 5 mg	5.00	MG	12,439	111,663
	N05CD07	Temazepam 2088 Tablet 10 mg	20.00	MG	66,414	580,953
		2089 Tablet 10 mg 25	20.00	MG	2,761,819	18,509,702
		5221 Tablet 10 mg	20.00	MG	1,775	11,487
		5375 Tablet 10 mg 50	20.00	MG	252	2,254
		5376 Tablet 10 mg 50	20.00	MG	217	2,019
		10815 Capsule 20mg 25	20.00	MG	42	—
		11356 Capsule 20mg 25	20.00	MG	136	—
		18340 Capsule 10mg	20.00	MG	51	—
		18585 Capsule 10 mg 25	20.00	MG	35	—
		18587 Capsule 10 mg 25	20.00	MG	2,608	—
	N05CD05	Triazolam 13374 Tablet 0.125 mg 50	0.25	MG	5,781	—
Opioids used for pain relief						
	N02AA05	Oxycodone 2481 Suppository 30 mg	30.00	MG	12,979	647,073
		2622 Tablet 5 mg	75.00	MG	460,235	5,853,021
		5195 Tablet 5 mg	75.00	MG	604	6,289
		8385 Tablet 10 mg (controlled release) 20	75.00	MG	205,369	5,444,622
		8386 Tablet 20 mg (controlled release) 20	75.00	MG	211,964	9,307,864
		8387 Tablet 40 mg (controlled release) 20	75.00	MG	131,878	9,365,685
		8388 Tablet 80 mg (controlled release) 20	75.00	MG	69,061	9,235,262
		8464 Capsule 5 mg 20	75.00	MG	26,934	318,145
		8501 Capsule 10 mg 20	75.00	MG	40,442	705,805
		8502 Capsule 20 mg 20	75.00	MG	33,616	1,044,162
		8644 Oral solution 5mg per 5mL, 250mL	75.00	MG	3,772	65,367
		8681 Tablet 5 mg (controlled release) 20	75.00	MG	58,275	1,066,833
		16414 Tablet 10 mg (controlled release) 60	30.00	MG	229	—
		16416 Tablet 20 mg (controlled release) 60	30.00	MG	205	—
		16418 Tablet 40 mg (controlled release) 60	30.00	MG	102	—
		16420 Tablet 80 mg (controlled release) 60	30.00	MG	13	—
		18295 Tablet 5 mg (controlled release) 60	30.00	MG	136	—

Notes: ATC refers to Anatomical Therapeutic Chemical Index.  
DDD refers to defined daily dose.

Source: Drug Utilisation Sub-Committee 2006, p.273 and p.287.

The Committee also accessed data from the National Drug-control System (NDS).

#### National Drug-control System (NDS) domestic transaction data

Australian pharmaceutical prescription and supply data has been extracted from the NDS. This is a database programme provided by the United Nations for the purposes of collecting import, export and consumption data and reporting on that data to the International Narcotics Control Board under the terms of international treaties to which Australia is a signatory. Clients (eg. hospitals, doctors, pharmacists etc.) are identified as either 'keeping stock' or 'not keeping stock' in the client master. Clients who do not keep stock are deemed to have consumed the stock. Stock movements can be imported into the NDS via an EXCEL spreadsheet and movements are tracked on an 'accounting ledger' basis. Once the initial stock levels have been entered, queries can be run on the amounts held for each client by substance or preparation. Transactions can be exported to EXCEL. This Report includes statistics extracted by analysis of this EXCEL data. In Australia the Commonwealth DoHA collects the NDS domestic transaction data.

## **Data sources on illicit use of pharmaceutical drugs**

### **Global data sources**

At a global level there is very little information available on illicit benzodiazepine and opioid analgesic consumption and markets. In March 2007 the International Narcotics Control Board (INCB) warned that the abuse of narcotic analgesics is set to 'exceed illicit drug use' and called on all Governments 'collect data on seized pharmaceutical products and to include the abuse of pharmaceutical preparations in the surveys aiming at establishing the extent and types of drug abuse' (INCB 2007, p.2). Reports by the World Health Organization and the United Nations Office on Drugs and Crime have raised concern regarding the misuse and abuse of benzodiazepines and the harmful effects they can have. However 'the effective monitoring of consumption and markets is difficult because much of the illicit consumption of these substances relies upon the diversion of licitly obtained benzodiazepines' (Department of Human Services 2007, p.123).

### **United States data sources**

The National Survey on Drug Use and Health (NSDUH) has been conducted in the United States since 1971 with the civilian, non-institutionalised people who are 12 or more years of age. The sample is approximately 67,500 annually. However, in 1998 and 2001 the survey underwent a major redesign (including an incentive payment of \$30), suggesting caution in making comparisons between surveys conducted before and after this period. While noting this caution, many sources do make such comparisons, including the CASA (2005) report. The NSDUH focuses on non-medical (ie. not prescribed for the person responding to the questionnaire) use of psychotherapeutic drugs – defined as including sedatives, tranquillisers and analgesics and stimulants (including methamphetamine). Data on pharmaceutical drugs is included, but is not routinely subject to extensive analysis in the NSDUH reports.

In addition:

The NSDUH is known to underestimate considerably all forms of substance use in the U.S. Because it is administered in the home, respondents – particularly teens – tend to under-report their substance use. Moreover, the survey does not include high-risk institutionalized populations, such as prison inmates, hospital patients, nursing home residents, patients in drug abuse treatment and others who cannot be reached in a home (e.g. the homeless) (CASA 2005, p.4).

The Monitoring the Future Study, conducted by the University of Michigan's Institute for Social Research, was begun in 1975 as a long-term study of American adolescents, college students, and adults through to age 45. The study has accumulated 32 years of data for students from Grades 8, 10 and 12. It is funded through a series of investigator-initiated, competitive research grants from the National Institute on Drug Abuse. The 2006 survey included nearly 50,000 students across the United States (Johnston, O'Malley et al 2007). The Monitoring the Future study provides an excellent source of data of interest to the current Inquiry, although the way the drug data are clustered and reported makes analysis of some individual drug types problematic. Furthermore, as the data are collected by administering surveys in the classroom, like other surveys of this kind, they are unlikely to reach those young people who may be most at risk of illicit drug use and who may not be attending school, or may be at school but have trouble completing the questionnaire due to literacy problems.

### **Australian and Victorian data**

#### *The National Drug Strategy Household Survey (NDSHS)*

The NDSHS has been undertaken in this country on eight occasions,<sup>68</sup> once approximately

68 The last survey was conducted in 2004 and the Australian Institute of Health and Welfare is conducting the ninth survey this year.



every three years. Conducted by the Australian Institute of Health and Welfare (AIHW), the NDSHS describes the use of licit and illicit drugs as well as the perceptions and attitudes associated with them among a representative sample of the Australian population aged 14 years and above (although in 2004 a sub-sample of 12- and 13-year-olds was also included) (AIHW 2005a).

Compared to national surveys of drug use in other countries, the Australian NDSHS is considered to be one of the best. However, like other surveys of this kind, it has a number of shortcomings. The NDSHS is conducted as a household survey, therefore those in prison, those in other institutions and the homeless are not included. Furthermore, those with unstable living arrangements are also less likely to be included. With regards to the current Inquiry, it should be noted that the NDSHS does examine the use of painkillers/analgesics and sleeping pills/tranquillisers. However, it does not specifically ask about benzodiazepines. Rather, benzodiazepines are included under the broad heading of 'tranquillisers'. Like other household surveys, because illicit drug use is a hidden activity, rates of illicit drug use based on NDSHS are likely to underestimate the true rates. This is addressed to some extent by guarantees of confidentiality and anonymity and the use of respondent sealed, self-completion sections on drug use. However, it is known that the NDSHS also substantially underestimates the amount of alcohol consumed in Australia, compared to national alcohol sales data (Loxley, Toumbourou & Stockwell 2004), so the problem of under-reporting is not simply about the illegal nature of drug use.<sup>69</sup>

While the NDSHS focuses on non-medical use when inquiring about pharmaceutical drug use, the authors of the 2004 survey report note that in some questions this was not clear, and some respondents may have answered regarding their use of these substances for medical purposes (AIHW 2005a). Furthermore, there have been a number of changes of methodology in the NDSHS over the years including substantial changes in the way questions about lifetime use was measured, and in 2004 Computer Assisted Telephone Interviewing was included for the first time. This makes analysis of trends over time difficult. Another problem with the NDSHS is that of falling response rates. In 1998 the response rate was 56 per cent, in 2001 it was 51 per cent and in 2004 it was 46 per cent (AIHW 2005b). Loxley, Toumbourou, and Stockwell (2004) noted that the drop in response rate is of concern, as those who don't participate, for whatever reason, are likely to be heavier users.

#### *The Illicit Drug Reporting System (IDRS)*

The IDRS is an ongoing illicit drug monitoring system coordinated nationally by the National Drug and Alcohol Research Centre and funded by the Department of Health and Ageing and the National Drug Law Enforcement Research Fund. It has been conducted in all Australian states since 2000. It aims to provide a coordinated approach to monitoring the use of illicit drugs – in particular, heroin, methamphetamine, cocaine and cannabis – and to identify emerging trends of local and national concern in illicit drug markets (O'Brien, Black, Degenhardt et al 2007). The IDRS collects data from three sources: interviews with a minimum of 100 injecting drug users in each jurisdiction; interviews with key experts who have regular contact with illicit drug users; and an examination of existing indicator data from the health and law enforcement sectors (O'Brien, Black, Degenhardt et al 2007).

To be eligible for the IDRS injecting drug users survey, such users must have injected an illegal drug on at least a monthly basis for the previous six months. Questions are asked about the range of other drugs including those pharmaceutical drugs often misused by injecting drug users. However, the degree to which particular pharmaceutical drugs are addressed varies, but has been increasing over recent years as concern about pharmaceutical drug misuse has grown. The strength of the IDRS is that it is nationally conducted and

<sup>69</sup> For a discussion of the limitations of the NDSHS see for example AIHW 2004: Loxley et al 2004 and Drugs and Crime Prevention Committee 2006.



provides comparable data on trends over time. The main disadvantage is that the IDRS provides summary quantitative data and not the detail required to understand the experience of users behind the basic prevalence data. Of course, as the IDRS focuses on data from only recent injecting drug users, information from this survey is not representative of illicit drug use in the general population. Data from both the national (eg. O'Brien, Black, Degenhardt et al 2007) and Victorian reports (eg. Jenkinson & Quinn 2007) are included in this chapter.

#### *The Ecstasy and Related Drugs Reporting System (ERDS)*

Also coordinated nationally by the National Drug and Alcohol Research Centre, the Ecstasy and Related Drugs Reporting System (ERDS) formerly the Party Drugs Initiative (PDI) is an offshoot of the IDRS and aims to identify emerging trends of jurisdictional and national interest in ecstasy and related drug markets. The ERDS has been conducted in each Australian capital city since 2003. It comprises three components: interviews with at least 100 regular ecstasy users (defined as those having used ecstasy at least six times in the preceding six months); interviews with key informants who are professionals in frequent contact with regular ecstasy users; and analysis and examination of indicator health and law enforcement data. Like the IDRS, the ERDS is designed to be sensitive to emerging trends and provide data in a timely manner rather than describe issues in extensive detail, so data is limited to basic prevalence and use information. Results from the surveys of regular ecstasy users are not representative of ecstasy users as a whole, or of use in the general population. Like the IDRS, the strength of the ERDS data is its capacity to monitor trends over time in a sentinel population of drug users, which can act as an early warning system detecting emerging drug trends (O'Brien, Black, Degenhardt et al 2007).

#### *The Australian Secondary Students' Alcohol and Drug (ASSAD) Survey 2005*

The Australian Secondary Students' Alcohol and Drug (ASSAD) Survey is coordinated nationally and within Victoria by the Centre for Behavioural Research in Cancer on behalf of the Drug Treatment Services Unit, Department of Human Services (DHS) Victoria. A representative sample of schools is selected randomly from all government and non-government schools in Australia. In the Victorian component of the 2005 survey, information from up to 80 students from 69 schools was obtained. Data was collected on tobacco, alcohol, cannabis, inhalants and some other illicit substances, with the 2005 report being based on data from 4,552 students aged 12 to 17 years (White & Hayman 2007).

#### *Drug Use Monitoring in Australia (DUMA)*

The Drug Use Monitoring in Australia programme, which commenced in 1999, is a quarterly collection of information from police detainees in seven police stations or watch-houses across Australia, although none of these are in Victoria. DUMA collects data from two sources: a questionnaire, which is conducted with a trained interviewer, and a urine sample tested for six different drug classes. Both sources of information are collected on a voluntary basis. (Mouzos, Hind, Smith et al 2007).

#### *The Victorian Youth Alcohol and Drugs Survey*

The Victorian Youth Alcohol and Drugs Survey is an interview study that measures drug use and attitudes regarding alcohol and illicit drugs among young Victorians aged 16–24 years. Three Victorian Youth Alcohol and Drugs surveys were conducted annually between 2002 and 2004 with 4,500, 6,000 and 6,005 young Victorians respectively. The Victorian Youth Alcohol and Drugs Survey employed computer-assisted telephone interviewing using randomly selected telephone numbers from electronic White Pages. Consequently there weren't any homeless or institutionalised persons included (Premier's Drug Prevention Council 2005). Prevalence of drug use reported is therefore likely to be underestimated.



### *DirectLine*

DirectLine provides a 24-hour telephone counselling, information and referral service for Victorians wishing to discuss drug-related issues. The service receives calls from individual drug users, relatives and friends of drug users, people seeking drug information generally and professionals in related services fields (DHS Victoria 2007). As such, analysis of DirectLine calls can be seen as a measure of general levels of drug use and concern in the community, but it is not possible from the summary statistics collected and analysed to determine whether the calls related to licit or illicit use of benzodiazepines and opioid analgesics.

Clearly, the data available includes a range of data sources that all have limitations. Turning Point Alcohol and Drug Centre has therefore suggested that:

In regards to future research priorities, the ongoing monitoring of trends in both licit and illicit use of benzodiazepines and pharmaceutical opioids is warranted. Particular areas to focus on in such surveillance are key illicit market indicators such as price, supply source and availability, as well as the adverse health and other outcomes associated with pharmaceutical misuse. Because of the nature of the use, relatively little is known about pharmaceutical misuse in the general population compared with IDU [injecting drug users]. Mechanisms to monitor trends in such use, such as the linking of databases and the routine surveillance of indicator data (e.g. ambulance attendances, help line contacts, treatment databases) need to be explored.<sup>70</sup>

### *Summary*

Australian and Victorian data sources on illicit drugs availability and use among the general population and particular groups such as young people, injecting and party drug users, is particularly useful, although the data is at times limited by the manner in which the use of pharmaceutical drugs are recorded and reported. Furthermore, the sampling strategies employed necessarily require caution in generalising results. Notable in this regard is the likely under-reporting of drug use rates caused by biases resulting from the use of household samples.

## **Legal use**

### *United States data*

The good news is that the increase in invention, production and distribution of controlled prescription drugs has brought relief to millions of people [in the USA]. The bad news is the 94 percent increase in the number of people abusing these drugs between 1992 and 2003, and the 212 percent increase among teens, while the population increased by only 14 percent. The problem of abuse of controlled prescription drugs in America has grown under the counter and under the radar to the point where this abuse now eclipses abuse of all illicit drugs combined except marijuana. The supply often comes from our own medicine cabinets or speedy delivery by ordering over the Internet (National Center on Addiction and Substance Abuse (CASA) 2005, p.1).<sup>71</sup>

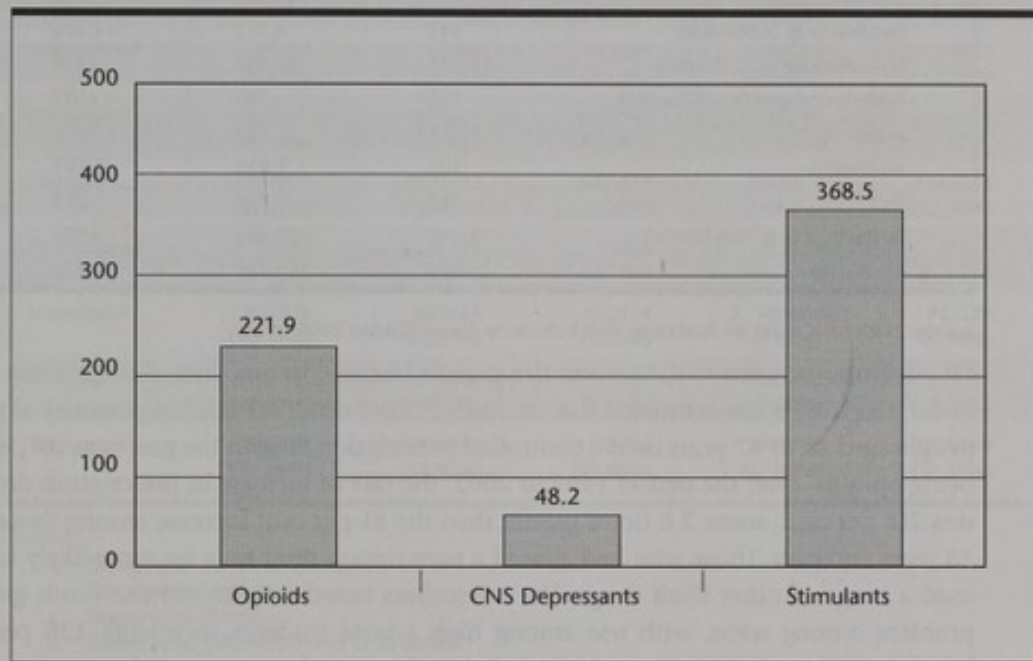
One of the best sources of international data on the extent of use and misuse of benzodiazepines and other prescription drugs is the work done in the United States by CASA (2005). This comprehensive report, entitled *Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S.*, is based on CASA's three-year study on the

70 Submission of Turning Point Alcohol and Drug Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

71 The problem of prescription drug abuse in the United States has created such concern that recently a United States Congressional Inquiry has been established to investigate the extent of the problem and strategies and interventions to address it. For further discussion see Chapter 4.1. See also the United States Congress, Committee on Government Reform, Subcommittee on Criminal Justice, Drug Reform and Human Resources, Hearings into Prescription Drug Abuse (Accessed at: <http://reform.house.gov/CJDPHR/Hearings/EventSingle.aspx?EventID=47888>).

diversion of prescription drugs with the potential for abuse and addiction (termed 'controlled drugs').

**Figure 2.1a: Per cent increase in prescriptions filled for controlled drugs, USA, 1992–2002**



Note: CNS (Central nervous system) depressants include benzodiazepines and barbiturates.

Source: National Center on Addiction and Substance Abuse (CASA) 2005, p.26.

CASA concluded that whilst the United States population had increased by 13 per cent between the years 1992 and 2002, the number of prescriptions written for controlled drugs increased by 154.3 per cent, 12 times faster than the population growth and almost 3 times faster than the growth in non-prescription drugs over the same period (CASA 2005). Figure 2.1a presents percentage increases in prescriptions filled for opioids, central nervous system depressants (barbiturates and benzodiazepines) and stimulants over this period. Tables 2.1b and 2.1c show the percentage changes for benzodiazepine and opioid prescriptions over the same period. These tables indicate that prescriptions for opioids as a whole rose by 222 per cent and for benzodiazepines by 49 per cent.

CASA also argued that while this increase could have been a function of improved treatment for the range of conditions treated by these medications, they found that the number of people who admitted 'abuse' of these medications increased some 94 per cent from 7.8 million in 1992 to 15.1 million in 2002, a rate 7 times greater than the population growth (CASA 2005).

**Table 2.1b: Per cent change in benzodiazepine prescriptions filled, USA, 1992–2002**

<b>Benzodiazepine Prescriptions Filled (000s)</b>			
<b>Benzodiazepine</b>	<b>1992</b>	<b>2002</b>	<b>percent change</b>
clonazepam (e.g. Klonopin)	2,286	8,040	+252
diazepam (e.g. Valium)	8,358	8,265	-1
estazolam (e.g. ProSom)	0	115	+115
lorazepam (e.g. Ativan)	7,449	12,068	+60
triazolam (e.g. Halcion)	2,091	760	-64
<b>Total</b>	<b>20,091</b>	<b>29,248</b>	<b>+49</b>

Notes: NPA refers to National Prescription Audit.

In NPA data '0' indicates that the volume of prescriptions filled was between 1 and 499.

Source: National Center on Addiction and Substance Abuse (CASA) 2005, p.26.



**Table 2.1c: Per cent change in opioid prescriptions filled, USA, 1992–2002**

<b>Opioid Prescriptions Filled (000s)</b>			
<b>Opioid</b>	<b>1992</b>	<b>2002</b>	<b>percent change</b>
codeine	9,120	10,169	+12
fentanyl (e.g. Sublimaze)	341	4,111	+1,106
hydrocodone (e.g. Vicodin)	15,843	75,357	+376
hydromorphone (e.g. Dilaudid)	380	785	+107
merperdine	1,039	1,728	+66
methadone	107	1,816	+1,597
morphine	715	2,706	+279
oxycodone (e.g. OxyContin)	5,641	27,053	+380
Total	33,186	123,725	+222

Source: National Center on Addiction and Substance Abuse (CASA) 2005, p.26.

Of particular concern to CASA was the growth in prescription drug abuse among those under 18 years. It was estimated that in 2003, 9.3 per cent (2.3 million persons) of young people aged 12 to 17 years used a controlled prescription drug in the past year, 83 per cent being opioids. Over the period 1992 to 2002, the rate of increase in prescription drug use was 216 per cent, some 2.6 times greater than the 81 per cent increase among those aged 18 years and over. Those who had abused a prescription drug were far more likely to have used a range of other illicit drugs. The researchers noted that steroid use was a growing problem among teens, with use among high school students increasing 126 per cent between 1991 and 2003. They also noted that the rate of increase was far greater among girls (342%) than boys (66%) (CASA 2005). As stated earlier in this chapter, the types of concerns expressed by CASA and illustrated in the data above have in part resulted in a Congressional Inquiry into prescription drug abuse in the United States.<sup>72</sup>

### **Australian data**

The statistics on legal supply and use of selected pharmaceutical drugs in Australia presented here are primarily from two major sources. Firstly, data has been extracted from the Australian Statistics on Medicines series, which shows the number of prescriptions subsidised by the PBS/RPBS dispensed in community pharmacies, and estimates of non-subsidised supply based on a sample of community pharmacists. Secondly, data from the unpublished work of Dobbin (2006a, b, c, d, e) is also used which shows how PBS and similar data on pharmaceutical drug supply can be analysed and trends identified.

### **Benzodiazepines**

Data extracted from the Australian Statistics on Medicines series presented in Table 2.1d below shows the number of prescriptions (subsidised by the PBS) for each kind of benzodiazepine across Australia. It shows that for the period 1999 to 2003 the number of benzodiazepine prescriptions in Australia has decreased for all types apart from alprazolam, and that temazepam prescriptions, in particular, have declined as a proportion of total benzodiazepine prescriptions from 39.26 per cent to 36.59 per cent over that period.

<sup>72</sup> See <http://reform.house.gov/CJDPHR/Hearings/EventSingle.aspx?EventID=47888>. See also discussion in Chapter 4.1.

**Table 2.1d: Number of subsidised PBS/RPBS prescriptions for benzodiazepines dispensed through community pharmacies in Australia, 1999-2003**

	1999	2000	2001	2002	2003
Alprazolam <sup>a</sup>	353732 (4.09%)	389249 (4.54%)	418960 (5.01%)	432337 (5.41%)	449127 (5.81%)
Bromazepam <sup>b</sup>	45312 (0.52%)	42506 (0.50%)	42264 (0.51%)	40313 (0.50%)	40819 (0.53%)
Clonazepam <sup>c</sup>	116049 (1.34%)	121504 (1.42%)	122148 (1.46%)	111770 (1.40%)	102111 (1.32%)
Diazepam <sup>d</sup>	1977892 (22.87%)	2007593 (23.43%)	2005620 (24.00%)	1968907 (24.62%)	1960086 (25.36%)
Flunitazepam <sup>e</sup>	85069 (0.98%)	11470 (0.13%)	13824 (0.17%)	65518 (0.82%)	71831 (0.93%)
Nitrazepam <sup>f</sup>	935324 (10.81%)	880665 (10.28%)	822804 (9.85%)	789106 (9.87%)	753108 (9.74%)
Oxazepam <sup>g</sup>	1740623 (20.12%)	1699806 (19.84%)	1621204 (19.40%)	1559090 (19.49%)	1524567 (19.72%)
Temazepam <sup>h</sup>	3395474 (39.26%)	3415033 (39.86%)	3308723 (39.60%)	3031290 (37.90%)	2828158 (36.59%)

**Notes:**

- a Brandname Xanax or Kalma.
- b Brandname Lexotan.
- c Brandname Rivotril.
- d Brandname Valium, Ducene or Antenex.
- e Brandname Hypnodorm or Rohypnol.
- f Brandname Mogodon or Alodorm.
- g Brandname Serepax, Murelax or Alepam.
- h Brandname Euhypnos, Nocturne, Normison.

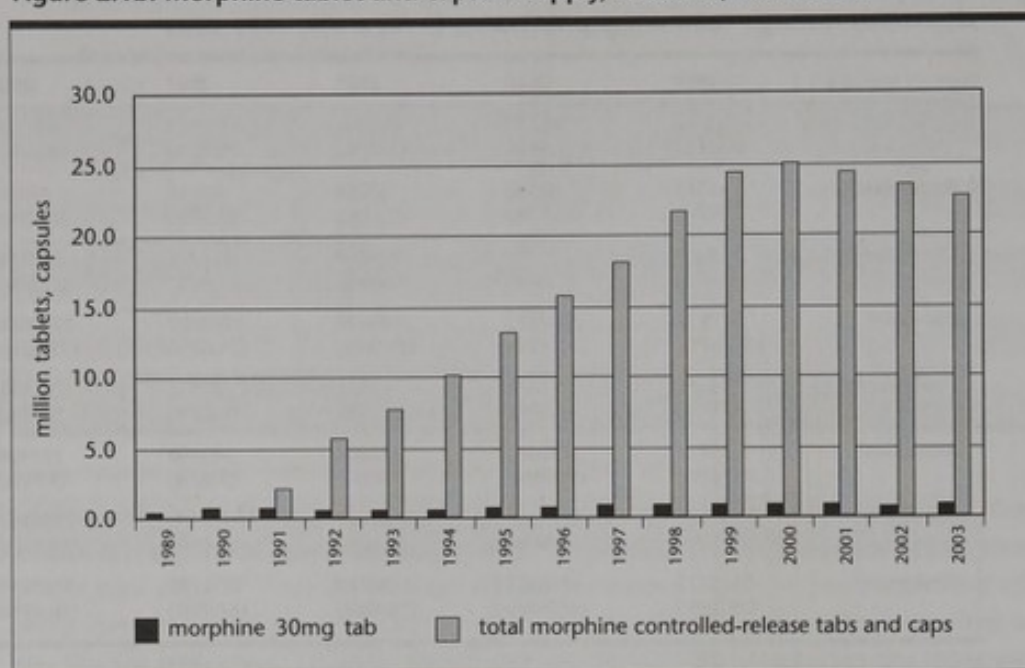
Source: Data extracted from the Drug Utilisation Sub-Committee of the Australian Pharmaceutical Benefits Advisory Committee 2003, 2004, 2005.

**Morphine**

Dobbin (2006b, unpublished) presented data on the supply of immediate release and controlled release morphine preparations in Australia. Controlled release tablets (MS Contin®) were introduced in Australia in 1991 and capsules (Kapanol®) in 1992. Over the period 1990 to 2003 the total number of morphine tablets and capsules supplied in Australia has increased from 651,360 to 25.7 million, representing a 40-fold increase (see Figure 2.1b).



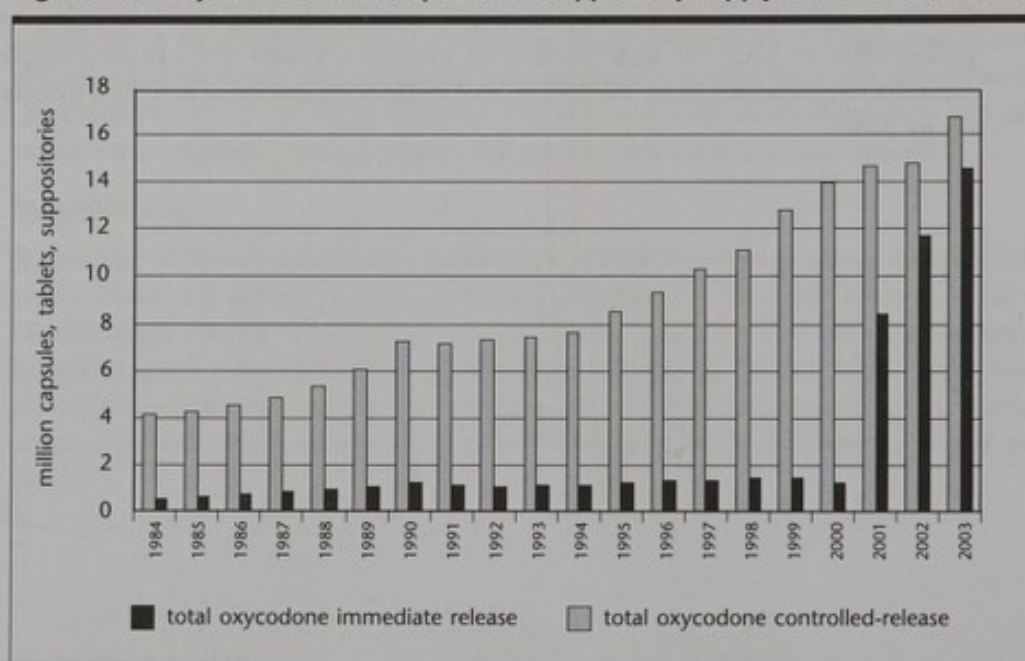
Figure 2.1b: Morphine tablet and capsule supply, Australia, 1989–2003



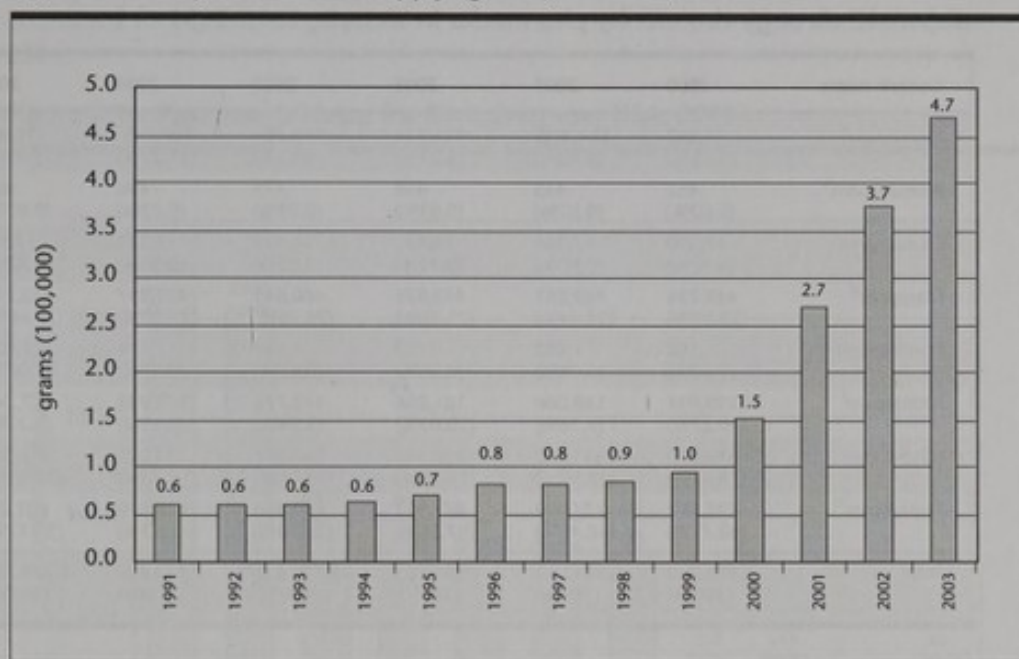
Source: Dobbin 2006b, 'Morphine', Unpublished paper provided to the Drugs and Crime Prevention Committee. Data extracted from the National Drug-control System (NDS) domestic transaction data, collected by the Commonwealth Department of Health and Ageing.

Dobbin (2006c, unpublished) has also used the data to track the growth of oxycodone supply in Australia, subsequent to the introduction of controlled release oxycodone tablets in 2001. This is apparent in Figures 2.1c and 2.1d, showing trends in oxycodone tablet, capsule and suppository supply in Australia and the resulting net increase in base grams of oxycodone. The total number of oxycodone capsules, tablets and suppositories supplied in Australia has grown from 8.4 million in 1990 to 31.4 million in 2003, representing a 3.75-fold increase.

Figure 2.1c: Oxycodone tablet, capsule and suppository supply, Australia, 1984–2003



Source: Dobbin 2006c, 'Oxycodone', Unpublished paper provided to the Drugs and Crime Prevention Committee. Data extracted from the National Drug-control System (NDS) domestic transaction data, collected by the Commonwealth Department of Health and Ageing.

**Figure 2.1d: Oxycodone base supply (grams) Australia, 1991–2003**

Source: Dobbin 2006c, 'Oxycodone', Unpublished paper provided to the Drugs and Crime Prevention Committee. Data extracted from the National Drug-control System (NDS) domestic transaction data, collected by the Commonwealth Department of Health and Ageing.

### **Victorian data**

#### **Benzodiazepines**

Benzodiazepines are among the most widely prescribed drugs in Victoria with just over 1.7 million prescriptions issued under the PBS in the state in 2005. In addition there are those that are dispensed on private, non-PBS prescriptions and large numbers dispensed by hospitals throughout the state (DHS Victoria 2007). Table 2.1e shows that temazepam, diazepam and oxazepam together comprise 82 per cent of all benzodiazepine prescriptions dispensed in 2005. Whilst there have been a number of changes in the number of individual benzodiazepines prescribed in Victoria over time, most notable has been a decrease in the number of temazepam prescriptions. This has occurred since the availability of the capsule formulation as a PBS pharmaceutical benefit was severely curtailed in May 2002. Evidence showed that there was a widespread problem of injection of the liquid contents of the capsules by injecting drug users, resulting in serious tissue and vascular harm (Dobbin et al 2003).<sup>73</sup> Consequently, in Victoria, prescriptions for temazepam fell by 13 per cent in 2002, 7 per cent in 2003, 2 per cent in 2004 and 3 per cent in 2005. As a result of these changes to regulations, temazepam 10mg capsules required approval from the Health Insurance Commission (HIC) before they could be dispensed under the PBS. However, no such condition was placed on tablets, which were less readily injectable. Subsequently in 2004 temazepam gel capsules were withdrawn from the market (DHS Victoria 2007). It is interesting to note that the number of diazepam and alprazolam prescriptions have continued to increase over the period.



**Table 2.1e: Numbers of subsidised PBS/RPBS prescriptions for benzodiazepines dispensed through community pharmacies in Victoria, 2000–2005**

Generic name	2000	2001	2002	2003	2004	2005
Alprazolam <sup>a</sup>	94,892 (4.85%)	104,230 (5.42%)	113,114 (6.27%)	119,284 (6.83%)	126,763 (7.27%)	126,957 (7.43%)
Bromazepam <sup>b</sup>	452 (0.02%)	455 (0.02%)	498 (0.03%)	475 (0.03%)	496 (0.03%)	487 (0.03%)
Clonazepam <sup>c</sup>	17,070 (0.87%)	17,364 (0.90%)	16,481 (0.91%)	14,426 (0.83%)	14,370 (0.83%)	13,931 (0.82%)
Diazepam <sup>d</sup>	469,234 (23.98%)	469,681 (24.44%)	463,076 (25.66%)	460,645 (26.36%)	471,897 (27.08%)	472,736 (27.66%)
Flunitrazepam <sup>e</sup>	1,568 (0.08%)	1,462 (0.08%)	652 (0.04%)	1,177 (0.07%)	1,124 (0.07%)	1,027 (0.06%)
Nitrazepam <sup>f</sup>	199,931 (10.22%)	188,006 (9.78%)	181,056 (10.03%)	173,776 (9.94%)	164,935 (9.46%)	157,745 (9.23%)
Oxazepam <sup>g</sup>	377,040 (19.27%)	363,307 (18.90%)	352,141 (19.51%)	347,044 (19.86%)	344,171 (19.75%)	335,201 (19.61%)
Temazepam <sup>h</sup>	796,592 (40.71%)	777,429 (40.45%)	677,947 (37.56%)	630,863 (36.10%)	618,970 (35.52%)	601,203 (35.17%)
<b>Total</b>	<b>1,956,779 (100%)</b>	<b>1,921,934 (100%)</b>	<b>1,804,965 (100%)</b>	<b>1,747,690 (100%)</b>	<b>1,742,726 (100%)</b>	<b>1,709,287 (100%)</b>

**Notes:**

- a Brandname: Xanax or Kalma.
- b Brandname: Lexotan.
- c Brandname: Rivotril.
- d Brandname: Valium, Ducene or Antenex.
- e Brandname: Hypnodorm or Rohypnol.
- f Brandname: Mogadon or Alodorm.
- g Brandname: Serepax, Murelax or Alepam.
- h Brandname: Euhypnos, Nocturne, Normison, Temaze or Temtabs.

Source: Department of Human Services (DHS) Victoria 2007, p.112.

**Summary**

In Australia as in the United States there appears to have been a substantial increase overall in the total numbers of these drugs in the community over recent years, as indicated by the number of community prescriptions and other indicators of supply. However, the increases are not universal across substances or locations. For example, numbers of benzodiazepine prescriptions as a whole have decreased in Victoria since 1999. Over the last one to two decades there have been large increases in the supply of a range of narcotic analgesics into the Australian community. Whilst recognising that much of this supply may be reflective of better pain management and other improvements in treatment for a range of conditions, it nevertheless also represents an increase in the total supply potentially available for diversion and non-medical use. As a result of changes in prescribing practices and regulations to both improve treatment options and reduce unintended consequences of misuse, there has been a decrease in the availability of some drugs.

**Illicit use****International data****United States data**

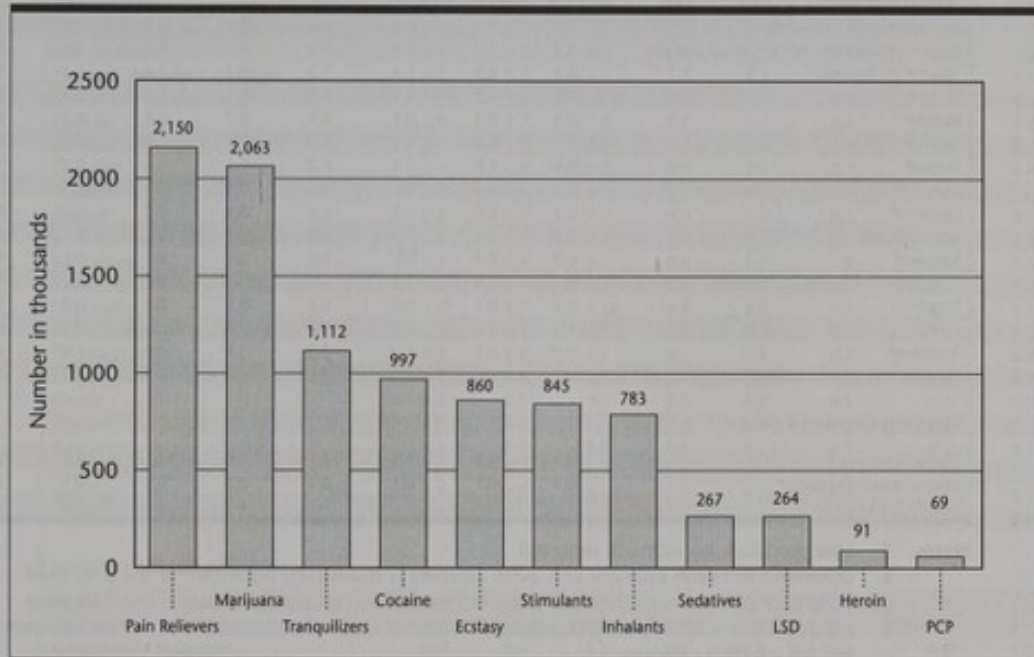
Approximately six percent of the U.S. population (15.1 million people) admitted abusing controlled prescription drugs in 2003, 23 per cent more than the combined number abusing cocaine (5.9 million), hallucinogens (4.0 million), inhalants (2.1 million) and heroin (328,000) (CASA 2005, p.3).

***National Survey on Drug Use and Health (NSDUH)***

Data from the NSDUH in 2006 includes the numbers who were 'new initiates' to illicit use in that year. Figure 2.1e shows that the category with the largest number of new users in that year was non-medical use of (prescription) pain relievers (2.2 million), followed by cannabis (2.1 million) and non-medical use of tranquillisers (1.1 million) (primarily

benzodiazepines). Thus, illicit users of prescription analgesics and benzodiazepines accounted for significant proportions of new users of illicit drugs in the United States in 2006.

Figure 2.1e: Past year initiates for illicit drug use, USA, 2006

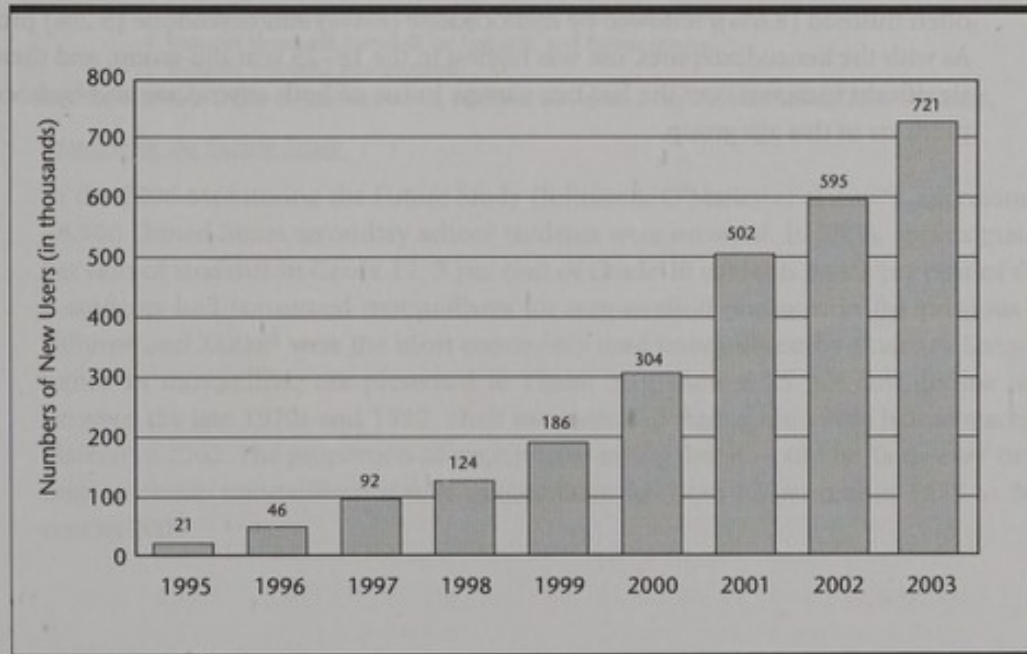


Note: Sedatives refers to barbiturates.

Source: Substance Abuse and Mental Health Services Administration 2007, at [www.samhsa.gov](http://www.samhsa.gov).

Data from the NSDUH shows the growth in new non-medical users of OxyContin® since it was first introduced in 1995. These statistics are shown in Figure 2.1f.

Figure 2.1f: Trends in new non-medical users of OxyContin® in USA, 1995–2003



Source: Substance Abuse and Mental Health Services Administration (SAMHSA) 2005, p.50.

Although the Substance Abuse and Mental Health Services Administration does not provide an extensive analysis of trends in non-medical use of pharmaceutical drugs by drug type, it does provide lifetime use by age for specific tranquillisers and analgesics and these are provided below (Tables 2.1f and 2.1g respectively). Table 2.1f shows that some 8.0 per cent of Americans aged 12 years or over illicitly used benzodiazepines in 2006, and that use was highest in the 18–25-year-old age group. Diazepam was the most commonly misused benzodiazepine.



**Table 2.1f: Non-medical lifetime use of specific tranquillisers by age group, per cent of respondents, 2005 and 2006**

Tranquillizer	AGE GROUP							
	Total		12-17		18-25		26 or Older	
	2005	2006	2005	2006	2005	2006	2005	2006
Klonopin® or Clonazepam	1.3	1.4	0.6	0.6	3.8	3.7	0.9	1.1
Xanax®, Alprazolam, Ativan®, or Lorazepam	4.2	4.4	1.8	1.9	9.3	8.9	3.7	3.9
Valium® or Diazepam	6.1	6.0	1.4	1.3	8.2	7.6	6.4	6.4
Atarax®	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
BuSpar®	0.3	0.3	0.1	0.1	0.7	0.6	0.2	0.2
Equanil®	0.1	0.0	0.0	0.0	0.1	0.1	0.1	0.0
Flexeril®	0.8*	1.0	0.3	0.2	1.5	1.6	0.7*	1.0
Librium®	0.3	0.3	0.0	0.1	0.3	0.2	0.4	0.3
Limbitrol®	0.0	0.0	0.0	0.0	0.1	0.1	0.0	0.0
Meproamate	0.1	0.0	0.0	0.0	0.1	0.1	0.1	0.0
Miltown®	0.0	0.0	0.0	0.0	0.1	0.0	0.1	0.0
Rohypnol®	0.1	0.1	0.1	0.1	0.4	0.3	0.1	0.1
Serax®	0.0	0.1	0.0	0.0	0.1	0.1	0.0	0.0
Soma®	1.0	1.2	0.5	0.4	3.3	3.2	0.7	0.9
Tranxene®	0.0*	0.1	0.0	0.0	0.1	0.0	0.0*	0.1
Vistaril®	0.1	0.1	0.1	0.1	0.2	0.2	0.1	0.1
SELECTED GROUPS OF DRUGS								
Benzodiazepines <sup>1,2</sup>	8.1	8.0	2.6	2.6	12.6	12.1	8.1	8.0
Meproamate Products <sup>3</sup>	0.1	0.1	0.1	0.1	0.2	0.1	0.1	0.1
Muscle Relaxants <sup>1,4</sup>	1.6*	1.8	0.6	0.6	3.9	4.0	1.3*	1.6

Notes: \* Low precision; no estimate reported.

a Difference between estimate and 2006 estimate is statistically significant at the 0.05 level.

b Difference between estimate and 2006 estimate is statistically significant at the 0.01 level.

1 Includes other – specify drug responses that are not asked about explicitly in the Tranquillizers module but fall into this category.

2 Includes Klonopin® or clonazepam, Xanax®, alprazolam, Ativan®, or lorazepam, Valium® or diazepam, Librium®, Limbitrol®, Rohypnol®, Serax®, and Tranxene®.

3 Includes Equanil®, meproamate, and Miltown®.

4 Includes Flexeril® and Soma®.

Source: Substance Abuse and Mental Health Services Administration (SAMHSA), Office of Applied Studies, National Survey on Drug Use and Health, 2005 and 2006.

Table 2.1g shows that in 2006 analgesics in the propoxyphene or codeine group were most often misused (8.6%), followed by hydrocodone (8.4%) and oxycodone (5.2%) products. As with the benzodiazepines, use was highest in the 18–25 year-old-group, and there were significant increases over the last two surveys in use of both oxycodone and hydrocodone products in this age group.

**Table 2.1g: Non-medical lifetime use of specific analgesics by age group, per cent of respondent, 2005 and 2006**

Pain Reliever	AGE GROUP							
	Total		12-17		18-25		26 or Older	
	2005	2006	2005	2006	2005	2006	2005	2006
Darvocet®, Darvon®, or Tylenol® with Codeine	7.9	7.9	4.9	5.0	13.3 <sup>a</sup>	12.3	7.3	7.5
Percocet®, Percodan®, or Tylox®	4.5	4.7	1.7	1.9	9.2	8.8	4.1	4.3
Vicodin®, Lortab®, or Lorcet®	7.2 <sup>b</sup>	8.0	4.6	4.9	17.7	18.0	5.7 <sup>b</sup>	6.6
Codeine	2.6	2.7	1.8	1.7	6.7	6.1	2.1	2.3
Demerol®	1.1	1.0	0.4	0.3	2.4 <sup>b</sup>	1.8	0.9	1.0
Dilaudid®	0.4	0.4	0.0	0.0	0.6	0.5	0.4	0.4
Fioricet®	0.2	0.2	0.0 <sup>a</sup>	0.1	0.4 <sup>a</sup>	0.2	0.2	0.2
Florinal®	0.2	0.2	0.1	0.0	0.2 <sup>a</sup>	0.1	0.2	0.2
Hydrocodone	2.9	3.0	1.7	1.7	7.6	7.8	2.2	2.3
Methadone	0.7	0.6	0.5	0.6	1.7	1.8	0.5	0.5
Morphine	1.0	1.0	0.7	0.8	2.9	2.7	0.7	0.7
OxyContin®	1.4 <sup>b</sup>	1.7	1.1 <sup>a</sup>	1.3	5.0	5.1	0.9 <sup>a</sup>	1.1
Phenaphen® with Codeine	0.3	0.3	0.1	0.2	0.7 <sup>a</sup>	0.5	0.2	0.3
Propoxyphene	0.1	0.2	0.1	0.1	0.4	0.2	0.1	0.2
SK-65®	0.0	0.0	0.0 <sup>b</sup>	0.1	0.0	0.1	0.0	0.0
Stadol®	0.0	0.0	*	0.0	0.1	0.1	0.0	0.0
Talacen®	0.0	0.0	0.0	0.0	0.1	0.1	0.0	0.0
Talwin®	0.1	0.1	0.0	0.0	0.1	0.1	0.2	0.1
Talwin® NX	0.0 <sup>a</sup>	0.1	0.0	0.0	0.1	0.0	0.0 <sup>a</sup>	0.1
Tramadol	0.1 <sup>a</sup>	0.2	0.1	0.1	0.5 <sup>a</sup>	0.7	0.1	0.1
Ultram®	0.4	0.4	0.2	0.1	1.2	1.2	0.3	0.4
<b>SELECTED GROUPS OF DRUGS</b>								
Propoxyphene or Codeine Products <sup>1,2</sup>	8.6	8.6	5.6	5.7	15.2 <sup>a</sup>	14.2	7.9	8.0
Oxycodone Products <sup>1,3</sup>	4.9	5.2	2.3	2.6	10.8	10.8	4.3	4.6
Hydrocodone Products <sup>1,4</sup>	7.8 <sup>b</sup>	8.4	5.1	5.4	18.9	19.2	6.2 <sup>b</sup>	7.0
Tramadol Products <sup>1,5</sup>	0.5	0.5	0.2	0.2	1.4	1.5	0.3	0.4

Notes: \* Low precision; no estimate reported.

a Difference between estimate and 2006 estimate is statistically significant at the 0.05 level.

b Difference between estimate and 2006 estimate is statistically significant at the 0.01 level.

1 Includes other-specify drug responses that are not asked about explicitly in the Pain Relievers module but fall into this category.

2 Includes Darvocet®, Darvon® or Tylenol® with Codeine, codeine, Phenaphen® with Codeine, propoxyphene, and SK-65®.

3 Includes Percocet®, Percodan® or Tylox®, and OxyContin®.

4 Includes Vicodin®, Lortab®, or Lorcet®, and hydrocodone.

5 Includes tramadol and Ultram®.

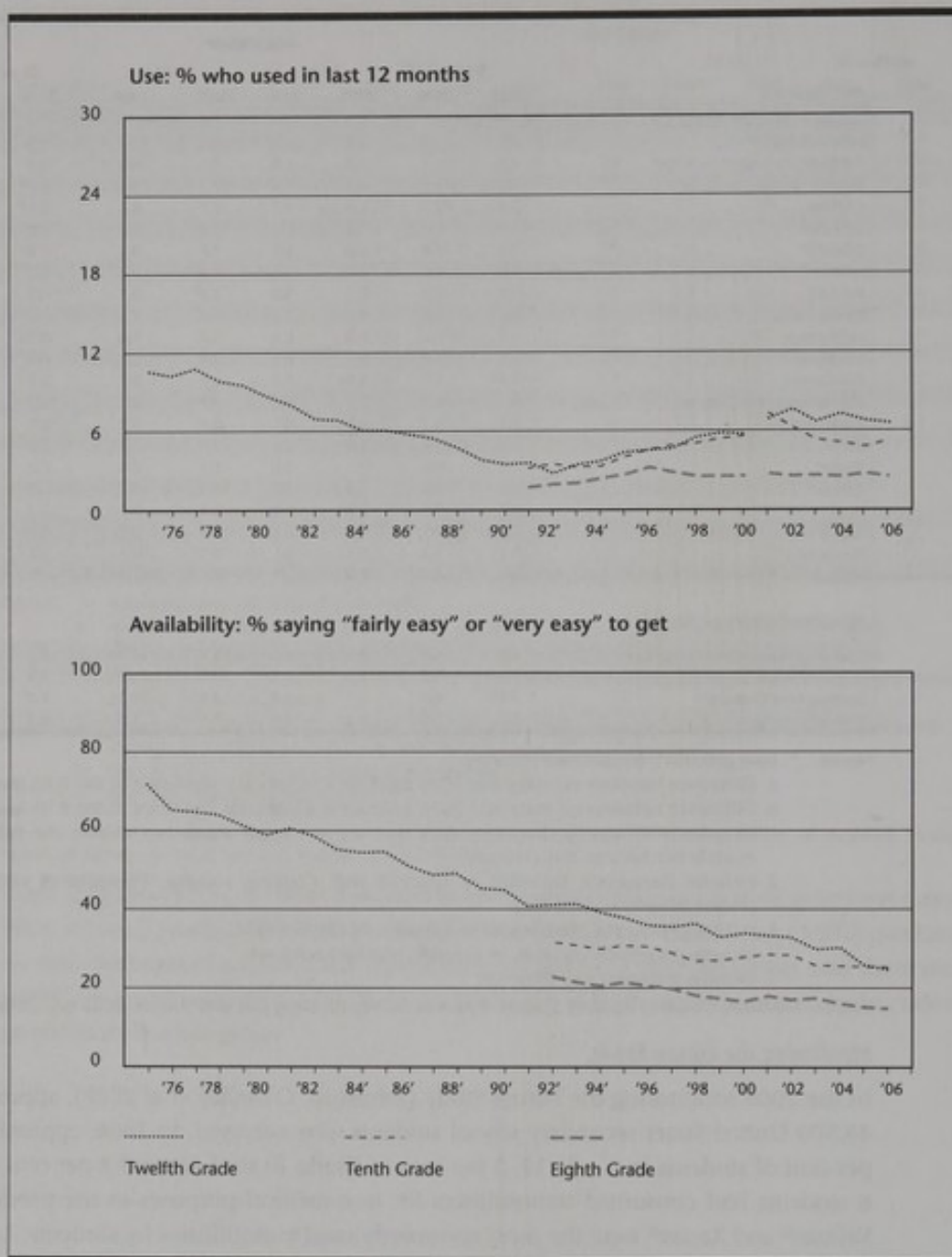
Source: SAMHSA, Office of Applied Studies, National Survey on Drug Use and Health, 2005 and 2006.

#### Monitoring the Future Study

In the 2006 Monitoring the Future Study (Johnston, O'Malley et al 2007), approximately 48,500 United States secondary school students were surveyed. In 2006, approximately 7 per cent of students in Grade 12, 5 per cent of Grade 10 students and 3 per cent of Grade 8 students had consumed tranquillisers for non-medical purposes in the previous year. Valium® and Xanax® were the most commonly used tranquillisers by students. Long-term trends in tranquilliser use presented in Figure 2.1g show a 75 per cent decline in use between the late 1970s and 1992. Their use increased during the 1990s before reaching a plateau in 2002. The proportion of respondents saying that it would be 'fairly easy' or 'very easy' to obtain tranquillisers if they wanted them fell from 72 per cent in 1975 to 24 per cent in 2006.



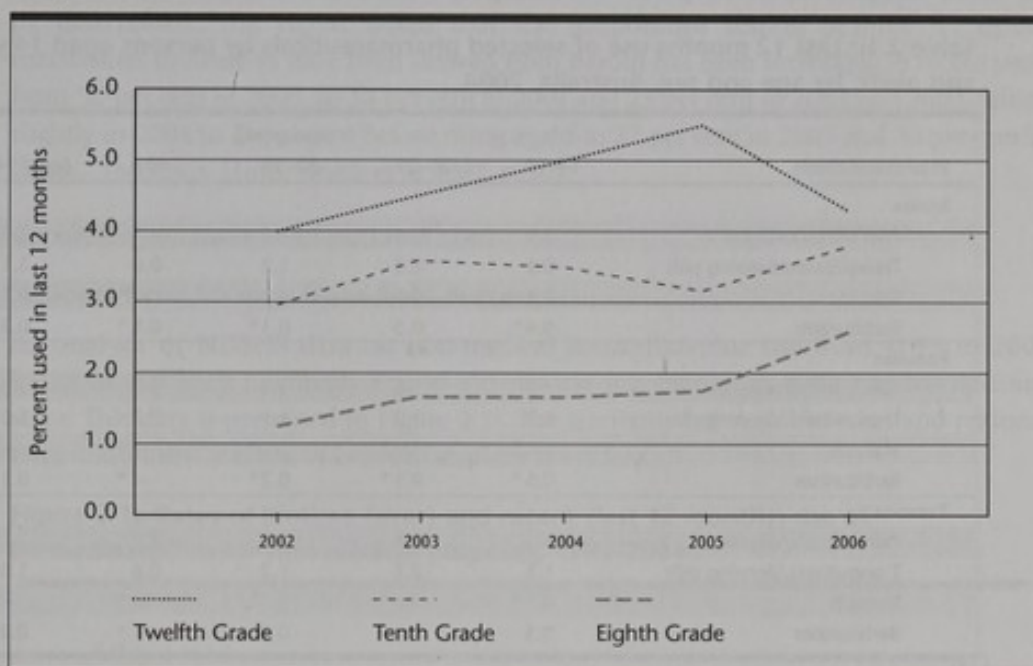
**Figure 2.1g: Recent use and availability of tranquillisers, secondary students, USA, 1975 to 2006**



Source: Johnston, O'Malley, Bachman & Schulenberg 2007, p.32.

Rates of OxyContin® use, which have been measured since 2002, have increased for all grades during the period from 2002 to 2006, although the increase did not continue into 2006 for the 12th Grade. Thus in 2006, 2.6 per cent of the students in year 12 and 3.8% and 4.3% in grades 8 and 10 respectively had used OxyContin®. These data are presented in Figure 2.1h. The Monitoring of the Future Study also found that use of Vicodin had been used in much higher levels than OxyContin® (Johnston, O'Malley, Bachman and Schulenberg 2007).

**Figure 2.1h: OxyContin® use in last 12 months by students in grades 8, 10 and 12, USA, 2002–2006**



Source: Data extracted from Johnston, O'Malley, Bachman & Schulenberg 2007, p.30.

### *The Australian situation*

#### **National Drug Strategy Household Survey (NDSHS)**

Data from the 2004 National Drug Strategy Household Survey presented in Table 2.1h indicate that 7.6 per cent of Australians (1,026,300 individuals) aged 14 years and over had used pharmaceutical drugs (pain killers, tranquillisers, barbiturates or steroids) for non-medical purposes at least once in their lives; 3.8 per cent in the past year (658,300 individuals) and 2 per cent in the past month (259,400). Males (8.2%) were more likely than females (7.0%) to have ever used these drugs, but roughly equal proportions of males (3.6%) and females (3.9%) had used them illicitly in the past 12 months. Those Australians 20 to 29 years of age were most likely to have used these drugs for non-medical purposes in their lifetime, and in the past 12 months or the last month (AIHW 2005a).

**Table 2.1h: Use of pharmaceuticals for non-medical purposes by persons aged 14 years and older, by age and sex, Australia, 2004**

Period	Age group				Sex		Persons
	14–19	20–29	30–39	40+	Males	Females	
	(per cent)						
In lifetime	6.3	10.8	9.0	6.4	8.2	7.0	7.6
In the last 12 months	4.0	5.1	3.9	3.3	3.6	3.9	3.8
In the last month	1.5	2.4	2.0	2.0	1.9	2.2	2.0
In the last week	0.8	1.2	1.2	1.2	1.1	1.3	1.2
	(number)						
In lifetime	103,900	172,900	186,300	563,200	506,300	520,000	1,026,300
In the last 12 months	66,600	110,900	119,500	361,200	324,500	333,500	658,300
In the last month	26,300	43,700	47,100	142,400	126,000	131,400	259,400
In the last week	14,000	23,400	25,200	75,100	68,400	70,300	138,700

Source: Australian Institute of Health and Welfare (AIHW) 2005a, p.47.

Table 2.1i shows use of pharmaceuticals in the previous 12 months by sex, age and drug type. It indicates that analgesics were the most common pharmaceutical used for illicit purposes with 3.1 per cent of Australians having done so in the past year. This was followed by tranquillisers or sleeping pills which were used by 1.0 per cent in that period. Australians



aged 20 to 29 years were most likely to have used analgesics or tranquillisers for non-medical purposes in the past 12 months (AIHW 2005a).

**Table 2.1i: Last 12 months use of selected pharmaceuticals by persons aged 14 years and older, by age and sex, Australia, 2004**

Pharmaceuticals	Age group				
	14–19	20–29	30–39	40+	Aged 14+
<b>Males</b>					
Pain killers/analgesics	1.9	4.1	2.6	2.8	2.9
Tranquillisers/sleeping pills	0.9	2.3	1.2	0.6	1.1
Steroids	0.1 *	0.1 *	0.2 *	— *	0.1 *
Barbiturates	0.4 *	0.5	0.3 *	0.1 *	0.2
<b>Females</b>					
Pain killers/analgesics	4.2	3.5	3.6	2.9	3.3
Tranquillisers/sleeping pills	1.3	1.9	1.1	0.7	1.0
Steroids	— *	— *	— *	— *	— *
Barbiturates	0.5 *	0.1 *	0.2 *	— *	0.1
<b>Persons</b>					
Pain killers/analgesics	3.1	3.8	3.1	2.9	3.1
Tranquillisers/sleeping pills	1.1	2.1	1.2	0.6	1.0
Steroids	0.1 *	— *	0.1 *	— *	—
Barbiturates	0.5	0.3	0.2	— *	0.2

Note: \* Figures unreliable as relative standard error is greater than 50%.

Source: Australian Institute of Health and Welfare (AIHW) 2005a, p.48.

Table 2.1j shows that among those who had used pharmaceutical drugs for non-medical purposes in the past 12 months, approximately one in four did this on a daily basis (AIHW 2005a).

**Table 2.1j: Frequency of non-medical use of pharmaceuticals in last 12 months by persons aged 14 years and older, by age and sex, Australia, 2004**

	Age Group				Sex		
	14–19	20–29	30–39	40+	Males	Females	Persons
	(per cent)						
Daily or weekly	10.9*	16.1	23.2	33.4	23.2	26.2	24.8
About once a month	24.5	24.6	25.7	20.0	19.9	25.3	22.7
Every few months	29.5	20.9	18.1	23.2	20.8	23.8	22.4
Once or twice a year	34.8	38.4	33.8	23.3	36.1	27.7	

Notes: 1. Base is recent users.

2. \* Figures unreliable as relative standard error is greater than 50%.

Source: Australian Institute of Health and Welfare (AIHW) 2005a, p.49.

### Drug Use Monitoring (DUMA) data

With regards to the use of pharmaceutical drugs among persons incarcerated by police or correctional services in Australia, some figures are provided by the DUMA project. DUMA data is collected from detainees on a quarterly basis from seven police stations or watch-houses around Australia. From the most recent DUMA report in which 4,555 detainees were interviewed, positive tests for benzodiazepines were recorded among 20 per cent of males and 36 per cent of females. However, because benzodiazepines can be detected in urine up to 14 days after use, and because they can be prescribed licitly, DUMA also enquires about non-medical use (not prescribed by a doctor or other health professional and not due to over-the-counter medications). Some 20 per cent of females and 9 per cent of male detainees said that they had taken prescription benzodiazepines during the previous two weeks and 30 per cent of these said they had also used these drugs illegally over the past month (Mouzos, Hind, Smith et al 2007).

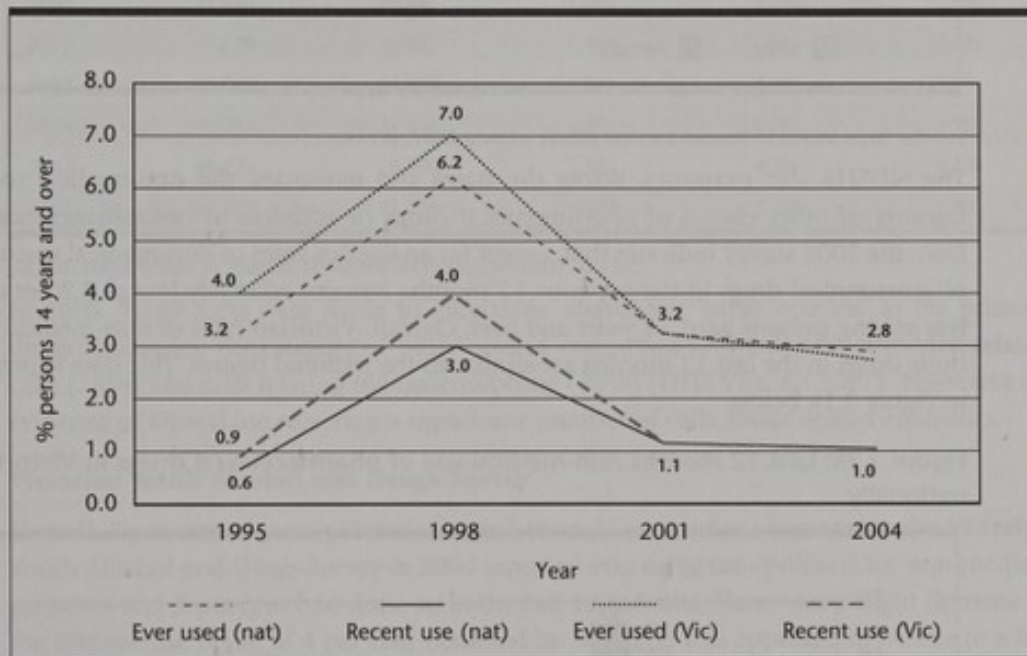
There were 488 positive tests for opiate metabolites of which 21 per cent were unlikely to have been derived from heroin, although the licit or illicit origins of these opiates could not be determined. The report noted that the proportions testing positive for opiate metabolites unlikely to have been derived from heroin has been increasing in recent years from '10 per cent in 2000, to 18 per cent in 2001 and 23 per cent in 2002 and 2003, falling slightly in 2004 to 21 per cent before rising again to 27 per cent in 2005 and 30 per cent in 2006...' (Mouzos, Hind, Smith et al 2007, p.30).

### *Comparing Victorian and national data*

#### **National Drug Strategy Household Survey**

An analysis of NDSHS data on non-medical benzodiazepine use from 1995 to 2004 indicates that both nationally and in Victoria use was highest in 1998 and has declined since. This data is presented in Figure 2.1i. The similarity between Victorian and national rates of non-medical use of benzodiazepines is evident.

**Figure 2.1i: Rates of lifetime (ever) and recent (last 12 months) use of benzodiazepines for non-medical purposes, 1995–2004**

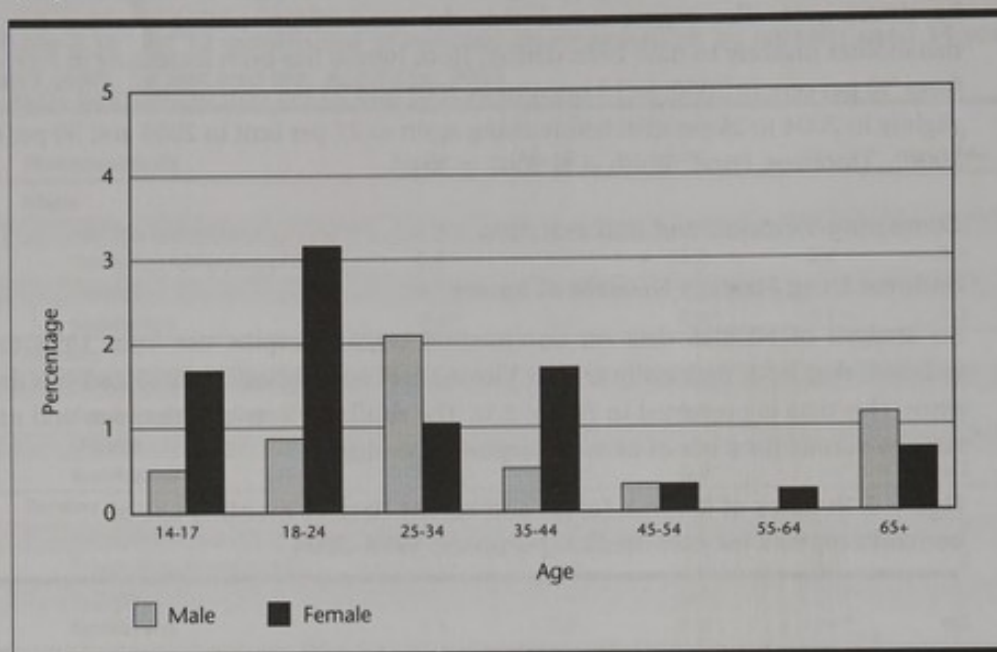


Source: Data from Department of Human Services (DHS) Victoria 2007; Australian Institute of Health and Welfare (AIHW) 1999, 2002, 2005a.

An analysis of 2004 NDSHS data found that more females reported lifetime tranquilliser use in all age groups except for those aged 25-34 years and 45-54 years (DHS Victoria 2007). Males aged 25-34 years and over 65 years of age reported higher use in the last 6 months whilst recent use of tranquillisers was higher in females in the younger age groups (See Figure 2.1j).



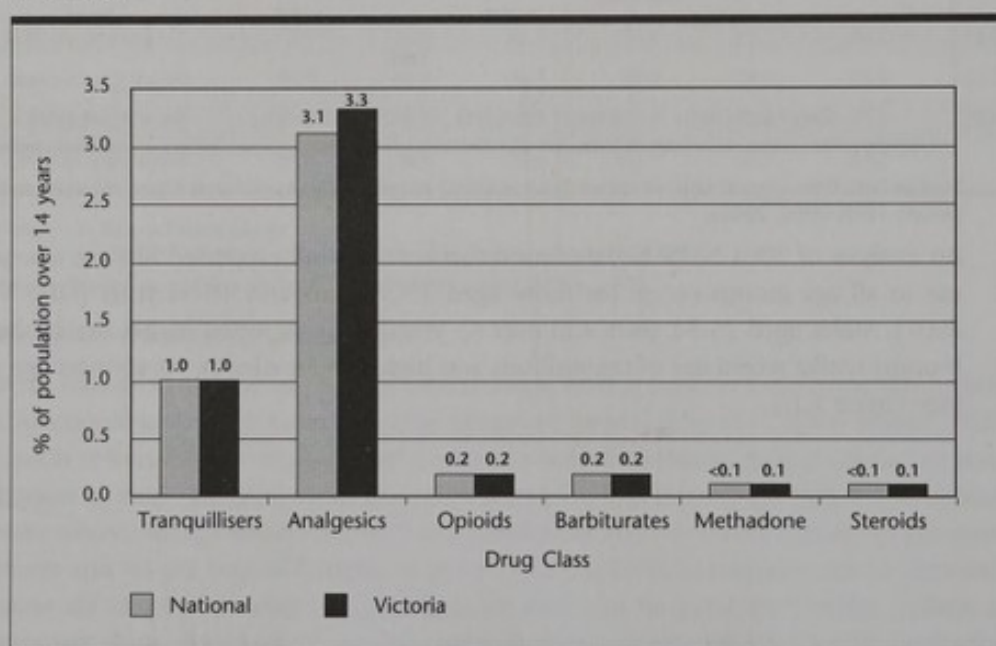
**Figure 2.1j: Prevalence estimates of last 12 months non-medical use of tranquillisers by age and sex, Victoria, 2004**



Source: Department of Human Services (DHS) Victoria 2007, p.114.

The NDSHS also examines, across the states and territories, the non-medical use of a number of other classes of pharmaceutical drugs in addition to benzodiazepines. Data from the 2004 survey indicates that, except for analgesics, rates of non-medical use of these pharmaceutical drugs in the previous 12 months remains relatively low at 0.2 per cent or less among persons aged 14 years and over. Overall, Victorian rates of non-medical use of these drugs in the last 12 months are similar to the national figures. This data is presented in Figure 2.1k below.

**Figure 2.1k: Last 12 months non-medical use of pharmaceutical drugs in Victoria and nationally**



Source: Data from Australian Institute of Health and Welfare (AIHW) 2005c.

### Calls to DirectLine

Table 2.1k shows the number of calls received by DirectLine between 1999 and 2005 where benzodiazepines and other tranquillisers were cited as the drugs of concern.<sup>74</sup> Over this period a total of 8,530 calls relating to benzodiazepines and/or other major tranquillisers were received, representing an average of 5.2 per cent of drug specific calls received by the service. The majority of callers were female (64%), with 61 per cent of calls relating to personal use and 69 per cent relating to the use of benzodiazepines and/or other major tranquillisers by others. The number of calls relating to the use of benzodiazepines and/or other major tranquillisers has remained relatively constant since 1999 although a peak in calls was apparent during 2001 and 2002 and a decline in 2005 (DHS Victoria 2007).

**Table 2.1k: Number of calls received by DirectLine between 1999 and 2005 where benzodiazepines and other tranquillisers were cited as the drugs of concern**

Year	Total number of calls to DL	Total calls drug-identified	Benzodiazepines and/or other major tranquillisers a drug of concern	% of drug-identified	% of all calls
1999	39,284	21,351	1,216	5.7%	3.1%
2000	39,440	19,746	1,087	5.5%	2.8%
2001	41,159	20,922	1,461	7.0%	3.6%
2002	45,307	24,990	1,341	5.4%	3.0%
2003	48,151	24,861	1,372	5.5%	2.9%
2004	48,776	26,990	1,205	4.5%	2.5%
2005	44,723	25,204	848	3.4%	1.9%

Source: Department of Human Services (DHS) Victoria 2007, p.118.

In 2005, 7,287 calls were made to DirectLine identifying 'other opioids' as the primary drugs of concern. The category of 'other opiates' comprised primarily of methodone-related calls (78%) and calls relating to buprenorphine (20%) (DHS Victoria 2007). There was no evidence of DirectLine receiving a significant number of calls about opioid analgesics.

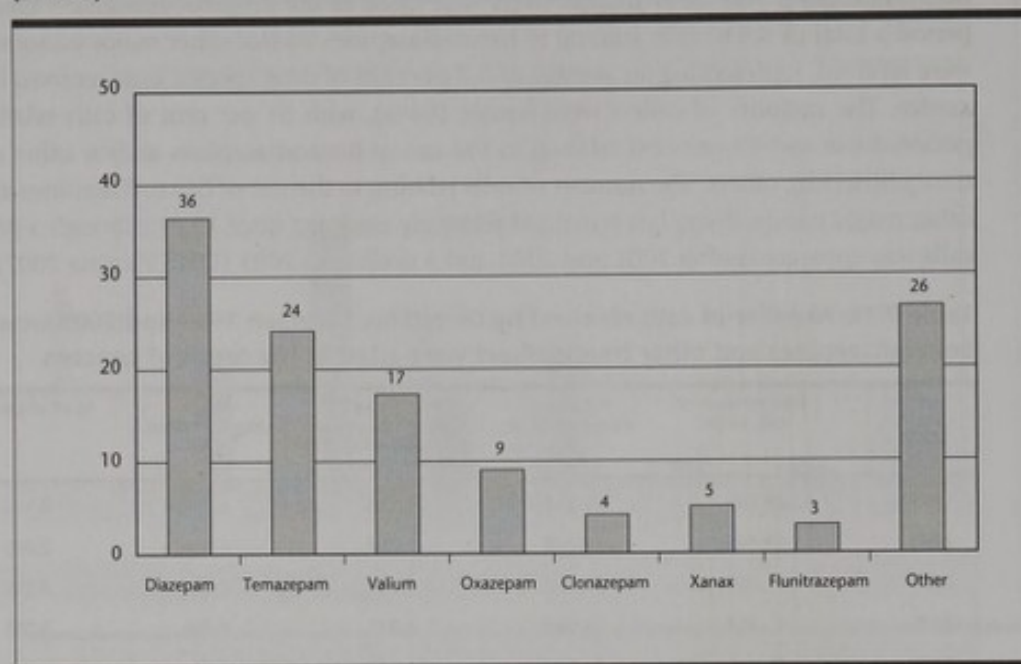
### Victorian Youth Alcohol and Drugs Survey

Overall, 3 per cent of young Victorians aged 16 to 24 years of age surveyed in the Victorian Youth Alcohol and Drugs Survey in 2004 reported ever using tranquillisers for non-medical purposes and 2 per cent had done so in the last 12 months. There was a slight decrease in the lifetime use figure of 4 per cent obtained in 2003 and this appeared to be due to a fall in lifetime use by females. Since the 2003 survey there has been no change in recent use. As shown in Figure 2.11, diazepam, temazepam, Valium® (which is diazepam) and oxazepam were the benzodiazepines most used by young Victorians for non-medical purposes in 2004 (Premier's Drug Prevention Council 2005).

<sup>74</sup> Data were limited to valid DirectLine calls by removing all administrative, hoax, immediate hang up or wrong number calls. HealthLink manages several addiction-related health information and referral telephone support services in Victoria and for other states or territories and calls for these services were also excluded from analysis (DHS Victoria 2006e).



**Figure 2.1l: Types of benzodiazepines used by Victorians aged 16–24 for non-medical purposes during the previous 12 months, 2004 – per cent of respondents (n=110)**

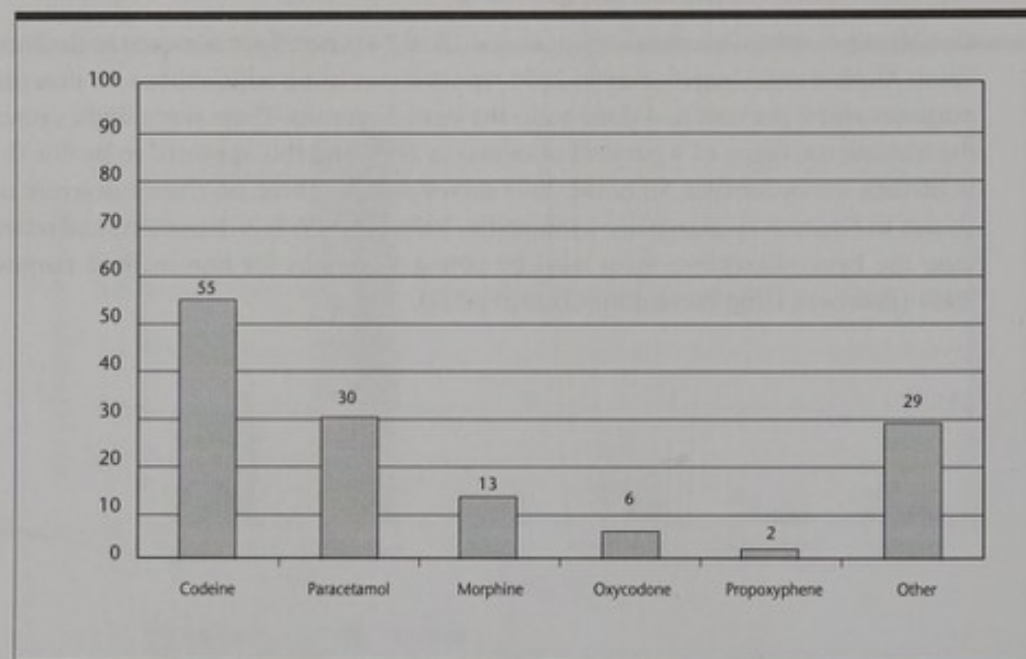


Note: This Table depicts both generic and trade name drugs, for example Valium is the trade name for diazepam and Xanax is the trade name for alprazolam.

Source: Premier's Drug Prevention Council 2005, p.21.

As in 2002 and 2003, 4 per cent of 16- to 24-year-old Victorians surveyed in 2004 reported ever using analgesics for non-medical purposes and 2 per cent of these had used in the last 12 months. There were little differences between males and females. The most frequent analgesic drugs used by this group in 2004 are presented in Figure 2.1m.

**Figure 2.1m: Types of analgesics used for non-medical purposes by Victorians aged 16–24 during the previous 12 months, 2004 – per cent of respondents (n=110)**



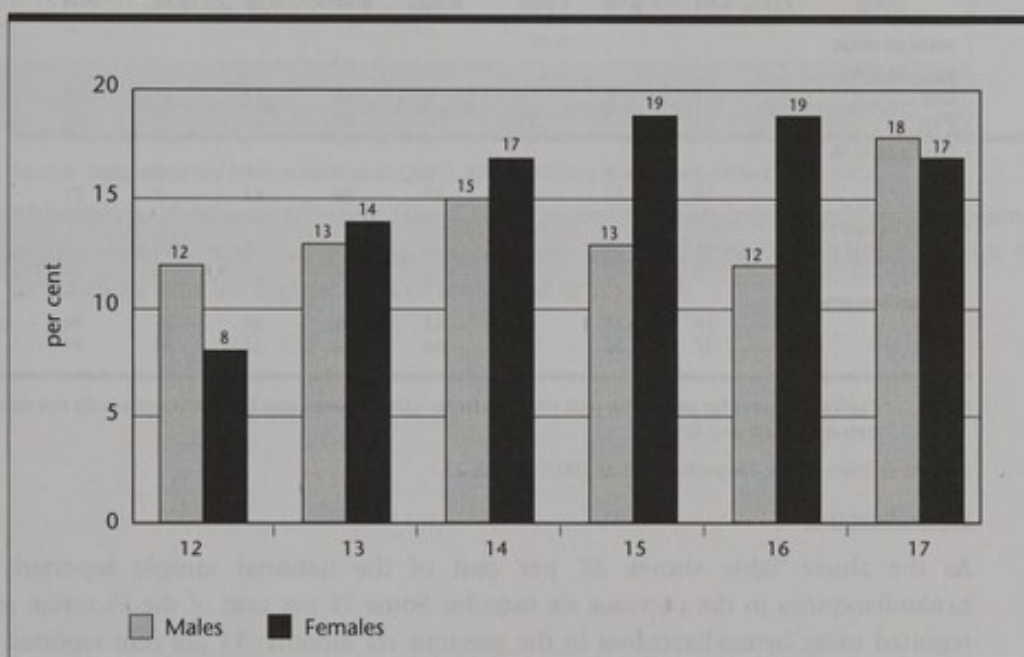
Source: Premier's Drug Prevention Council 2005, p.20.

### The Australian Secondary Students' Alcohol and Drug (ASSAD) survey

Although the ASSAD survey reports on a range of drugs including sedatives (tranquillisers) and 'pain killers', questions regarding the latter class do not distinguish between the type of medicine (over-the-counter vs. prescription) or whether they have been taken for medical or non-medical reasons. As a consequence, the data on analgesics from this survey is of limited use in the current Inquiry, as almost all students have used some painkillers at least once recently.

However, the data on tranquilliser use is useful as it refers to non-medical use. Victorian data from the 2005 ASSAD survey indicate that use of benzodiazepines for non-medical purposes is relatively low with 85% of students never having used tranquillisers for non-medical purposes. Data on lifetime use by age and sex is presented in Figure 2.1n. It shows rates of use were higher among females who were 13, 14, 15 and 16 years of age (White, Hain & Fairthorne 2005).

Figure 2.1n: Lifetime use of tranquillisers (other than for medical reasons), Victorian students aged 12 to 17, 2005



Source: White, Hain & Fairthorne 2005, p.126.

Table 2.1l presents the percentage of Victorian students who reported that they had ever used tranquillisers other than for medical reasons, across the previous four years of the ASSAD survey: 1996, 1999, 2002 and 2005. Overall, there was no significant change in lifetime use of tranquillisers across the survey years. However, the decrease in use for 12- to 15-year-old students was statistically significant, with fewer students (14%) reporting tranquilliser use in 2005 than in 1996 (18%).

Table 2.1l: Trends in the lifetime use of tranquillisers (other than for medical reasons) by Victorian students by gender and age, 1996–2005

Sedatives	12- to 15-year-olds				16- to 17-year-olds			
	1996	1999	2002	2005	1996	1999	2002	2005
Lifetime use (%)								
Male	17 **	17 **	12	13	18	20	15	14
Female	19 **	13	13	15	19	20	18	18
Total	18 **	15	13	14	19	20	16	16

Note: \* Significantly different from 2005 at p<01 level.

Source: White, Hain & Fairthorne 2005, p.127.



### The Illicit Drug Reporting System (IDRS)

The latest data from the IDRS, which includes surveys with injecting drug users in each Australian state and territory on a national basis, indicates that significant proportions of the sample had used pharmaceutical drugs illicitly over the previous six months. These drugs included methadone, buprenorphine, morphine, oxycodone, benzodiazepines and antidepressants.

Table 2.1m presents data on selected pharmaceutical drugs that are used by injecting drug users in the past six months. It can be seen that in the Northern Territory and Tasmania rates of illicit use of morphine are higher than in other jurisdictions. This phenomenon is common where heroin is less available on the illicit market, as is the case in those two jurisdictions.

**Table 2.1m: Selected pharmaceutical drugs used by injecting drug users in the preceding six months by state and territory, 2006**

	NSW n=152	ACT n=100	VIC n=150	TAS n=100	SA n=100	WA n=100	WA n=100	QLD n=112	National
<b>FORM OF DRUG</b>									
<b>Morphine %</b>									
Licit	7	8	7	4	10	12	31	11	11
Illicit	31	52	31	58	48	51	70	51	47
<b>Oxycodone %</b>									
Licit	5	6	5	2	5	8	5	8	6
Illicit	18	22	24	29	20	42	7	21	23
<b>Other Opiates %</b>									
Licit	4	7	6	3	5	3	0	7	9*
Illicit	3	2	3	15	2	3	0	5	
<b>Benzodiazepines %</b>									
Licit	26	31	53	48	55	54	21	44	67*
Illicit	37	36	31	46	32	32	34	41	

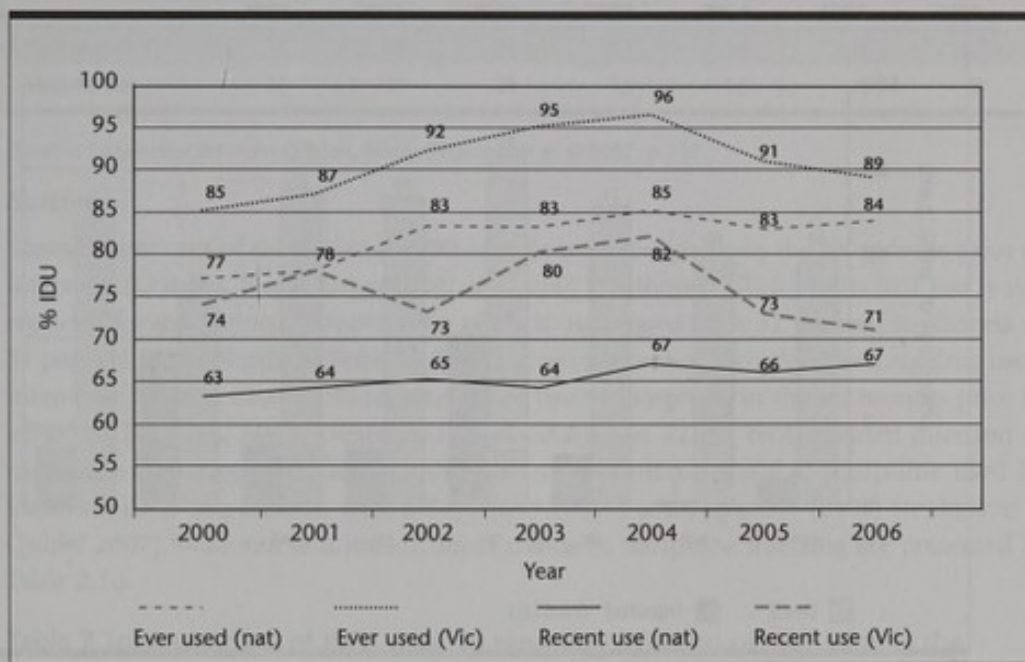
Note: \* National figures for use in the past six months for other opiates and benzodiazepines do not distinguish between illicit and licit.

Source: O'Brien, Black, Degenhardt et al 2007, pp.22–23.

#### Benzodiazepines

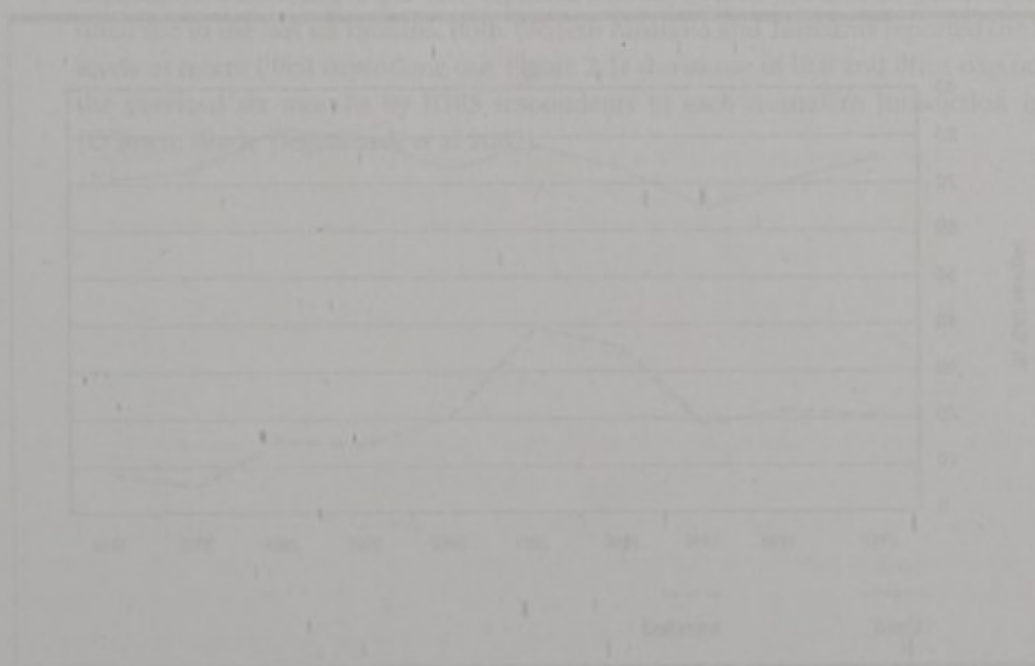
As the above Table shows, 67 per cent of the national sample reported using benzodiazepines in the previous six months. Some 71 per cent of the Victorian sample reported using benzodiazepines in the previous six months: 53 per cent reported using prescribed benzodiazepines and 31 per cent illicitly obtained ones. The types most commonly used were diazepam (eg. Valium® (60%); Antenex (8%)); and alprazolam (eg. Xanax®) (14%) (Jenkinson & Quinn 2007). Figure 2.1o shows that Victorian rates of ever and recent (last 6 months) use of benzodiazepines have been higher than the national rates but have decreased in the 2005 survey to a greater extent than the national figures.

**Figure 2.1o: Victorian and national rates of illicit benzodiazepine use among IDRS interviewees 2000–2006**



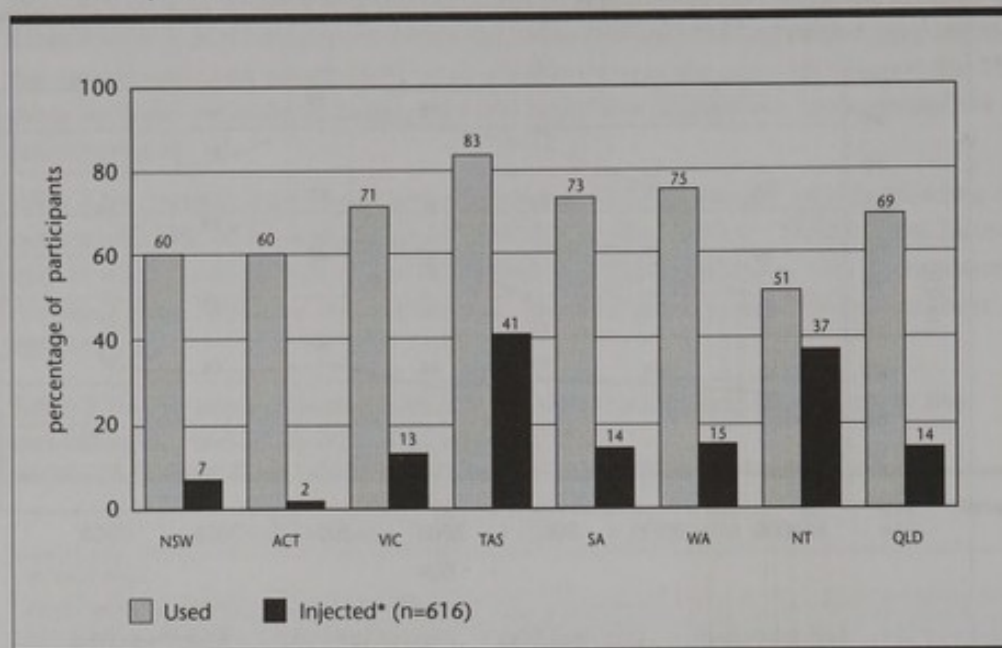
Source: Data extracted from Jenkinson & Quinn 2007; O'Brien, Black, Degenhardt et al 2007.

Although in 2006 rates of recent (last 6 months) benzodiazepine use in Victoria remained higher than the national average, one can see that in Figure 2.1p Victoria is not the jurisdiction with the highest rates of recent use or injection.





**Figure 2.1p: Proportion of injecting drug users that reported use and injection of benzodiazepines in the previous six months, by jurisdiction, 2006**

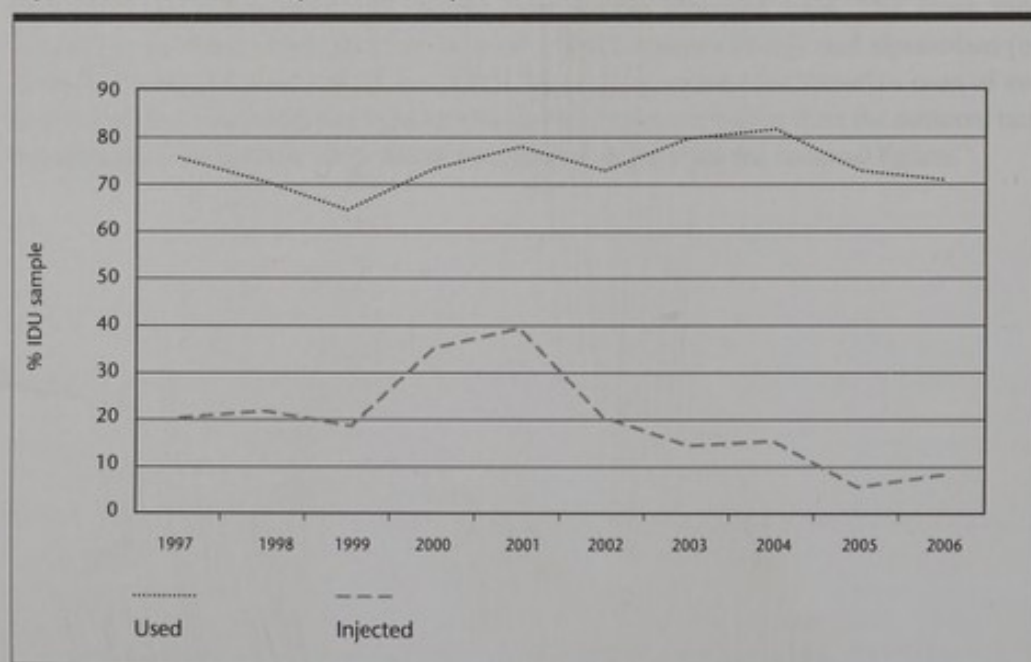


Note: \* among those who reported recent use (n=616).

Source: O'Brien, Black, Degenhardt et al 2007, p.137.

Importantly, trend data on the proportion of Victorian injectors interviewed as part of the IDRS over the period 1997 to 2001 show that while the proportion injecting benzodiazepines increased up until 2001, this proportion decreased following changes to the PBS prescribing authority for temazepam in May 2002. Indeed, in 2005 the reported rates of injecting were the lowest reported in Victoria since the IDRS commenced (Jenkinson & Quinn 2007). Jenkinson and Quinn (2007) also note that the DHS Victoria's Temazepam Injection Prevention Initiative was implemented in November 2001, and in March 2004 gel-cap temazepam formulations were withdrawn from the market. Trends in use and injection of benzodiazepines in Victoria and nationally are presented in Figure 2.1q and Table 2.1n.

**Figure 2.1q: Trends in proportion of Victorian injecting drug users reporting use and injection of benzodiazepines in the previous six months, 1997–2006**



Source: Jenkinson & Quinn 2007, p.64.

**Table 2.1n: Injection of benzodiazepines in previous six months, 2000–2006**

	2000	2001	2002	2003	2004	2005	2006
National %	21	24	21	17	14	8	12
Victoria %	36	40	21	15	16	6	9

Source: Data extracted from O'Brien, Black, Degenhardt et al 2007, p.137.

### Morphine

Some 52 per cent of the national IDRS sample used morphine in the six months prior to interview (O'Brien, Black, Degenhardt et al 2007). Although illicit versus licit use is not reported for the national sample, rates of illicit use ranged from 32 per cent in Victoria to 81 per cent in the Northern Territory. Thirty-seven per cent of Victorian injecting drug users interviewed in the 2006 IDRS reported illicit use of morphine in the six months prior to interview (O'Brien, Black, Degenhardt et al 2007), and 32 per cent reported injection of morphine in the previous six months. The most common types of morphine used by Victorian IDRS respondents were MS Contin® (68%) and Kapanol® (24%) (Jenkinson & Quinn 2007). National and jurisdictional trends in morphine injecting are presented in Table 2.1o.

**Table 2.1o: Proportion of IDRS samples reporting injection of morphine in the previous six months by jurisdiction, 2001–2006**

	National	NSW	ACT	VIC	TAS	SA	WA	NT	QLD
2001	40	12	33	31	72	34	32	84	31
2002	46	18	34	47	73	44	49	85	32
2003	40	20	49	39	69	42	40	80	40
2004	46	24	40	41	60	40	43	86	45
2005	41	24	30	39	55	34	48	79	28
2006	49	32	51	32	61	49	53	81	52

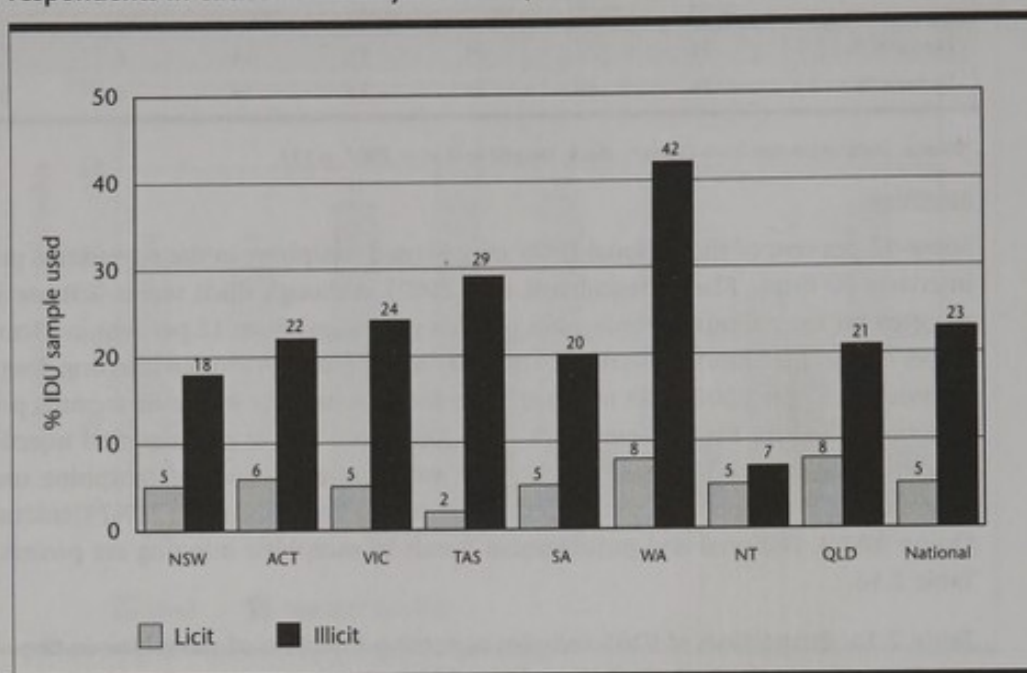
Source: O'Brien, Black, Degenhardt et al 2007, p.125.

### Oxycodone

In 2005 IDRS interviewees were for the first time asked specifically about the use of oxycodone. Nationally, 6 per cent reported licit oxycodone use and 23 per cent reported illicit use in the last six months. Both Western Australia and Tasmania reported the highest levels of recent illicit oxycodone use. Figure 2.1r shows use of licit and illicit oxycodone in the previous six months by IDRS respondents in each Australian jurisdiction in 2006 (O'Brien, Black, Degenhardt et al 2007).



**Figure 2.1r: Licit and illicit oxycodone use in the previous six months by IDRS respondents in each Australian jurisdiction, 2006**



Note: IDU = injecting drug users

Source: O'Brien, Black, Degenhardt et al 2007, p.127.

Among the Victorian sample, 27 per cent reported use of oxycodone in the last six months, with 25 per cent having injected the drug and 7 per cent swallowing the drug over this period. Eighty-two per cent of those Victorian injecting drug users who used the drug over that period said they mostly used illicit oxycodone. The most commonly used brand was OxyContin® (Jenkinson & Quinn 2007).

### The Ecstasy and Related Drugs Reporting System (ERDS)

Data from the 2006 Ecstasy and Related Drugs Reporting System Party Drugs Initiative (formerly the Party Drugs Initiative) indicated that non-medical use of benzodiazepines and prescribed narcotic analgesics among regular 'ecstasy' (drugs sold as MDMA) users was less common than among regular users of injecting drugs. However, a comparison of Victorian data with that from the other states and territories, presented in Table 2.1p, suggests that Victorian 'party drug' users surveyed had higher rates of lifetime and recent (last six months) use of benzodiazepines and other opiates than 'party drug' users in other states except for the Northern Territory and Western Australia.

**Table 2.1p: Lifetime and last six months use of selected pharmaceutical drugs among recent users of 'ecstasy', Australian states and territories, 2006**

	National N=100	NSW	ACT	VIC	TAS	SA	WA	NT	QLD
<b>Benzodiazepines</b>									
Ever used (%)	48	47	37	51	48	50	57	53	44
Used last 6 months (%)	31	25	20	36	33	33	29	29	37
<b>Other opiates</b>									
Ever used (%)	25	17	22	29	33	21	24	39	23
Used last 6 months (%)	11	6	12	15	14	4	13	22	10

Source: Data extracted from Dunn, Degenhardt, Campbell et al 2007, pp.10–11.

In 2006, only 3 participants (0.24%) in the Ecstasy and Related Drugs Reporting System national sample said benzodiazepines were their drugs of choice and only 5 per cent (n=39) of the sample had ever injected them. Only one participant had injected benzodiazepines in the preceding six months. Among those that had used benzodiazepines in the previous six months, the frequency of use varied from less than monthly (52%) to daily use (6%) (Dunn, Degenhardt, Campbell et al 2007).

Twenty-five per cent of the national sample had used 'other opiates' (including drugs such as morphine and pethidine) and 11 per cent had done so in the previous six months. Among those who used it in this period, the median days of use in the last six months was three days. Some 4 per cent had injected other opiates in the previous six months (Dunn, Degenhardt, Campbell et al 2007). Recent users of ecstasy are another group where rates of prescription drug misuse are higher than the general population and will likely be an important sentinel group in monitoring misuse of these drugs.

## Conclusion

There are limitations in the capacity of any research methodology to provide an accurate representation of the extent of illicit drug use. This is particularly the case with the misuse and abuse of pharmaceutical drugs.

In Victoria the legal use of benzodiazepines, particularly tamazepam and diazepam is quite common. However, according to population surveys the illicit use of these drugs is low. Conversely, the illicit use of benzodiazepines is commonly reported by injecting drug users. Their method of use is most frequently through oral consumption, and their preferred drug for this use is diazepam.

Whilst opioid analgesics are used illicitly there is very little available information on the extent of their misuse and abuse. Monitoring of oxycodone misuse by injecting drug users only commenced in the IDRS in 2005, but it will be interesting to see how trends in use of OxyContin® by this group unfold.



## Conclusion

## 2.2 The Adverse Consequences of Pharmaceutical Drug Abuse and Misuse

### Introduction

Numerous problems can occur when pharmaceutical drugs such as benzodiazepines and narcotic analgesics are used for non-medical purposes. Even when used as prescribed and under the care of a medical practitioner these drugs can have adverse effects. An example of this is the problems associated with long-term use of benzodiazepines, as TRANX (Tranquilliser Recovery and New Existence) Inc. explained in their submission to this Inquiry:

In the case of the benzodiazepines, significant harm has been and continues to be caused to people taking these drugs in prescribed doses, but for inappropriately long periods of time. Many of these people have taken doses within the recommended daily dose limit, have only seen one GP and have taken the drugs as advised by their medical practitioner. It may be more appropriate to describe the drugs as being 'mis-prescribed' rather than 'misused'.<sup>75</sup>

There is now widespread recognition that the use of benzodiazepines, even at the appropriate prescribed dose, for more than a few weeks can result in a dependence syndrome, and if the drug is abruptly ceased seizures can result.

The main problem associated with long term use of the benzodiazepines is dependency. The withdrawal syndrome from benzodiazepines can be painful and protracted, making reduction from these drugs problematic. Withdrawal symptoms include headaches, depression, dizziness, loss of balance, nausea, and depersonalisation. The most common symptoms of withdrawal are extreme anxiety with panic attacks and insomnia – often the very reason for which the person was prescribed a benzodiazepine.<sup>76</sup>

The misuse of benzodiazepines and prescribed opioids can also have an effect at a macro level, in terms of impacts on the health budget, such as through hospital admissions and ambulance call-outs, crime rates and other outcomes at a population level. The impacts can be significant, as noted by Dr Rodger Brough from the Western Region Alcohol and Drug Centre who gave an excellent snapshot of both the immediate and 'ripple' effects of this from a regional Victorian perspective in his submission to the Inquiry:

...there is a potentially dangerous and deteriorating situation for both healthcare workers (GPs, A&D workers and pharmacists) and many 'innocent' patients, related to a distinct shift to the preferential use of prescribed opioids over heroin by opiate users in South West Victoria. The virtual absence of heroin supplies in the region in the last 5 or 6 years, causally associated as I believe it is with the equally impressive rise in prescribed opiate users (and prescribed opiate 'abuse'), has created a heightened need for specialist pain management

75 Submission of Gwenda Cannard, Director, TRANX (Tranquilliser Recovery and New Existence) Inc., to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006. The organisation TRANX has since been renamed ReConnexion.

76 Submission of Gwenda Cannard, Director, TRANX (Tranquilliser Recovery and New Existence) Inc., to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006. See also Ashton 2002; Barker et al 2003.



and pharmacotherapy services. Persistent advocacy has been determinedly ignored. At the same time, the cultural shift from the illicit market-place (of the heroin networks) to the dependence on the 'licit' opiate supply network (through the region's GPs and pharmacies) has a number of very worrying consequences that are becoming increasingly evident:

- The use of this 'licit supply network' provides a great degree of 'cover' for the pernicious activities of the dedicated 'addicts' and makes effective policing and control much more difficult (for medicos and law enforcement alike).
- The veneer of 'safety' and 'respectability' provided for this new breed of opiate addict by their 'association' with their 'de facto suppliers' (doctors and pharmacists) belies the real and malignant nature of the underlying problem.
- Increased exposure to overt threats and 'intimidating requests' from opioid 'doctor shoppers' is effectively producing greater resistance from GPs and pharmacists in dealing with anyone who remotely looks like this 'new breed of opiate addict'.
- Doctors (predominantly) and pharmacists (to the extent that some won't agree to dispense S8<sup>77</sup>) are effectively being perceived as the 'cause of the problem'.
- It is making it harder for people who are genuinely trying to seek help for chronic pain or drug problems to access the support and services they need and may tentatively seek. Furthermore, despite the DPU's [Drugs and Poisons Unit] apparent view to the contrary, it is no easy task to accurately pick these 'real sheep' from 'the wolves dressed up as sheep' – particularly so, when there is such limited specialist support available in the regional areas, and the 'wolves' are so deviously cunning.
- While both Federal and State health departments are aware of the issue, the particular wide-reaching detrimental consequences experienced in rural communities, beyond the population of drug users, are simply not appreciated.<sup>78</sup>

This chapter, however, primarily focuses on the effects on individuals and, to a lesser extent, significant others. The main reasons for this is that most of the adverse consequences of pharmaceutical drug *misuse* can be distinguished from the adverse effects of *medical use* of these drugs at the individual and community level. The exception to this is the impacts of benzodiazepines on aggression and violence – the so-called 'Rambo effect' – and the impacts of both the benzodiazepines and the opioids on psychomotor skills, which can contribute to motor vehicle and other accidents. Consequently, both these issues are addressed in this chapter.

## Social and emotional consequences of non-medical use of prescription drugs

As noted by the National Center on Addiction and Substance Abuse (CASA) (2005), non-medical use of prescription drugs can cause problems in relationships with family and friends, employment and educational problems, and legal problems. Indeed, non-medical users who are dependent on pharmaceutical drugs can experience social, emotional and health problems at rates comparable to users of so-called 'hard drugs'. CASA's analysis of data from the 2003 United States National Survey on Drug Use and Health (NSDUH) found that abusers of controlled prescription drugs experienced these problems at similar or higher rates than alcohol abusers, but at lower rates than those problems occurring as a result of illicit drug use. However, those misusing prescription drugs at a level that met the diagnostic criteria for 'abuse or addiction' suffered these problems at rates similar to dependent heroin users (see Table 2.2a).

77 That is, Schedule 8 drugs. Schedule 8 drugs are subject to strict controls with regard to prescribing and dispensing. See Chapter 3.1 for further discussion of drug scheduling.

78 Submission of Dr Rodger Brough, Western Region Alcohol and Drug Centre (WRAD) in Warrnambool, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

**Table 2.2a: Impact of illicit drug use and pharmaceutical drug misuse on users, United States, 2003 (per cent of respondents)**

Problems	Abusing				Using				
	All Controlled Prescription Drugs	Opioids	Tranquillizers	Sedatives	Stimulants	Alcohol	Cocaine	Heroin	Clinical Abuse or Addiction All Controlled Prescription Drugs
Emotional or mental health problems	7.4	6.6	4.5	9.5	10.7	8.5	18.5	46.2	46.1
Family/friendship problems	5.1	4.6	3.9	7.6	7.6	7.6	14.6	33.0	37.1
Serious problems at home, work or school	4.6	3.9	3.8	6.7	7.6	4.2	12.6	36.8	37.4
Trouble with law	1.8	1.5	1.5	3.4	4.1	2.1	5.6	13.2	14.9
Worsened health problems	2.5	2.0	1.7	3.9	1.8	2.9	3.4	2.6	11.7
Used drug while doing dangerous activities	5.4	4.7	4.7	7.8	7.5	13.0	13.9	22.8	43.5

Source: National Center on Addiction and Substance Abuse (CASA) 2005, p.43.

There is often a strong relationship between severe dependence on benzodiazepines, pharmaceutical opioids and other substance use and mental health problems. For example, a Canadian study of 30 people undergoing inpatient treatment for benzodiazepine dependence found all had used benzodiazepines and other drugs at high doses for long periods and most had substantially impaired social functioning and lifetime psychiatric diagnoses, notably depression (33%), other drug dependence (100%) and panic disorder (30%). Most (83%) had another current substance use problem including opioids (67%), cocaine (13%) or multiple substances (17%). Other current diagnoses included generalised anxiety disorder (20%) and panic disorder (13%) with substantial proportions having personality disorders (antisocial 42%, avoidant 25%, and borderline 17%) (Busto, Romach & Sellers 1996).

Research suggests that particularly women experience these types of harms, especially when the drug abuse is restricted to benzodiazepines alone. A submission from Darebin City Council that draws upon Boyd's 2003 research suggests:

Women are at greater risk of harms from the unsafe use of medications. Medication use was prevalent amongst women who had experienced childhood sexual abuse and who had a history of family violence, both as a child and in current or recent relationships.

Data collated for DAREBINsafe's Injury Profiles 2004 show a disturbing trend in the use of medications to assist suicide and self-harm attempts:

There are over 300 presentations to hospital emergency departments each year for self-harm and suicide. Around 70% of attempts use medications. In Darebin, women are more likely to attempt suicide and are more likely to use medications in their attempts.<sup>79</sup>

Darebin City Council also suggests that:

While there is no doubt that benzodiazepines are used as part of polydrug use, this submission urges caution in assuming that this is where the bulk of harms occur...Research conducted in Darebin and Moreland in 2002/03 found that contrary to local assumptions, the harmful impacts of benzodiazepines were felt by women who were not taking any other illicit substances. The research...instead found that – in particular – the women who were admitted to hospital or attended by ambulance were not using other substances at the time of their overdose.<sup>80</sup>

<sup>79</sup> Submission of Darebin City Council to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

<sup>80</sup> Submission of Darebin City Council to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.



The fact that there may be a significant minority of people, particularly women, who misuse benzodiazepines without recourse to other drugs also has implications for the development of appropriate treatment services. This will be discussed later in this Report.

### *Prescription drugs as 'gateway drugs'*

Some commentators and academics have posited that prescription drugs, particularly narcotic analgesics such as OxyContin®, have acted as 'gateway' drugs initiating young people in particular to heroin use. American studies have observed this phenomenon, especially among OxyContin® users. An Ohio study, for example, found that 50 per cent of its sample reported abusing prescription opioids before initiating heroin. Whilst these findings were limited by a small sample:

However, we continually identify persons who report a similar progression from prescription opioid abuse to heroin injection...The results of investigation suggest that the abuse of opioid analgesics constitutes a new route to heroin abuse, placing new populations at risk for heroin addiction. This is a reversal of the classic pattern in which heroin users would turn to prescription opioids when heroin was unavailable (Siegal et al 2003, p.945).

Whilst such findings are disturbing, they cannot automatically be generalised to other population groups, particularly in the Australian context, because of the limited number of studies undertaken and the size of the samples used. Further research is required in this area. It is true, however, as Siegal et al comment that such findings indicate how important it is that drug abuse prevention programmes, particularly aimed at young people, address the dangers of prescription drug abuse in addition to heroin use.<sup>81</sup>

## **Drug-specific adverse effects from misuse**

### *Benzodiazepines*

In terms of the contribution of benzodiazepine use to mortality in general, it is worth noting the evidence to the Committee given by Professor Olaf Drummer of the Victorian Institute of Forensic Medicine. He explained:

Over the years benzodiazepine has been, perhaps second to alcohol, the major drug of interest or concern to us at the Institute and, indeed, to the coroner as well. They are of concern because they are present in a large number of cases of various types. In terms of drug deaths, they are present in about half to two-thirds, depending on the type of drug death, not because they themselves are so dangerous that by themselves they cause people to die but they are often misused with other drugs and they add to the effects of other drugs, whether they be prescription drugs such as antidepressants, or people who choose to use heroin...

There are a variety of situations where benzodiazepines play a role – and occasionally they cause death by themselves. In motor vehicle accidents it is certainly by far the most commonly seen prescription drug...As a prescription or legal drug they are by far the most common type. It has been well shown that their misuse leads to people who are impaired and unable to drive properly, and there is an increased risk of them having a crash.<sup>82</sup>

Whilst recognising that there is anecdotal and other evidence that suggests a sizeable cohort of people who abuse benzodiazepines do so without contemporaneously abusing other drugs, it nonetheless remains the case that most misusers of benzodiazepines are 'polydrug users' in that they use a number of drugs in combination or at different times (Rall 1992;

81 See Chapters 6.1 and 6.2 for a discussion of the importance of education and information programmes.

82 Professor Olaf Drummer, Head (Forensic and Scientific Services), Victorian Institute of Forensic Medicine, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 13 July 2006.

Ashworth, Gerada & Dallmeyer 2002).<sup>83</sup> Perhaps the most notable feature of benzodiazepine misuse by polydrug users is that the doses taken vary enormously (Ashworth, Gerada & Dallmeyer 2002) but can be many times greater than the usual therapeutic dose. For example, Ashworth and colleagues cite earlier work suggesting that a typical dose for an injecting drug user could be between 40mg and 100mg of temazepam or diazepam per day, but that use of over 1,000mg per day is not uncommon and some addicts consume over 3,500mg per day.

With regard to the adverse effects of benzodiazepines, Dr Malcolm Dobbin, Senior Medical Adviser at the Drugs Policy and Services Branch of the Department of Human Services in Victoria observed in his evidence to the Committee:

They can contribute to central nervous system (CNS) depression separate from other opiate central nervous system depression, and that, working through a different pathway, can contribute to coma and death. It also causes people to be confused, if they have taken a number of drugs and, particularly if they have co-abused it with alcohol or other CNS depressants as well, [they] can cause impaired driving. It contributes to culpable driving as well. It can cause what is called anterograde amnesia: people can remember taking the tablets but they do not remember what happened afterwards. People can go into a kind of a fugue state and shoplift in front of a shop assistant and then, when they find themselves in the cells, not remember what they did. That has implications for people who might seek treatment and may have some understanding of what they have done while they have been counselled and undertake to do certain things, but then forget their appointments or that they have made appointments. Their compliance with treatment might be impaired as well. Of course, benzodiazepines can cause dependence. People can experience an uncomfortable and quite dangerous withdrawal syndrome. It is quite dangerous because it can cause seizures. Once people become dependent on them, if they stop suddenly they can have a seizure, similar to an epileptic fit.<sup>84</sup>

### **Sedation**

The sedation associated with benzodiazepine misuse, particularly at high doses, can contribute to concentration and memory problems to a greater extent than other drugs of abuse<sup>85</sup> (Ashworth, Gerada & Dallmeyer 2002). Memory problems can also lead to chaotic behaviour and disorganisation. For instance, risky drug use can take place when users forget whether the needle they are about to use has been used previously by someone else. Similarly, sex workers who use temazepam before seeing their clients can be at risk as they are reported to be less able to practise safe sex when affected by such drugs (Ashworth, Gerada & Dallmeyer 2002).

### **Amnesia**

Amnesia is listed as a possible adverse effect for all benzodiazepines. This type of amnesia is anterograde; that is, the memory of events occurring after taking benzodiazepines is affected, whilst long-term memory remains intact (Barker et al 2003). The cause of benzodiazepine-induced amnesia is unclear. It has been linked with the sedative effects of the drugs and also with the neurological systems responsible for the laying down of new memories (Ashton 2002). Whether these effects on memory are permanent or resolve once the drugs are removed is also unclear. Some studies have found that short-term, or recent, memory problems are still present up to two years after the drug has been discontinued,

83 Polydrug use is defined by the United Nations International Drug Control Program (UNIDCP) (2000) as 'the use of more than one psychoactive drug either simultaneously or at different times. The term is often used to distinguish persons with a more varied pattern of drug use from those who use one kind of drug exclusively' (p.56).

84 Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, Department of Human Services, Briefing given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Melbourne, 29 May 2006.

85 For example, a loss of concentration due to the sedative effects of these drugs can cause driver impairment and consequent road trauma, see discussion later in this chapter and in Chapter 8.1.



whilst others have found little effect following long-term use (Barker et al 2003). The type of benzodiazepine used, the dose taken and the method by which the dose is administered (ie. oral versus injection) affect the severity of the amnesia (Barker et al 2003).

### Contribution to overdose

There have been few reported cases of overdose death following the ingestion of any of the benzodiazepine drugs on their own (Gossop et al. 2002). Indeed, benzodiazepines were introduced as a safer alternative to the barbiturates which they have all but replaced. Most overdose deaths involving benzodiazepines also involve the consumption of other drugs, as Dr McDonough, Medical Director of Drug and Alcohol Services at Melbourne's Western Hospital explained in his evidence to the Inquiry:

Since the fifties there has been a dramatic decline in 'tranquillizer' overdose mortality, and since the increased availability of benzodiazepines there has been a dramatic decline in overdose death. Most overdose cases that present to our hospitals now are able to be discharged within 24 hours. They do not generally have a fatal outcome. There surely are some (still 'too many') but the overwhelming majority are non-lethal and the overwhelming majority, as I said earlier, present as cases that we in the hospitals call 'cocktails', because there is often alcohol with some benzodiazepines – sleeping pills washed down with some grog. Most of those people survive quite well, and those that do not do well often have some other misadventure associated with that cocktail. For example, they fall back and vomit and the vomit gets inhaled, and that can have a lethal outcome or, at the very least, can give them serious pneumonia.<sup>86</sup>

Although rare, benzodiazepine-only overdose deaths have been recorded. For example in Australia, Drummer and Ranson (1996) reported on 16 deaths resulting from toxic amounts of benzodiazepines between 1990 and 1994. Deaths that involved a combination of benzodiazepines and other drugs were excluded leaving five of the 16 deaths attributed to benzodiazepines alone. In order of prevalence, the benzodiazepines involved were nitrazepam, temazepam, oxazepam and flunitrazepam. The authors suggested that flunitrazepam might be more toxic compared to other benzodiazepines (Drummer & Ranson 1996).

Thus, whilst the effects of benzodiazepines are usually benign when taken alone, even in overdose, they can potentiate the effects of other central nervous system depressants such as alcohol and opiates, sometimes with lethal effects.

### Dependence and withdrawal

The Interhospital Liaison Group provided the Inquiry with a concise but informative summary of the issues regarding benzodiazepine dependence and withdrawal:

Benzodiazepines lead to rapid, profound neuro-adaptation<sup>87</sup> which leads to:

- tolerance – marked by diminished effects at equivalent dose and reduced sensitivity to high doses
- dependence – unpleasant, dangerous manifestations of neuro-adaptation when dosage is reduced/ceased.

The benzodiazepine dependence syndrome is very difficult to treat, often leading to months of unpleasant physiological and psychological manifestations that require significant resolve to endure. Of particular difficulty are the symptoms of:

86 Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 20 June 2006.

87 Neuroadaptation is a term used to describe what happens at a cellular level in the brain during physical dependence as the cells change to accommodate the presence of a drug in a new 'normal state'. It is defined by the UNIDCP as 'Adaptation by the central nervous system to repeated administration of psychoactive drugs resulting in increased tolerance and sometimes a withdrawal syndrome following cessation of drug use' (UNIDCP 2000, p.48)

- anxiety
- insomnia
- agitation

which may be accompanied by physical signs of tachycardia and hypertension, and may be markers of an increased risk of seizure phenomena.

This withdrawal syndrome is not dissimilar to alcohol withdrawal apart from having a time course of weeks to months rather than days. There is also the issue of cross-tolerance to consider; benzodiazepine and alcohol dependence often coexist and patients may switch between these as a strategy to cope with withdrawal.

One of the difficulties of engaging dependent individuals in treatment is their extreme fear of the anxiety that accompanies withdrawal and the positive reinforcement of the relief of symptoms with benzodiazepines.<sup>88</sup>

In evidence to the Inquiry Dr Frank Giorlando, Interhospital Liaison Group, described the extent of discomfort of benzodiazepine withdrawal:

...I think that benzodiazepines are as much a problem as heroin, alcohol, the so-called hard drugs. They cause a great degree of suffering to people because they become dependent, and all the things that originally these drugs were prescribed for become worse over a long period of time. The sleeping quality becomes worse, the anxiety is terrible without medication or if there is a reduction in medication, and one of the worst things about benzodiazepines is that the withdrawal symptoms last for months upon months, whereas with alcohol, for instance, most of the physical withdrawal symptoms are over in a week. I think they cause a massive amount of suffering in the community.<sup>89</sup>

There is a small body of literature relating to the use of and dependence on benzodiazepines among illicit drug users, much of it conducted in the United Kingdom and Australia. In one study in London, 36 per cent of 169 admissions to a drug treatment centre met the criteria for benzodiazepine and other pharmaceutical dependence and 43 per cent of these underwent a withdrawal programme for these drugs (Williams, Oyefeso & Ghodse 1996). Another English study reported that 28 per cent of 158 injecting drug users were classified as having ever been dependent on benzodiazepines, although this study did not report on rates of current benzodiazepine use (Dinwiddie et al 1996). In Sydney, Ross, Darke & Hall (1996, 1997) found that approximately one-quarter of heroin users who also used benzodiazepines displayed some degree of dependence. In a later Sydney study using a different method of classifying dependence, Ross and Darke (2000) found 22 per cent of current benzodiazepine users were found to be 'dependent' on the drug with 3 per cent being 'mildly dependent', 7 per cent 'moderately dependent', and 12 per cent 'severely dependent'. Ross and Darke (2000) concluded that:

A disturbingly high proportion of heroin users meet the criteria for benzodiazepine dependence, a condition that should be regarded as a significant marker for co-morbidity among this group (Ross & Darke 2000, p.1785).

### **Paradoxical aggression – the 'Rambo effect'**

Benzodiazepines are frequently prescribed for their tranquillising effect in the relief of insomnia and anxiety. Paradoxically, they can trigger incidents of central nervous system stimulation, which manifests as talkativeness, mania, anxiety, restlessness and sleep disturbances and nightmares (Barker et al 2003). This can also result in episodes of acute rage and extreme aggression which is sometimes referred to as the 'Rambo' effect, 'a paradoxical increase in aggressive or disinhibited behaviour is experienced by some, both

88 Submission of the Interhospital Liaison Group to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

89 Dr Frank Giorlando, Addiction Medicine Registrar, Interhospital Liaison Group, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 19 June 2006.



at therapeutic doses and at the much higher levels consumed by illicit users' (Ashworth, Gerada & Dallmeyer 2002, p.391).

Dr Malcolm Dobbin described the effect to the Committee:

...the Rambo effect. That is identified in the forensics scene. As it has been described to me, people feel invisible and invincible where...they are quite unaware of what they are doing and are detected committing minor crime. They can also get into this Rambo thing, where they can become violent and feel invincible. A Belgian doctor has identified the Rambo effect and written about it, but I have heard it described locally as well.<sup>90</sup>

Whilst the mechanisms by which such aggression is triggered are unclear, it has been hypothesised that although benzodiazepines reduce anxiety through depression of the central nervous system they may also reduce inhibitions and result in impaired judgement (Ben-Porath & Taylor 2002). A number of laboratory-based studies have tested this hypothesis by administering diazepam or a placebo to male and female volunteers and challenging them within a controlled competition. The results showed that those who had taken the diazepam were more aggressive than those who took the placebo (Taylor & Chermack 1993). Other laboratory-based experiments have shown similar effects with lorazepam and oxazepam (Ben-Porath & Taylor 2002). These experiments were performed under controlled conditions during which other drugs or alcohol were not involved and therapeutic doses of benzodiazepines were administered. Under conditions that are uncontrolled, where other drugs are likely to be involved and benzodiazepines consumed in excess of therapeutic doses, the situation can result in serious crime and significant harms.

In a study of male forensic psychiatric patients in Sweden, 30 per cent of the 60 subjects were found to be abusers of flunitrazepam and indicated a preference for this benzodiazepine because it gave them feelings of 'power and self-esteem', 'reduced fear and insecurity' and 'stimulated the belief that nothing is impossible' (Daderman & Edman 2001). When comparing the group of flunitrazepam abusers with non-abusers, the authors found that, although there were no differences between the groups in terms of the actual violent crimes, those in the flunitrazepam group were significantly more likely than non-users to have been previously admitted as forensic psychiatric patients for weapons offences, drug-related offences and theft (Daderman & Edman 2001).

In Germany, an estimated two-thirds of heroin users are reportedly dependent on flunitrazepam. When intoxicated with flunitrazepam the behaviour of these people caused considerable concern due to the 'aggressive, criminal and self-destructive behaviour' that apparently was affected by the amnesic effects of flunitrazepam (de Crespigny & Wodak 1995). Further evidence that flunitrazepam is associated with aggression and violence was found in the report of an Australian study investigating factors affecting young drug users' completion or cancellation of parole. The following quotes illustrate the problem:

We've had kids coming in here when they've been 'Rohied', and not knowing the next day they've been in time loss, they lose days at a time. With 'Rohies' [they] steal cars, go joy-riding and then not know what they've done – riding dangerously or in a manner which could cause injury and having no recollection of doing it. They get charged, but don't know

<sup>90</sup> Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, Department of Human Services, Briefing given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Melbourne, 29 May 2006.

where they got the car from or how it happened – Avil,<sup>91</sup> car-sickness tablets, have the same effect (Alder & Read 1992, p.26).

and,

there was a large commotion outside work at the project one night...and here were all the kids we were dealing with...they had an iron bar and they had assaulted the tram driver on the basis he was Asian. They put his head through the window and then kept pumping his head on the broken jagged edges of the glass...they claimed innocence on the basis they had no intention because they were so pilled (Alder & Read 1992, p.26).

### **The relationship between benzodiazepine and pharmaceutical opioid misuse and crime:**

There has been very little research work undertaken on the links between prescription drug abuse and misuse and the occurrence of criminal activity. This is particularly the case at local level. A study that has provided a useful starting point however is one auspiced by the National Drug Law Enforcement Research Fund (NDLERF).

The National Drug Law Enforcement Research Fund (NDLERF) recently funded a research report outlining possible links between prescription drug abuse and crime. NDLERF was established by the Ministerial Council on Drug Strategy (MCDS) and commenced operations in August 1999. The Fund supports research into *inter alia* the links between drug abuse and criminal activity. It functions within the broader context provided by the National Drug Strategic Framework.

The report acknowledges there has been very 'few Australian studies that have sought to investigate the nexus between prescribed pharmaceutical misuse and crime' (NDLERF 2007, p.xi) and that further research is needed to clarify the exact nature of this relationship.

The purpose of the study was to contribute to law enforcement sector understanding of the relationship between benzodiazepine and pharmaceutical opioid misuse and crime in three select Australian jurisdictions where there is evidence of illicit prescription pharmaceutical markets (Victoria, Tasmania, Northern Territory). As the Report comments, such an understanding is important as:

The increase in pharmaceutical-related crime has the potential to impact on the law enforcement sector through increased levels of theft from pharmacies and other suppliers, other methods of diversion of the drugs to the black market, crime committed whilst under the influence of the drugs or whilst withdrawing from them, and also the disinhibition ('Rambo effect') that is associated with benzodiazepine intoxication that may lead to violent behaviour and other types of crime (NDLERF 2007, p.xii).

The report is a comprehensive account of prescription drug abuse, particularly by injection, and its relationship to criminal activity.

91 There have been other concerns expressed with regard to the motion sickness tablets Avil®. For example, a submission from Ms Carol Andrew, a psychiatric nurse with Moreland Continuing Care Mental Health Programme states:

'In my experience this medication [Avil] plays a major role in presentations of psychosis and aggression, but there is very little documented about its abuse.

What I know is only anecdotal unfortunately, but it is a common practice amongst "those in the know" particularly psychiatric patients, to take a packet of Avil, in one sitting, often with alcohol to wash the tablets down, and then be in a "cloud 9" haze for a period of time, until they come down. Then during this period people can present as very psychotic as if they are in Delirium Tremens; seeing spiders crawling over them and their surrounds, or being irrationally violent.

The chemist our clinic deals with no longer stocks Avil for this reason, but I also understand that it is generally available over the counter through other chemists. I would be very interested to see this drug reassessed for its over the counter availability' (Submission of Ms Carol Andrew to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006).

Further discussion of Avil® is beyond the scope of this Report. See Chapter 1.1 for an account as to why over-the-counter medicines have been excluded from discussion in this Report.



### The Report found that:

Misuse and injecting of benzodiazepines and pharmaceutical opioids, especially morphine and buprenorphine, has become entrenched among some groups of PWID (persons who inject drugs) in Melbourne. The findings suggest that the drugs are diverted to the black market and can be sold for considerable profit. The drugs may be diverted from legitimate prescriptions and prescribed doses, via doctor-shopping, or from forged prescriptions or stolen drugs. Prescription drugs appear to be relatively easy to obtain on the street, and seem to be available from a diffuse network of users, friends of users, dealers and suppliers, some of who also sell all kinds of illicit drugs. The findings also suggest criminal behaviour may be related to the dependence on, and the use of, prescription drugs; for instance shoplifting, property crime, drug dealing, violence and intoxicated driving. In addition, disinhibited, aggressive, and bizarre behaviour, and feelings of invincibility, were attributed to the drugs, in particular benzodiazepines (NDLERF 2007, p.xxviii).

The NDLERF Report is a valuable addition to a hitherto paucity of material on prescription drug abuse. Nonetheless, it is still true as the Victorian Alcohol and Drug Association (VAADA) states in a submission to this Inquiry that 'there is little statistical data available examining the social and criminal impact of misuse of pharmaceutical drugs in Victoria'.<sup>92</sup> The NDLERF Report also acknowledges this (NDLERF 2007, p.xi). Consequently, VAADA recommends to the Committee that:

Statistical data be gathered concerning the social and criminal harms associated with the misuse of pharmaceutical drugs; and that this data be used to inform the development of Victorian government alcohol and other drug policy.

VAADA considers that the following factors should be taken into account when gathering statistical data relating to the social and criminal harms associated with misuse of pharmaceutical drugs:

- That misuse of pharmaceutical drugs often occurs in a context of polydrug use and it would require careful analysis to distinguish the harms associated with one drug from another,
  - It may be the case that cultures/patterns of polydrug misuse (including pharmaceuticals) will be best explained by qualitative research;
- That many of the harms associated with pharmaceutical misuse impact through family and relationship breakdown. Given the difficulty of quantifying some of these harms,
  - It may be the case that these sort of harms are best understood through qualitative rather than quantitative research.<sup>93</sup>

### A note on alprazolam (Xanax)

Throughout this chapter benzodiazepines have been discussed in a generic sense without very much differentiation between one type of drug within the class and another. This has been because as a general rule both the positive and negative aspects of the benzodiazepines could be viewed as being generally applicable to most drugs within the class. One possible exception to this rule however, is arguably the drug alprazolam, commonly known as Xanax.

Xanax is a benzodiazepine prescribed to alleviate anxiety and related conditions. It is a drug with a particularly high potency, short onset and longer duration of action, which makes it a preferred drug for recreational abuse.<sup>94</sup> Whilst it is acknowledged as being a useful drug

92 Submission of the Victorian Alcohol and Drug Association (VAADA) to the Drugs and Crime Prevention Committee Inquiry into the Misuse/Abuse of Benzodiazepines and other Forms of Pharmaceutical Drugs in Victoria, June 2007.

93 Submission of the Victorian Alcohol and Drug Association (VAADA) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

94 See comments of Joseph Rannazzisi made in a presentation to the Drugs and Crime Prevention Committee, Washington, July 2007 (Drug Enforcement Administration (DEA) 2007a).

in treating anxiety, concerns have been expressed by many witnesses who gave evidence to this Committee that Xanax, particularly when used for recreational purposes, or administered in the wrong way can be particularly dangerous.<sup>95</sup> Experts in the field have also testified to its highly addictive qualities and the difficulties associated with withdrawing from the drug – even more so than with other forms of benzodiazepines. For example at a forum on prescription drug abuse in Bendigo, Ms Penny Buykx of the Faculty of Health Sciences, La Trobe University, stated to the Committee that:

Xanax dependence is one of the most difficult to assist people with because of the half-life of the medication and the immediate drug effect. If a person is feeling quite jittery, Xanax is fantastic at fixing the symptoms immediately but it is quite difficult to deal with. It is also difficult if you are transferring someone from that medication to a longer acting medication in order to do a gradual withdrawal. It is harder to get an accurate equivalent. So I am interested in alprazolam and why it has become so popular, because it seems that some of the harms associated with it are more than amongst some of other benzodiazepines.<sup>96</sup>

Similar concerns have been expressed about Xanax in other rural areas of the state<sup>97</sup> including Swan Hill<sup>98</sup> and Echuca.<sup>99</sup>

Dangers associated with inappropriate Xanax use are not restricted to rural Victoria. Reports of its abuse have also surfaced from urban Melbourne. For example, Dr Mark Stoové of Turning Point Alcohol and Drug Centre, drawing from Turning Point research, told the Committee that:

Key informants are saying that Xanax is increasingly becoming popular both as a licit prescription amongst injecting drug users but also being used illicitly.<sup>100</sup>

Dr Stoové's colleague Mr Peter Muhleisen, senior pharmacist at Turning Point, added:

What has happened is that whilst alprazolam has been promoted primarily for anxiety disorders, which it is appropriate for, drug-using populations have found that that is the drug that gets the effect that they like. Xanax has now become the hot new drug after they cannot get temazepam any more [due to a change in drug formulation].<sup>101</sup>

Of equal concern to some witnesses appearing before the Committee was that alprazolam appears to feature more prominently in crime related activity such as diversion and theft. For example in a submission to this Inquiry by the Pharmacy Board of Victoria, it was stated that it is not uncommon for Xanax tablets (100) to be prescribed and dispensed as private

95 Alprazolam is a benzodiazepine in pill form which is not soluble in water. Injecting this drug therefore can result in major medical complications similar to those that have occurred when the benzodiazepine temazepam is injected (see discussion later in this chapter).

96 Ms Penny Buykx, Research Officer, Faculty of Health Sciences, La Trobe University, Bendigo, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Bendigo, 30 May 2007.

97 And also particularly in rural areas of the United States such as the Appalachian states of Kentucky and West Virginia. See discussion in Chapter 4.1 and see also Leukefeld et al 2007; Havens, Leukefeld & Walker 2006. In this regard Joseph Rannazzisi of the United States DEA has presented statistics to this Committee detailing that alprazolam was ranked third in the number of prescriptions for controlled substances in the USA from 2003 to 2006 inclusive and that it was ranked 7th for all sales of generic pharmaceuticals for those years (Drug Enforcement Administration 2007a).

98 See the Submission of Dr Mike Moynihan, President of the Rural Doctors Association (Victoria) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2007.

99 See the Submission of Ms Dot Moon, Alcohol and Other Drugs Withdrawal Co-ordinator, Echuca Regional Health, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2007.

100 Dr Mark Stoové, Research Fellow, Turning Point Alcohol and Drug Centre, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 9 July 2007.

101 Mr Peter Muhleisen, Senior Pharmacist, Turning Point Alcohol and Drug Centre, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 9 July 2007.



prescriptions and then on-sold on the street at \$5.00 per tablet.<sup>102</sup> A submission from Youth Projects, a Melbourne based provider of drug and alcohol services for young people, has even reported anecdotal evidence of the stronger formulations of benzodiazepines, particularly Xanax, being used as a 'date rape' drug and/or to facilitate robberies.<sup>103</sup> Whilst such reports are disturbing there is insufficient evidence of this happening to constitute an established trend.

Given these concerns it is not surprising that in some quarters there have been calls for stronger regulation of the prescribing of Xanax. For example, a submission from a group of clinicians working in the Victorian public hospital sector noted that alprazolam (Xanax) is only listed at Schedule 4 despite the concerns of many clinicians:

The overwhelming consensus among alcohol and drug clinicians is that alprazolam is one of the most widely abused of the benzodiazepines, and that management of withdrawal of patients using alprazolam is particularly difficult.

While recognising that the scheduling of medications is currently administered at Commonwealth level, it is appropriate that the idea of rescheduling be raised in this document. Given the extent of abuse of alprazolam and the risks of withdrawal and overdose associated with this benzodiazepine, a change in schedule to S8 (alongside drugs like morphine and oxycodone) would be a positive public health measure. This change in regulation would increase the controls on alprazolam prescribing, may restrict duration of prescribing of this drug and could raise prescriber awareness of the risks of alprazolam.<sup>104</sup>

This is in fact a path that one state has gone down. In 2006 a review was conducted in relation to alprazolam prescribing in Tasmania. As a result of the review it was recommended that:

- The prescribing of alprazolam will be required to be reported monthly by the dispensing pharmacist.
- This reporting will be in a similar manner as the current reporting of dispensed schedule 8 medications.
- Any prescribing of alprazolam for more than one month to persons receiving opioid analgesics will require an authority to prescribe.
- Prescribers will be notified not to prescribe alprazolam if the patient is receiving opioid analgesics from another prescriber. (Currently persons declared as drug dependent cannot have S4 drugs prescribed by prescribers other than their authorised prescriber. However this is only detected when the prescribing comes to our attention through other ad hoc reports. The branch does not have access to PBS [Pharmaceutical Benefits Scheme] data in order to detect such prescribing.)
- Patients receiving methadone or who are on the pharmacotherapy program will not be allowed to have alprazolam prescribed concurrently unless this is endorsed by the Director of Alcohol and Drug Services in accordance with the pharmacotherapy policy and guidelines.
- Consultation with the Tasmanian Branch of the Royal Australian and New Zealand College of Psychiatrists will be sought in regard to these recommendations, along with their opinion in relation to the appropriate use of alprazolam given the concerns raised in this report.

102 Submission of Pharmacy Board of Victoria to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007. See also the submission of Dr Mike Moynihan, President of the Rural Doctors Association (Victoria) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2007.

103 See submission of Youth Projects Inc to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2007.

104 Submission of the Interhospital Liaison Group to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

- Medicare Australia will be consulted as to possible audits of prescribing of alprazolam outside their authority criteria.
- An education campaign be undertaken through the Division of General Practice to highlight the problems with alprazolam and give advice in relation to its prescribing and use.<sup>105</sup>

Many of these recommendations have now been implemented in Tasmania. In particular, the new state regulatory requirements came into effect on 1 September 2007. Prior to this date, an education campaign and information sessions were conducted under the auspices of the General Practice Divisions throughout Tasmania. Also, a clinical guideline sheet has been prepared in consultation with representatives of the Royal Australian College of Psychiatrists (RACP), the Royal Australian and New Zealand College of General Practice (RANZCGP) and the Pharmaceutical Services Branch of the Tasmanian Health Department that addresses the problem and the appropriate clinical use of alprazolam. This will be available to all medical practitioners in the state.

In their submission to this Inquiry Mr John Galloway and Ms Mary Sharpe state that increased monitoring of alprazolam will now achieve the following purposes:

- A clear picture of all prescribing, not just those prescriptions claimed on the PBS
- Ability to limit/prevent prescribing where there are concerns about safety
- Patients most at risk of misusing alprazolam will now only be able to have it prescribed under highly controlled circumstances
- Reduction in availability of alprazolam for illicit use and diversion.<sup>106</sup>

It may be that rescheduling of alprazolam to Schedule 8 is an appropriate strategy.<sup>107</sup> However, there is insufficient evidence as to whether or not this is a problem in Victoria to make conclusive findings in this area. Nonetheless, it may be appropriate as a first step to conduct a review with regard to the use and prescribing of this drug.

## Psychomotor impairment and driving

Given the common side effects associated with the benzodiazepines – sedation, drowsiness, ataxia, psychomotor slowing, motor incoordination and mental confusion – it is not surprising to find that these drugs, among others, are associated with an increased risk of motor vehicle accidents, particularly when taken in larger doses or in combination with other drugs. According to VicRoads' submission to the Inquiry, 'the misuse/abuse of benzodiazepines is a major road safety issue in Victoria, with significant numbers of drivers killed and drug impaired drivers testing positive to these drugs'.<sup>108</sup>

Professor Drummer, in his evidence to the Inquiry, explained that:

There has been a system in Victoria since 2000 for police officers to detect what was called impaired drivers. In that system, if a police officer forms the view a person is impaired and their alcohol breath-test is largely negative or very low and not consistent with their apparent behaviour, the person can be assessed at a police station by an appropriately trained assessor. If they fail that sobriety test, a blood sample can be taken by a clinical forensic physician. Our laboratory will then screen that specimen for a variety of drugs,

105 Review summarised in Submission of Mr John Galloway, Chief Pharmacist and Ms Mary Sharpe, Deputy Chief Pharmacist, Pharmaceutical Services Branch, Department of Health and Human Services, Tasmania, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

106 Submission of Mr John Galloway, Chief Pharmacist and Ms Mary Sharpe, Deputy Chief Pharmacist, Pharmaceutical Services Branch, Department of Health and Human Services, Tasmania, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

107 For further discussion of drug scheduling, see Chapter 3.1.

108 Submission from George Mavroyeni, Director, Road Safety and Network Access, Vicroads, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 13 June 2007.



including benzodiazepines, using modern analytical techniques and clearly provide a report to that effect to the police and to the courts.<sup>109</sup>

Professor Drummer analysed the cases that had been referred to the Victorian Institute of Forensic Medicine. This showed that benzodiazepines were present in 65 per cent of impaired drivers (defined above by Professor Drummer), 15.8 per cent of injured drivers and between 3 and 5 per cent of fatally injured drivers. Professor Drummer also noted that 33 per cent of injured women drivers aged more than 56 years tested positive.<sup>110</sup>

Professor Drummer explained how driving performance could be impaired by benzodiazepines.

They [benzodiazepines] tend to have manifestations that are similar to alcohol misuse. Their [drivers'] reflexes are not as good; perhaps they are wobbling on the road a bit; they are drifting in and out of lanes; their attention span is reduced; their peripheral vision is reduced...A police officer could well think they are drunk but be surprised there is no alcohol present in their breath.<sup>111</sup>

Dr Drummer's evidence concurs with that in the published literature. On-road driving studies have found that the benzodiazepines significantly impair driving competence. For example, Alford and Vester (2005) reviewing six such studies found that the impairment associated with some benzodiazepines was the equivalent of driving above 0.10 per cent blood alcohol level. In a comprehensive review of the literature published between 1970 and 2002 on benzodiazepine use and driving, Kelly, Darke and Ross (2004) found that, after cannabis, benzodiazepines were the most commonly detected drug in drivers who had been involved in road crashes.

More recent research undertaken by Dr Chin Wei Ch'ng and Associate Professor Mark Fitzgerald and their colleagues (2007) at the National Trauma Research Institute found 15.6 per cent of adult drivers who presented for treatment at the Alfred Hospital Emergency and Trauma Centre between December 2000 and April 2002 as a result of a motor vehicle crash had benzodiazepines in their system. Similar results were found in a study conducted by Associate Professor Griggs (2007) and his colleagues at the Royal Adelaide Hospital Trauma Service, which found that benzodiazepines were present in 14 per cent of drivers attending the hospital's Emergency and Trauma Departments.

However, drug driving is an extremely complex issue and there are numerous complicating factors that need to be taken into consideration when developing strategies to address addressing pharmaceutical drugs and driving. Firstly, limited research has been undertaken to ascertain the actual degree of impairment caused by pharmaceutical drugs on driving (Kaba, Dannzer & Lehner 2000), and findings from studies that have investigated the impact of benzodiazepines on driving performance have been inconsistent. For example, a 2007 review of the literature undertaken for the Australian Drug Foundation (ADF) found:

A case-control study analysing the blood taken from 2500 crash-injured South Australian drivers indicated a clear and significant relationship between benzodiazepines and culpability (Longo, Hunter, Lokan, White & White, 2000). Interestingly, Longo et al (2000) also found a significant relationship between benzodiazepine concentration and culpability. That is, among those who had a benzodiazepine concentration at or above the therapeutic level, culpability was significantly greater than for the non-user group.

109 Professor Olaf Drummer, Head (Forensic and Scientific Services), Victorian Institute of Forensic Medicine, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 13 July 2006.

110 Submission of Professor Olaf Drummer, Head (Forensic and Scientific Services), Victorian Institute of Forensic Medicine, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

111 Professor Olaf Drummer, Head (Forensic and Scientific Services), Victorian Institute of Forensic Medicine, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 13 July 2006.



In another study conducted in the Netherlands, it was found that the likelihood of a driver having a motor vehicle crash is five times higher for those who consume benzodiazepines, compared with those who do not (Movig, Mathijssen & Nagel, 2004). In contrast, however, a case control study analysing the bloods sample from 3398 fatally injured crash victims from Victoria, New South Wales and Western Australia suggested weak and insignificant associations of benzodiazepines with culpability (Drummer, 2004). The lack of an association found by Drummer et al. (2004) may have been due to the small number of cases detected with benzodiazepines. Indeed, Boorman and Papfotiu, Carter and Stough (2005) found that, in drivers arrested for driving under the influence, benzodiazepines were the most commonly detected drugs, being detected in 35 per cent of cases (Mallick et al 2007, p.90).

Similarly, another report by the United States Highway Traffic Safety Administration (2003) found that most benzodiazepines can cause significant impairment of driving and driving related tasks, especially when high doses are involved.

However, despite the inconsistent findings, 'there is little doubt, however, that benzodiazepines do produce relevant impairment of skills required for safe driving' (Drummer 2004, p.246).

The research also tends to suggest that benzodiazepines are more like to impair driving performance and increase the risk of collision in the initial stages of use. Various studies have shown that driving impairment and collision risk is highest in the two weeks after they are first consumed and that once the medication is stabilised and a tolerance is developed the risk of impairment is reduced (International Council on Alcohol Drugs and Traffic Safety 2001; Kelly Darke & Ross 2004; Ogden & Moskowitz 2004).

The second factor requiring consideration is that a patient's medical condition may impair his or her driving performance, which may be improved by taking benzodiazepines according to prescription (Ausroads 2006; United States National Highway Safety Administration 2003). Clearly the problem of pre-existing medical conditions also complicates efforts to determine conclusively the impact of pharmaceutical drugs on driving and the type of counter measures needed to counter such drug-impaired driving. Some such measures could be counterproductive if people did not take the medication they needed: 'Misinformation may lead to patients stopping their medication which could have negative health consequences' (Mallick et al 2007 p.83).

In addition, research on driver impairment is complicated because many drivers who drug-drive have more than one substance in their system. There is increasing evidence that poly-drug use may be associated with a greater degree of impairment than that associated with single drug types (Mallick et al 2007). In particular, alcohol combined with cannabis or benzodiazepines has the potential to negatively impact on driving skills (Mallick et al 2007; Drummer et al 2004).

Clearly the impact of benzodiazepines on driving performance is extremely complex and far more research is needed to ensure that any counter measures developed to address the problem are evidenced based. However, as Mallick et al conclude in their recent comprehensive report *Drugs and Driving in Australia*, 'Despite the mixed findings and complicated issues related to pharmaceutical drugs and driving, there is considerable evidence to suggest that some pharmaceutical drugs, benzodiazepines in particular, have a significant impact on driving ability' (Mallick et al 2007, p.37).

### *Opioid analgesics*

In the most part, the adverse effects of the pharmaceutical opioids such as morphine, and oxycodone are similar due to their central nervous system depressant effects, and therefore are dealt with together in this section. There are other adverse effects specific to some of these drugs that are addressed separately. Opioids lower respiration rates and heart rates and suppress reflex reactions such as coughing. They dilate blood vessels producing a feeling of warmth. They may also cause slow bowel activity producing constipation. Other adverse effects of opioid use include: sweating; muscles and joint pain; reduced libido; skin



rashes and itching; sedation; fluid retention; loss of appetite; nausea and vomiting; abdominal cramps; dry mouth resulting in tooth decay; and irregular menstruation (Downie & Kettle 2000).

Saunders and Young note that:

Opioids...have little toxic potential per se. They may, however, cause anoxia [lack of oxygen] due to overdose because of the variable quality of street drugs and co-use with other drugs acting as central nervous system depressants. Neuropsychological damage can result from anoxic episodes and subsequent necrosis [death] of brain tissue. Ancillary problems can occur from, for example, cigarette burns due to smoking while in a drowsy drug-induced state, anorexia [poor appetite] or nausea leading to poor nutrition, or reproductive system impairment, for example menstrual irregularities. The greater part of the associated morbidity is related to injecting drug use (Saunders & Young 2002, p.39).

### **Sedation**

One of the classic adverse effects associated with opioid use which is also apparent with other central nervous system depressant use, particularly soon after injecting, is sedation. This acute intoxication results in drifting in or out of consciousness, but without the signs and symptoms of an opioid overdose, which includes difficulty breathing, turning blue, lost consciousness, collapsing or being unable to be roused (Strang et al 1999).

### **Tolerance and withdrawal**

Tolerance to opioids involves a shortened duration and reduced intensity of their analgesic, euphoric and sedative effects. This means once dependent, people need larger or more frequent doses to have the same effect. There are large individual differences in the development of tolerance, and tolerance to the different effects of these drugs does not develop at the same rate. Thus even chronic, long-term users can experience the respiratory depression effects associated with opioid use, but might experience less of the pleasant euphoric effects. Most people experience some withdrawal symptoms even in mild reduction of dosage (Young et al 2002).

Signs of opioid withdrawal can start to occur within four to six hours after the last dose, depending on the half-life of the opioid that has been abused. Maximum effects occur normally after 36 to 72 hours, but this will vary according to opioid; if untreated, effects will take five to 10 days to subside. The severity of the withdrawal symptoms increases with the size of the opioid dose and duration of dependence. The symptoms of opiate withdrawal start initially with anxiety, craving, restlessness, lacrimation [teary], yawning, sweating and rhinorrhoea [runny nose]. A reliable early sign of withdrawal is a respiratory rate greater than 16 breaths per minute. Other symptoms include mydriasis [prolonged dilation of the pupil], piloerection [goose bumps], tremors, muscle twitch, hot and cold flushes, aching muscles and anorexia. In severe cases, tachycardia, hypertension or hypotension may occur (Downie & Kettle 2000, p.244).

There is not a great deal of literature with regard to dependence on pharmaceutical opioids among illicit drugs users. This is probably because there is a recognised dependency syndrome related to all opioids, which has been described above. It is reasonable to believe that people using these drugs illicitly are at high risk of becoming dependent and that the dependence will be similar to that for other drugs in this class.

A small number of studies have been undertaken in the United States on OxyContin® dependence. This is probably because of the rapid growth in the spread of this drug in that country and its use beginning in mid-adolescence for some with relatively little or no other prior opioid use or heroin use (Katz & Hays 2004).

Two cases from the study by Katz and Hays (2004) are presented here. They show how adolescents may quickly develop serious addictions to OxyContin®:

This 18-year-old single white girl with no known history of prior drug abuse reported using OxyContin® for 2 years, on a daily basis for the previous year and a half. She snorted the OxyContin® and had recently been leaving her infant son with her mother so she could spend her time using drugs. She reported selling all of her belongings and described not taking insulin for her diabetes because of her drug use, which escalated to 150 and then 200 mg of OxyContin® per day. As a result of this, she dropped out of school and was spending most of her time crying, unable to sleep and unable to eat. She was finally admitted to an acute inpatient unit for detoxification from OxyContin®.

This 17-year-old single boy described using OxyContin® for 1 month. His substance use had begun with cigarettes at age 11 and escalated to marijuana at age 12 and cocaine at age 16. He stole the OxyContin® from his mother's supply and quickly escalated his use to 100 mg a day, which he snorted. The OxyContin® use rapidly supplanted the use of all other substances and resulted in inpatient admission for detoxification 1 month after his use began (Katz & Hays 2004, p.232).

Another study using a small sample (n=10) described how new initiates to heroin use had commenced that drug after first becoming dependent on prescription opioids such as OxyContin®. Those interviewed reported turning to heroin after developing tolerance to OxyContin® and then experiencing withdrawal when they could no longer access the drug (Siegal et al 2003). Whilst acknowledging that these findings were limited to a very small sample size, the authors postulated that non-medical use of opioids such as OxyContin® could provide a new pathway to heroin use.<sup>112</sup>

On the other hand, an Australian study found quite a different pattern of progression whereby 'Many polydrug misusers progress from illicit drugs to prescription drug use as they become chronically ill. Such prescription drug use is thought to escalate over time' (Bird 2006, p.60).<sup>113</sup>

### Opioids and overdose

Most users of heroin also use benzodiazepines and prescription opioids. Heroin users are about 13 times more likely to die in any one year than their age-mates who do not use heroin (English et al 1995), with annual mortality rates of between 1–3 per cent (Darke & Zador 1996). Although there has been an unprecedented decline in heroin-related overdose in Victoria (Woods et al 2006), as elsewhere in this country, since the 'heroin drought' commenced in early 2001, overdose remains a real risk for many users of heroin and other opioids.

Some commentators claim, however, that the number of deaths associated with overdose from *prescription* opioids have been understated. For example, a submission to this Inquiry from Mr John Galloway, Chief Pharmacist of the Tasmanian Department of Health stated:

There is increasing concern at the number of deaths associated with prescription opioids. In Tasmania, a number of deaths came to the attention of the Branch where the deceased had a known history of misuse or abuse of pharmaceutical opioids. However, not all cases appeared to have been recognised as having a connection with prescription drug use. The cases included people who were current or former clients of the methadone program, and also people who had never been treated for drug dependence but had been recipients of prescription opioids.

It is sometimes difficult to establish a precise link between the use of a prescription drug and the cause of death. Fatal levels of opioids at autopsy are uncommon and other drugs including benzodiazepines are usually present. However, many of these people have died prematurely and unexpectedly. It is also clear that a significant number of such deaths do not appear in statistical reports, leading to a concern that prescription drug related deaths are likely to be under-reported.

112 OxyContin® is discussed further in the context of the acquisition of prescription drugs in Chapter 2.3 of this Report.

113 For further discussion on polydrug use as it relates to benzodiazepine and opioid use, see Chapter 2.3.



Coroners in Tasmania are expressing concern about the increasing frequency of cases of death where prescription opioids appear to be a significant contributory factor. A dedicated research project is needed to document the circumstances and frequency of deaths which are related to misuse and abuse of pharmaceutical substances. In particular, research data is needed to help inform and educate medical organisations about clinical policy and practice.<sup>114</sup>

### ***Polydrug overdose deaths where benzodiazepines are involved***

Most heroin-related overdose deaths are associated with polydrug use; that is, a number of drugs and/or alcohol used in combination. Turning Point Alcohol and Drug Centre remarked in a submission to this Inquiry that:

Benzodiazepines were detected in 71 per cent and morphine in 16 per cent of heroin related deaths in 2001 (Wallington et al 2002). In addition, a recent examination of risk behaviours associated with non-fatal heroin overdoses attended by the Melbourne Metropolitan Ambulance service (July 1999 to May 2001) found a higher likelihood of benzodiazepines or alcohol use in the 12 hours prior to overdose event (Dietze et al 2005).<sup>115</sup>

Despite such data, it should be noted that where a number of drugs are detected in post-mortem tissues, it is often difficult to attribute the death to one particular drug. The Victorian Institute of Forensic Medicine (VIFM) produces reports on heroin and other opioid-related deaths in Victoria on a regular basis (eg. Woods et al 2006). Because the body rapidly converts heroin to morphine once it is administered, morphine is the drug measured toxicologically. As a result it is not possible from this data to separate cases where people have died from drug combinations containing heroin alone, those containing heroin and pharmaceutical morphine, or those containing morphine alone. However, the toxicological analysis does allow other synthetic opioids such as methadone, propoxyphene, oxycodone, etc. to be identified, along with benzodiazepines. Data from the most recent VIFM reports are presented in Table 2.2b showing the presence of drug classes in deaths containing morphine (termed 'heroin deaths'). It shows that other synthetic opioids were found in 7 per cent of all heroin deaths over the period. The apparent increase in this proportion from 4 per cent in 2001 to 8 per cent in 2004 and 2005 is not significant. Overall the data from 2001–2005 shows that benzodiazepines are found in 60 per cent of all cases and there was an initial drop from 2001, but the proportion of deaths involving benzodiazepines has remained fairly steady since 2002 (Woods et al 2006).<sup>116</sup>

**Table 2.2b: Presence of other drugs in heroin (morphine)-related overdose deaths, Victoria, 2001–2005 (per cent)**

	2001	2002	2003	2004	2005	Overall*
Morphine only	16	16	<u>32</u>	18	15	20
Morphine + benzodiazepines	<u>71</u>	67	48	59	54	60
Morphines + alcohol	31	24	31	<u>36</u>	34	31
Morphine + cannabinoids	22	12	9	11	21	15
Morphine + amphetamines	<u>22</u>	14	9	8	14	13
Morphine + other opioid drugs#	4	6	7	8	8	7

Notes: \* Total percentage equals more than 100%, as multiple combinations of other drugs were also present.  
# i.e. methadone, propoxyphene, oxycodone, etc. — Significant values are underlined.

Source: Woods et al 2006, p.4.

114 Submission of Mr John Galloway, Chief Pharmacist and Ms Mary Sharpe, Deputy Chief Pharmacist, Pharmaceutical Services Branch, Department of Health and Human Services, Tasmania, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

115 Submission of Turning Point Alcohol and Drug Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

116 Whilst deaths by overdose from the pharmacotherapy drug buprenorphine are relatively rare when the drug is used by itself, evidence suggests that taken in combination with other central nervous system depressants, such as benzodiazepines, the risk is much higher. Reynaud et al (1998) suggest that concomitant use of benzodiazepines and buprenorphine seems to be strongly implicated in buprenorphine overdose. See also European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) 2005.



Consistent with earlier research (eg. Darke & Zador 1996; Darke, Ross & Hall 1996; McGregor et al 1998), Table 2.2b shows that heroin (morphine)-only overdose deaths make up a small proportion of all deaths involving heroin. The use of other central nervous system depressants, notably alcohol and benzodiazepines, is common in overdoses involving heroin. More recently, Martyres, Clode and Burns (2004) found that polydrug use was evident in 90 per cent of toxicology reports of 254 heroin-related fatal overdose cases of 15- to 24-year-olds in Victoria between 1994 and 1999.

The discussion in this section has shown that both benzodiazepines and narcotic analgesics can have adverse effects when used as prescribed and under the care of a medical practitioner. But when used for non-medical purposes they are often consumed at a far higher dose, for longer periods, in combination with other drugs, and in ways that can exacerbate potential problems. As a consequence, the adverse effects of misuse of these drugs are substantial. They can include sedation contributing to confusion, memory loss and problems with driving or operating machinery, tolerance leading to escalating use, and severe withdrawals when access is restricted. Overdose is probably one of the most serious consequences of pharmaceutical drug misuse. The 'Rambo effect' is one that is specific to the use of benzodiazepines, usually at high doses, and is at odds with the prescribed use to reduce anxiety and induce sleep. Although benzodiazepines on their own rarely result in fatal overdose they are often involved in fatal overdoses involving heroin.

### **Adverse consequences of injecting diverted pharmaceutical drugs**

Data presented in Chapter 2.1 shows that among Australian injecting drug users injection of diverted pharmaceuticals is occurring. For example, 45 per cent of injecting drug users surveyed for the Illicit Drug Reporting System (IDRS) in 2006 reported injecting non-prescribed morphine in the preceding six months. Nineteen per cent had injected illicit methadone, 20 per cent had injected buprenorphine, 20 per cent had injected oxycodone and 12 per cent had injected benzodiazepines (O'Brien et al 2007).

Included in the IDRS are questions relating to problems the respondents have experienced as a result of injecting benzodiazepines and other pharmaceutical drugs. The most commonly reported problems were difficulty in injecting, and scarring and bruising following injection. Although the proportion of injecting drug users who reported the injection of benzodiazepines declined between 2001 and 2005, the proportion has increased in 2006.

Also of concern in injecting drug use is the increased risk of exposure to blood borne viruses, in particular hepatitis C. The prevalence of hepatitis C among injectors is high, with approximately 60 per cent of injecting drug users being infected (National Centre for HIV Epidemiology and Clinical Research 2007). HIV/AIDS among injecting drug users in Australia remains at less than 2 per cent, due primarily to the introduction of harm reduction measures such as needle and syringe programmes in the mid 1980s (National Centre in HIV Epidemiology and Clinical Research (NCHECR) 2007). In other countries, however, the prevalence of HIV/AIDS is considerably higher and the risk of exposure through injecting is considerable. Hepatitis B is also of concern despite the fact that there is an efficient and cost-effective vaccine available to prevent the transmission of this virus (Carruthers 2003).

#### ***Injection of drugs formulated for oral administration***

Physical problems from injecting pharmaceutical drugs that have been formulated for oral consumption can occur through two related processes. Firstly, either because of the way the drugs are manufactured or because of the un-sterile way in which they can be administered, there can be damage to veins, skin, muscle, major organs and other body systems as a direct result of these factors. Secondly, as a consequence of damage to the smaller, peripheral veins they become unusable for injection so the person may go searching for larger, more central veins. Unfortunately they can miss the vein and inadvertently inject into nearby



arteries or surrounding tissue. This can lead to arteries being blocked, or obstructed due to swelling, which can cut off the blood supply to parts of the body and result in tissue damage and major injuries, at its worst resulting in amputation.

As Dr Malcolm Dobbin explained:

There are the problems arising from the illicit injection of medications that are intended for oral use. It can cause damage to blood vessels. The peripheral blood vessels can be closed down, so people then have to inject it into bigger, more central, veins, and can start injecting it into the groin or around areas where the arteries are in close proximity to the vein. It can cause inadvertent injection into the arteries as well, and you can have injection outside a vein into the tissues, which can cause inflammation and ischemia and blockage to the blood supply to certain areas. It can also cause ulceration.<sup>117</sup>

#### **A case study: Temazepam injection in Australia 2000–2004<sup>118</sup>**

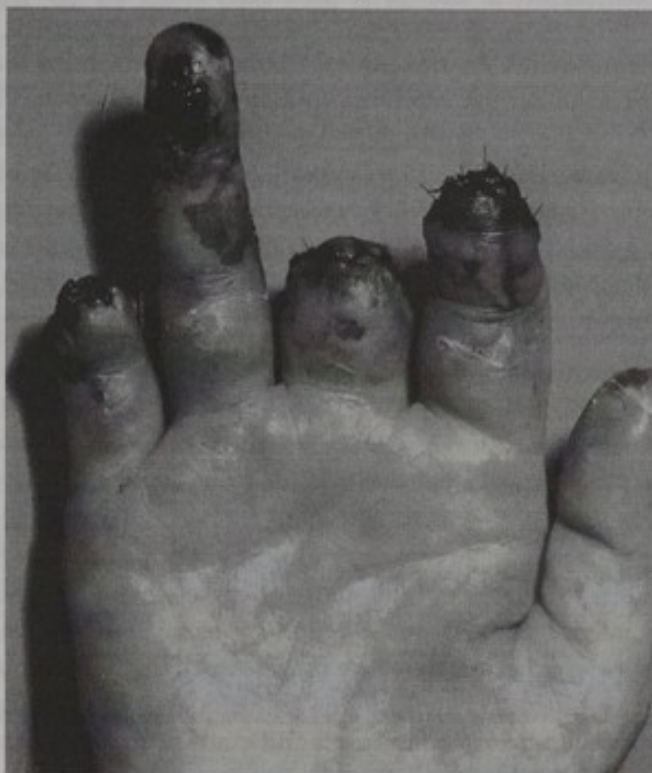
Injection of the liquid contents of temazepam capsules was first documented in the United Kingdom in 1987. The first reports of serious harm began in 1988. These included gangrene from injecting into arteries, skin inflammation and ulcers, abscesses, damage to veins in the groin, along with escalating crime and black market dealing in the capsules. In 1996 the problem was finally resolved when doctors were banned from prescribing the capsules on the National Health Service (NHS) after nine years of largely unsuccessful attempts at doctor education and voluntary bans on prescribing.

In Australia, by 1999/2000 the liquid filled gel capsules had become one of the 10 most frequently prescribed drugs on the Pharmaceutical Benefits Scheme (PBS), with some 2.2 million prescriptions being written in that year. Temazepam tablets became available a few years after the gel capsules had reached the market and there was an increasing trend in their prescription. By 2001 they accounted for about 25 per cent of all (PBS) prescriptions in Victoria.

Use of the readily-injected liquid gel capsules was well established among injecting drug users in Victoria by 2000 (see data presented in Chapter 2.1), with injuries being reported in Victoria and elsewhere in Australia similar to those found in the United Kingdom. These injuries began to be documented in academic papers such as that published in the *Medical Journal of Australia* by Feeney and Gibbs (2002) describing gangrene of the fingers (Figure 2.2a).

<sup>117</sup> Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, Department of Human Services (DHS), Briefing given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Melbourne, 29 May 2006.

<sup>118</sup> This summary is largely drawn from an unpublished paper (2006a) by Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, DHS, submitted to the Drugs and Crime Prevention Committee.

**Figure 2.2a: Digit loss following temazepam injection**

Note: Image shows patient's hand after surgical debridement and amputation of necrotic areas, three weeks after injection of temazepam.

Source: Feeney & Gibbs 2002, 'Digit loss following misuse of temazepam', *Medical Journal of Australia*, vol. 176, p.380. Copyright 2002. Reproduced with permission.

From late 2000 there was a dramatic decrease in the availability of heroin in Australia – the 'heroin drought' – with a concomitant reduction in the number of heroin-related fatal and non-fatal overdoses (in Victoria down from 339 and 312 in November 1999 and 2000 respectively, to 37 in November 2001). However, in response to the heroin shortage there was a marked increase in the injection of contents of temazepam capsules. This was associated with an increase in trafficking of capsules, pharmacy burglaries and increasing episodes of doctors being intimidated to write prescriptions for the capsules. Many of the thefts, ram raids and burglaries were exclusively targeting capsules (and not tablets) of temazepam. Capsules were being sold on the street for between \$50 and \$100 for a 'slab' of 25 capsules.

Authorities considered what might be the unintended adverse complications of restricting access to the capsules, which included looking at overseas experiences. In the United Kingdom and the United States temazepam capsules had not been available since 1996, and whilst there was a shift to injecting other benzodiazepines in the United Kingdom this shift did not include temazepam tablets. In Australia, there was also concern that any restriction would adversely impact on patients using the drug legitimately, however this had not caused major inconvenience in the United Kingdom or the United States.

In 2001 the Victorian Department of Human Services (DHS) established a professional, and peer (injecting drug users, needle exchange workers and others) reference group to develop a response. Dr Malcolm Dobbin described this to the Committee:

We had a Temazepam Injection Prevention Initiative in which we sent a pack with a letter from our Chief Health Officer asking prescribers not to prescribe the capsules except for long-established patients and to prescribe the tablets instead; providing them with information, with posters for their waiting rooms and scripted responses to the kinds of scams that users were using; and asking them to use our borrowed protection – that we were asking them not to do it: 'It wasn't me; it was the Department' or 'the Medical Board.'...We did decrease the supply in Victoria marginally, but it was not until it was made difficult to



obtain on the PBS that there was a profound drop, so it was a regulatory change that made all the difference.<sup>119</sup>

In May 2002, the Australian Pharmaceutical Council recommended that temazepam gel capsules be restricted under the PBS. Prior to May 2002, temazepam (10mg tablets) and 10mg capsules (Euhypnos, Nocturne, Normison and Temaze) were subsidised by the PBS or available on private prescription. Temazepam 20mg could only be obtained through a private prescription. From 1 May 2002, temazepam 10mg capsules required an authority<sup>120</sup> to allow subsidy on the PBS. Temazepam 10mg tablets, 10mg capsules and 20mg capsules were still available on private prescription. These changes were designed not to restrict the use of temazepam per se, but to reduce the diversion and injection of temazepam capsules.

The effect of these restrictions was assessed by a study conducted by the National Drug and Alcohol Research Centre in Sydney, NSW (Breen, Degenhardt, Bruno et al. 2004). The study found there had been a decrease in prescriptions for temazepam 20mg capsules (393,370 prescriptions) and a corresponding increase in the prescription of temazepam 10mg tablets (368,951 prescriptions) following the policy change. Injectors continued to inject benzodiazepines and temazepam capsules and were still being prescribed the capsules even after the restrictions. The authors of the study concluded that limiting the prescription of temazepam might have reduced the injection by some injecting drug users but that additional strategies were needed to reduce the misuse of the drug within the study group. Approaches recommended included further restrictions on capsule prescription, further education of doctors and injecting drug users and examination of the prescribing practices of some doctors.

Following the Temazepam Injection Initiative, and partly as a result of it, in early 2004 the pharmaceutical companies voluntarily removed the temazepam products from the Australian market as a result of concerns about the above harms. This effectively ended the problem of serious vascular injury and serious tissue damage resulting from temazepam injection.

#### **Talc problems associated with injecting or intranasal use of pharmaceuticals in tablet form**

People who inject diverted pharmaceutical drugs in tablet form can experience problems due to the talc incorporated in the tablets. Talc (magnesium silicate) is an inert substance most often used as a lubricating powder. It is also used in the pharmaceutical manufacturing process. When taken orally this substance is harmless but when injected or snorted can result in a condition called Talc Pulmonary Granulomatosis (Ward et al 2000). Minute particles of talc lodge in the lungs and create an inflammatory reaction that can result in emphysema, a condition mostly associated with cigarette smoking. Small talc particles which get past the lung's filter action can also lodge in and block the arteries in the retina of the eye causing blindness (Raspiller et al 2005). In a submission to the Inquiry, Dr Malcolm Dobbin described Talc Pulmonary Granulomatosis in the following way.

This is a case involving talc. If you inject intravenously, the blood goes first to the right side of the heart and then is circulated through the pulmonary artery to the lungs. Most things injected intravenously will first of all either be lodged in the lung or pass through the lung, and that is what you see here with these sorts of collections of granules in the lung. You see these talc particles surrounded by inflammatory cells. They cause granulomas, and this condition is called talc pulmonary granulomatosis. You see a talc granule there. It can then break through the pulmonary system into the general vascular system and be lodged in the lung and cause liver granulomatosis, and affect the retina and other areas through the blood supply. Once it is lodged in the lung, you have obstruction to the blood supply through the lung so that the blood pressure in the pulmonary arteries, which is usually quite low,

119 Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, DHS, Briefing given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Melbourne, 29 May 2006.

120 Prior approval from the Health Insurance Commission.



becomes very high. You get pulmonary hypertension, and that is a potentially fatal condition. We are seeing these kinds of particles in post-mortem specimens in State Coroner's Office cases.<sup>121</sup>

Anex, the Association for Prevention and Harm Reduction Programs Australia, has also commented on the dangers associated with injecting 'non-injectable' drugs:

Both opioid and stimulant pharmaceutical tablets that are injected carry the risk of injecting travelling particles (when not filtered adequately prior to injection). The injection of tablets containing talc has been linked to chronic inflammatory granulomas in the lung. This can lead to respiratory failure and potentially lethal pulmonary hypertension.

Anecdotal evidence suggests that despite the removal of temazepam (and a reduction in the particular harms associated with injecting the gel from temazepam gel caps), clients accessing NSPs (needle and syringe programmes) are continuing to inject pills including a variety of benzodiazepines and other pharmaceuticals. Clients are presenting with a variety of physical harms including vein damage, infection and associated health problems.<sup>122</sup>

Anex states further that it is imperative that further information, education and simple harm prevention measures are provided to injecting drug users to ensure safe injecting practices to minimise such harms.<sup>123</sup> The issues of education, information and harm prevention measures are discussed further in Section Six of this Report.

### Victorian service utilisation statistics as indicators of harm

Having described the adverse effects of benzodiazepines and opioid analgesic drugs, the question remains as to what extent these harms are realised in the Victorian community. Whilst primary indicators of specific harms are often difficult to source, there are a number of secondary indicators of harm from these drugs. These include ambulance attendance data, hospitalisations data, and specialised drug service data.

In general it is easy to obtain data on how much demand for health services is due to benzodiazepine use, however it is difficult to determine to what extent these demands for service are due to the adverse consequences of licit use of these drugs as prescribed or to the illicit use – that is, for non-medical purposes. However, there is more difficulty in identifying the health service impacts attributable to prescription opioids. Whilst this data is probably available from the agencies that keep records, most publicly available reports refer to 'heroin and other opioids' (eg. DHS Victoria 2007). This is an understandable consequence of the extent to which illicit heroin use has dominated opioid misuse in Australia. However, the increasing interest in misuse of prescription opioids, reflected in the

121 Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, DHS, Briefing given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Melbourne, 29 May 2006.

122 Submission of Anex to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

123 With regard to the specific issue of injecting benzodiazepines Anex states:

'The equipment requirements for those injecting benzodiazepines and a variety of pharmaceutical drugs can vary from those required for injecting opioids like heroin. In Victoria, the Department of Human Services supplies all NSP [needle and syringe program] outlets with sterile needles and syringes, alcohol swabs, condoms and lubricant as well as sharps containers and paper and plastic bags for used needles and syringes. They do not however provide a variety of consumables required for the injecting process including plastic spoons, sterile water, cotton wool (for basic filtering) or tourniquets.

The provision of such equipment is one practical measure to assist in reducing the spread of blood-borne viruses such as hepatitis C amongst people who inject drugs. However, for those using benzodiazepines and other pharmaceutical tablets intravenously, a range of equipment is required including filters. The equipment required for those using tablets and pills includes:

- Sterile water
- Spoons
- Larger barrels (3ml, 5ml & 10ml)
- Cotton wool (for basic filtering)
- A variety of filters (including small, medium and large) (Submission of Anex to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006).



current Inquiry, points to a need for more routine reporting of the contribution of pharmaceutical opioids as a separate category of service utilisation statistics.

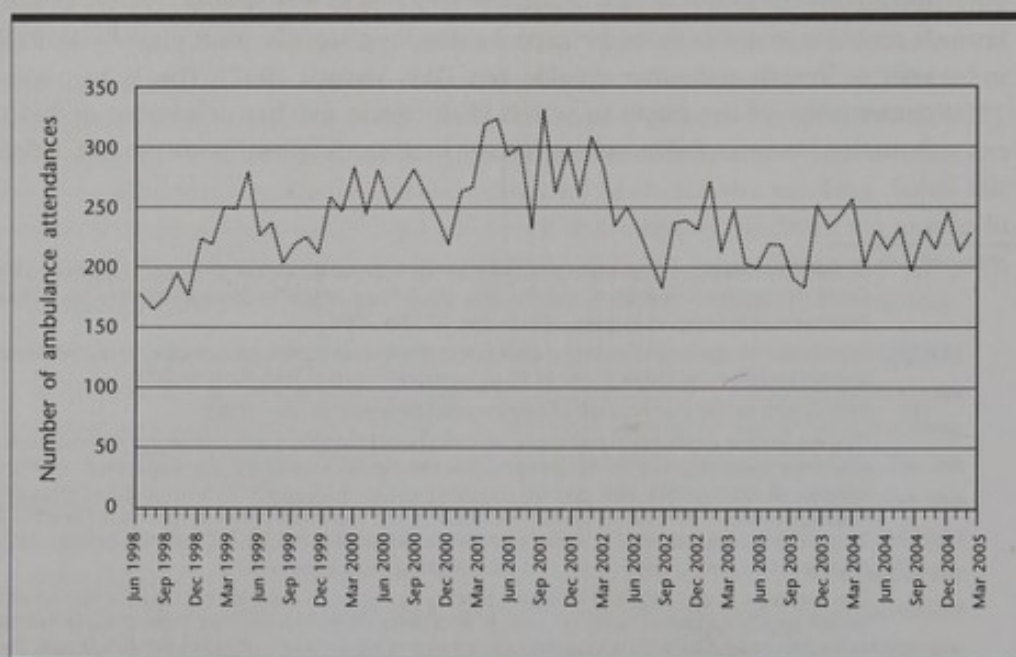
### **Melbourne Metropolitan Ambulance Service data**

In a submission to this Inquiry, Turning Point Alcohol and Drug Centre described a joint project it is undertaking to provide drug-related analysis of ambulance records:

The Turning Point Alcohol and Drug Centre and the Melbourne Metropolitan Ambulance Service (MAS) run a collaborative project, funded by the Department of Human Services, to collect and analyse all ambulance service records on drug-related attendances (Dietze, Cvetkovski, Rumbold & Miller, 2000). Data can be analysed and reported according to general drug classes (e.g. benzodiazepines), specific drugs (e.g. Diazepam) or combinations of drug classes/specific drugs (e.g. overdoses solely on benzodiazepines, benzodiazepines with alcohol, both benzodiazepines and prescription opioids, benzodiazepines with any other drug class etc). Data such as MAS drug attendance data can be an effective way of monitoring the harms associated with the use of particular types of drugs. The MAS drug attendance dataset can be analysed according to time (e.g. year, month, day of week, time of day), place (e.g. postcode, public/private or indoor/outdoor attendance) or characteristics of the patient (e.g. sex, age), and such data are valuable for informing a profile of the use and harms of particular types of drug use. For example, benzodiazepine-related attendances made indoors/private residence versus outdoors/public places can be used as a proxy for harms associated with the licit versus illicit use of these drugs.<sup>124</sup>

Figure 2.2b presents Turning Point data showing ambulance calls where benzodiazepines were mentioned. The number of calls peaked in 2001–2002 and was followed by a decline, which probably reflects the increased injecting of temazepam gel capsules and the subsequent decline as restrictions on these capsules, described elsewhere in this chapter, came into effect. No data was included in the Turning Point submission on ambulance calls involving prescription opioids, although the above quotation indicates that such data should be able to be extracted from their joint database.

**Figure 2.2b: Monthly benzodiazepine-related ambulance attendances, Melbourne, June 1998 to March 2005**



Source: Submission to the Inquiry by Turning Point Alcohol and Drug Centre, May 2006.

<sup>124</sup> Submission of Turning Point Alcohol and Drug Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

Table 2.2c shows that females comprised the majority of benzodiazepine-related ambulance attendances, and that the average age of people attended to was 37. Most people (91%) were transported to hospital.

**Table 2.2c: Summary of the main characteristics of non-fatal benzodiazepine overdose ambulance attendances in metropolitan Melbourne, May 2004–March 2005<sup>a</sup>**

Main characteristic	Measure
Number of attendances	2,008
Age of victim	Mean = 37.36 years range = 1-94 years
Sex of victim	57% females
Location of attendance <sup>b</sup>	81% indoors 73% private space
Outcome	91% transported to hospital

Notes: a June and July 2004 data not available

b Attendances are categorised as either indoors or outdoors and private space or public space.

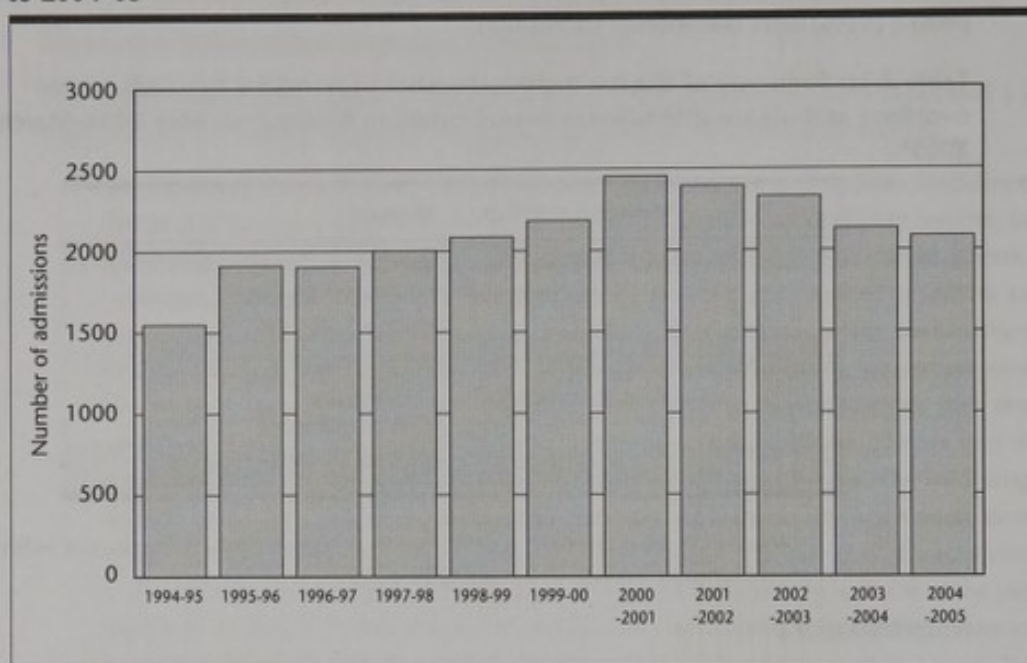
Source: Department of Human Services (DHS) Victoria 2007, p.119.

### **Hospitalisations**

The DHS (Victoria) estimated that in Victoria there were 2,072 inpatient admissions attributable to consumption of benzodiazepines and other sedatives and hypnotics, resulting in 4,242 bed days in the 2004/05 financial year. This comprised some 29 per cent of all drug-related hospitalisations, and 18 per cent of all drug-related bed days, excluding alcohol and tobacco. Benzodiazepines and other sedatives and hypnotics were responsible for less than 0.11 per cent of all hospitalisations in Victoria in that period. Figure 2.2c shows that since 1994 there has been a slow increase in hospital admissions for these drugs in Victoria up until 2001, then a gradual decline thereafter. Intoxications and poisonings accounted for 91 per cent of admissions and 80 per cent of hospital bed days in Victoria during the 2004/05 financial year (DHS 2007). It is interesting to note that 'Approximately half (49%) of the hospitalisations for these drugs involved people aged 30–49 years...' (DHS 2007, p.121). Data on opioid-related hospitalisations is not included here as those reported in publicly available documents include heroin-related admissions in this category.



**Figure 2.2c: Benzodiazepine-related inpatient hospitalisations,<sup>125</sup> Victoria, 1994–95 to 2004–05**



Source: Victorian Admitted Episode Dataset, Department of Human Services, analysis by Turning Point Alcohol and Drug Centre Inc.

#### *Specialist alcohol and drug treatment service data*

Specialist drug service data in Victoria is collated in the Alcohol and Drug Information System (ADIS). Community agencies are funded by the Victorian DHS to provide specialist alcohol and drug treatment services to clients and are required to collect basic client data, which is collated by ADIS (DHS 2007). In the 2004–05 financial year benzodiazepines were identified as the primary drug of concern in 1,139 (2.4%) courses of treatment undertaken by specialist drug treatment agencies, 56 per cent of which were treatment of female clients (DHS 2007). In the same financial year opioids other than heroin were identified as the primary drug of concern for 1,857 (4%) courses of treatment at specialist drug agencies in Victoria. The DHS (Victoria), the lead agency in the National Intentional Misuse of Pharmaceuticals Prevention Initiative, recently called for tenders to study the nature, extent and adverse consequences of pharmaceutical drug misuse among patients presenting for treatment at drug and alcohol treatment agencies across the country. The project is due to be completed in mid 2008.<sup>126</sup>

#### *Summary*

This section shows that whilst there are some secondary data available on service utilisation as indicators of harm in the Victorian community, extraction of this data from publicly available sources is difficult, especially for the pharmaceutical opioids. What data is available, however, shows that benzodiazepines comprise a small proportion of hospitalisations and specialist drug treatment episodes. Trends in both ambulance attendances and hospital admissions appear to reflect trends in patterns of drug availability and use, such as the impact of the heroin drought and the measures put in place to restrict the availability of readily-injectable gel-cap formulations of temazepam.

<sup>125</sup> This includes 166 cases of other sedative/hypnotic drugs (DHS 2006e).

<sup>126</sup> Submission of Turning Point Alcohol and Drug Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

## Conclusion

When most people think of drug-related harm they tend to think of harm due to illegal drugs. Over the last 20 or so years there has been a concerted push to have the wider community recognise the adverse effects of the legal, and most widely-used drugs, namely alcohol and tobacco. But prescription drugs, whilst of great benefit to many ill people in the community, are also increasingly being misused and associated with serious harms. Indeed, as efforts to disrupt illicit drug markets and further restrict their use continue, we can expect the non-medical use of diverted pharmaceuticals to grow. This should be of concern to us as a community, not least because evidence suggests that pharmaceutical drug misuse may be an early pathway into misuse of a range of drugs, but also because the misuse of these drugs in themselves poses major risks to health and wellbeing at an individual, family and community level.

For many in the community the misuse of prescription drugs and the associated adverse health consequences has been happening 'beneath the radar'. This chapter has attempted to give an insight into some of the adverse consequences of pharmaceutical drug misuse. This form of drug abuse can have very serious consequences and is worthy of further attention by policymakers, bureaucrats, health service providers, drug users and the broader community.

An essential part of further research and policy development with regard to this form of drug abuse is to develop a strong understanding of the causes.





## 2.3 Misuse and Abuse of Benzodiazepines and Other Pharmaceutical Drugs – Profiles of Use and Reasons for Use

### Introduction

Unfortunately there is a relative dearth of information and research giving insights from a drug user perspective on the culture of pharmaceutical drug misuse. Certainly this is the case compared to other licit drugs such as alcohol and illicit drugs such as heroin and amphetamines.<sup>127</sup> Nonetheless, it is known that there is a great variety of user profiles and demographics pertaining to prescription drug use and abuse. This can range from an elderly person who has become inadvertently dependent on benzodiazepines through long-term prescription to these drugs, to a street injector of opioids, often in conjunction with the use of illicit drugs. Consequently, the reasons why a person may abuse prescription drugs will vary according to the profile of those abusing them.

Whilst some user accounts have been included in this chapter where available, most of the information presented here is based on research and accounts from service providers' perspectives. Although it is likely that accounts of pharmaceutical drug misuse will be embedded in accounts of polydrug use, there appears to be a need for in-depth qualitative research of non-medical use of prescription drugs from a user's perspective, both in Victoria and nationally. Victorian researchers have also made this observation, for example Jenkinson and O'Keefe (2006). Research of this nature will be invaluable in informing regulatory, preventive, and treatment responses to this growing phenomenon.

The use of short-acting benzodiazepines such as flunitrazepam (eg. Rohypnol®) as a 'date rape' drug will not be addressed here because this has received recent extensive coverage elsewhere (Taylor, Prichard & Charlton 2004). This is particularly the case given that the motivation for use in this context is to take advantage of another person rather than to experience the drugs' psychoactive effects.

### Profiles of use

There is no one snapshot or profile of a prescription drug misuser or abuser just as there is not one reason why a person may use these drugs in excess of therapeutic need.

A submission to this Inquiry from Dr Benny Monheit, a drug and alcohol clinician based in Melbourne, indicated how important it was to understand the heterogeneity of prescription drug users. For example, psychiatrists may see a completely different profile of user (and abuser) than doctors in drug and alcohol clinics or even general practice:

[it is] difficult to achieve a consensus among the medical profession [on benzodiazepine use and misuse]. For example, psychiatrists are keen to be able to continue to prescribe benzodiazepines in an unrestricted manner as they find the anti-anxiety effect of

127 See for example other reports tabled by the Drugs and Crime Prevention Committee such as the *Final Report of the Inquiry into Amphetamine and 'Party Drug' Use in Victoria* (Drugs and Crime Prevention Committee 2004) and the *Final Report of the Inquiry into Strategies to Reduce Harmful Alcohol Consumption in Victoria* (Drugs and Crime Prevention Committee 2006). Both these reports drew on a voluminous research literature discussing the cultural aspects of drug use and abuse.



benzodiazepines very helpful for their patients...The psychiatrists often point out that they see a different group of patients for benzodiazepines than GPs see. The psychiatrically disturbed patients often have co-existing mood disorders, agitation or schizophrenia where benzodiazepines may play a useful role. The psychiatrists rarely see the doctor shopping patient or even the one with a mild personality disorder where benzodiazepines can aggravate existing behaviour problems. In the medical profession there is still ongoing debate on how to best manage these difficult issues.<sup>128</sup>

This point was also stressed to the Committee in a submission from Dr Alex Wodak, Director of St Vincent's Hospital's Alcohol and Drug Service, Sydney and Ms Mary Osborn, Senior Policy Officer, Royal College at Physicians. Dr Wodak is also the Chair of a Royal Australian College of Physicians subcommittee on benzodiazepine use. They stated in his submission:

It is very important to separate out the very different problems arising in different age groups and populations in terms of developing effective interventions...Very different problems arise in quite different settings; for example amongst young poly drug users, middle-aged people with chronic severe illness and the elderly. Most of the problems are seen in the first and third groups.<sup>129</sup>

Similarly, in his submission the Chief Pharmacist with the Tasmanian Department of Health Dr John Galloway outlined a list of the various 'subgroups' of patients who may attempt to access prescription drugs legitimately and illegitimately:

#### **Patient Subgroup 1 ("The bona-fide patient")**

These are ordinary members of the public who are only interested in having their medical problems resolved. Their focus is not on the drugs but on obtaining relief from their condition or disease. They usually have no history of substance misuse problems...

#### **Patient Subgroup 2 (The dependent patient)**

These are patients who may have genuine pain problems. Some have come to rely on the drugs to improve their mood and how they feel. Others have general problems coping with life's problems (eg social and family problems) and medication provides relief for their psychological stresses. In general, they become more interested in ensuring continuing and increasing supplies of drugs than in resolution of their medical problems...

The supply of medication usually needs to be rationed in some way to prevent overuse.

#### **Patient Subgroup 3 (The drug abuser)**

These patients have a history of substance abuse activities, but may also have some evidence of pain. They also have social or drug-trading connections with other persons abusing drugs. They are likely to be injecting prescribed and other drugs. Prescription drugs have a high value on the black market and such patients work hard at developing their presentations to doctors. Many are not likely to have regular work and obtaining drugs for personal use or trading becomes a high priority in their life...

#### **Patient Subgroup 4 (The drug seller)**

These patients attend doctors with the one of their primary aims being to obtain drugs to sell or trade. This group may include

- some from Subgroup 3 above,
- "scammers" who may use stolen or forged ID or documents (much less common now compared with a decade ago),

<sup>128</sup> Submission of Dr Benny Monheit, Drug and Alcohol Specialist, SouthCity Clinic/Alfred Hospital, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

<sup>129</sup> Submission of Dr Alex Wodak, Director, Alcohol and Drug Service, St Vincent's Hospital, Darlinghurst, and Ms Mary Osborn, Senior Policy Officer Royal Australian College of Physicians to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

- apparently ordinary patients who have come to know and rely on the income that can be made from selling a proportion of their medication (some of these patients may be elderly or even have cancer ),
- patients who intimidate or threaten doctors and who may have some evidence of a pain condition.<sup>130</sup>

Dr Galloway's subtypes reflects Quigley's view that benzodiazepine prescription and use/abuse is a 'complex cultural and social process, with [different] political, economic and moral implications' each reflecting the different profile of those who abuse them (Quigley 2001, p.336). Commenting further on the chameleon like nature of prescription drug abuse, Quigley argues that:

It was possible two decades ago for healthcare policymakers to downplay tranquillisers, which tended to be seen as a 'women's issue'. The 'benzo problem' has since been placed back firmly on the agenda by a much more socially threatening group [marginalised youth and street users] (Quigley 2001, p.336).

And yet for some people the stereotype summed up by the term 'prescription drug abuser' may still be the 'depressed housewife' reliant on 'mother's little helpers'. This at least may be the perception for some Americans according to a representative of the National Alliance for Model State Drug Laws with whom the Committee met in Washington DC in July 2007:

Quite frankly for a long time it was very difficult for this country to even acknowledge the problem [of prescription drug misuse] because most of the people who have the problem look like me. They were not what people viewed as the typical drug addict. They were the Mayor's wife, and the assumption was, because... 'well, yeah, if my doctor prescribes it, it can't possibly be addictive.'<sup>131</sup>

## Reasons for use

As indicated above, the reasons why prescription drugs may be used illegitimately and the patterns of their use are as many and varied as the profile of person who is abusing the drugs.

Lloyd, Guibert & Bell (2000), for example, note that there are many reasons people seek to obtain pharmaceutical drugs without legitimate prescription. These include those who:

- are not prescribed as much of a pharmaceutical drug as they want and/or think they need and thus seek to continue or augment the medication prescribed for them;
- have become habituated or addicted to a drug that has been previously prescribed for them and seek further quantities of the drug;
- abuse illicit drugs and use pharmaceutical drugs to counteract or mitigate their effect; and
- use them as a source of revenue by selling them to the illicit market (Lloyd, Guibert & Bell 2000, p.57).

The reasons and patterns of non-medical use of pharmaceutical drugs at an individual level need to be understood in terms of the macro factors that may influence this trend, Thus:

Factors that may contribute to the growth of diverted pharmaceutical markets include: (1) a sizeable licit supply of prescription and controlled medications; (2) the routine prescription of benzodiazepines and opioids to alleviate drug-related symptoms, such as anxiety, insomnia or withdrawal for people who inject illicit drugs; (3) the inherent instability of illicit

<sup>130</sup> Submission of Mr John Galloway, Chief Pharmacist and Ms Mary Sharpe, Deputy Chief Pharmacist, Pharmaceutical Services Branch, Department of Health and Human Services, Tasmania, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

<sup>131</sup> Ms Sherry Green, Executive Director, National Alliance for Model State Drug Laws, Meeting with Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Washington DC, 26 July 2007.



drug markets, compared to the constant availability of pharmaceuticals; (4) the potential profits from selling prescription drugs because of their relatively low pharmacy dispensed cost; (5) the reduced legal risks in supplying and possessing prescription drugs compared to illicit drugs; and (6) the impact of new technology in facilitating prescription fraud (Topp 2006, p.6).

The demand for pharmaceutical drugs for illicit use is dynamic, varying from time to time and location to location. Fountain and colleagues (2000) describe such a phenomenon in their account of the London drug scene:

As the supply of diverted prescription drugs differs between markets, so does demand. In some markets, diverted prescription drugs are not a marketable commodity (Whynes et al., 1989), while others trade primarily in these substances (Edmunds et al., 1996; Fountain et al., 1996). Contradictory reasons for demand have been reported, and there have been calls for further research into this issue (Ruben & Morrison, 1992; Strang et al., 1993; Darke, 1994). Patterns of use of diverted prescription drugs range from regular and heavy use by polydrug using opiate addicts to occasional use by so called 'recreational' drug users. Purchases of diverted drugs are not necessarily made on a regular basis. The diverted drug can be a 'treat', for use as an experiment, or in an emergency such as buying oral methadone to avoid withdrawal symptoms when no heroin is available (Dale & Jones, 1992; Fountain et al., 1996). Thus the amounts of substances purchased from the illicit market vary from, for example, a single dose of methadone occasionally to 2 weeks' supply regularly, or from a couple of benzodiazepine tablets as a 'one-off' experiment to 20 tablets every day. Some buyers are discerning about the drugs they buy, others are less particular. In addition, an individual is likely to change his or her reasons for purchasing prescription drugs according to his or her current drug-using pattern, treatment status and financial situation (Fountain et al. 2000, p.398).

Factors such as the drug user's location are also relevant considerations. For example Dr Rodger Brough, a specialist drug and alcohol doctor working in rural Victoria, observed that:

My impression is that this issue assumes greater relative significance the further away from Melbourne you go...The explanation for this phenomena I suspect, relates to the fact that the further the users are away from Melbourne, the less viable it is for them to spend the time and effort travelling to and from Melbourne to buy heroin, particularly when they are at the end of that distribution chain, with [a] relatively 'poor quality' drug.<sup>132</sup>

Having given an overview of the general factors that may explain an individual's non-medical abuse of pharmaceutical drugs the following section will outline some more detailed and specific reasons for such abuse. These include but are not restricted to:

- Dependence occurring as a result of medical treatment (iatrogenic dependence);
- Self medication;
- Dealing with withdrawal symptoms;
- Drug substitution,
- Enhancement of other drug use;
- Use by clients in opiate treatment;
- Use as a currency by street users;
- Having a preference for pharmaceutical over street drugs; and
- Prescription drug use as 'recreational culture'.

Each of these factors is discussed briefly in turn.

<sup>132</sup> Submission of Dr Rodger Brough, WRAD Centre in Warrnambool, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

### *Iatrogenic dependence*

People might seek pharmaceutical narcotics and benzodiazepines because they have become dependent on a drug they were prescribed through their treatment for a previous or continuing medical condition. A good example of this is chronic pain patients who may become opioid dependent as a result of long periods of consuming prescribed or over-the-counter analgesics. Another example is long-term users of benzodiazepines. As noted by the support agency TRANX in their submission to the Inquiry, it has been known for many years that use of benzodiazepines at the appropriate prescribed dose for more than a few weeks can result in a dependence syndrome and serious physical complications associated with withdrawal.<sup>133</sup>

Abuse of prescription drugs as a result of iatrogenic treatment is a serious and to a certain extent unrecognised problem according to Mr Keith Evans, Chief Executive Officer of Drug and Alcohol Services of South Australia. He told the Committee:

The worldwide explosion – we see it here, you see it in Victoria – over the last five years in particular has been in what is called iatrogenic treatment. In other words, what has happened is that a practitioner has treated somebody and created a dependence, rather than a person is out on the street becoming dependent by accessing drugs through illegal means, and that is the largest single area of growth. It is the pain management, it is the attempt to deal with a person's pain, and creating dependence as a by-product of that.

I am a clinician who worked in treatment, and the biggest problem we then have is that it is much easier to treat somebody who is street-dependent on heroin than somebody who has become dependent for a pain that is very hard to identify – the pain is there but you cannot go in and see where it is – and has become tolerant to enormously high doses. That is the other thing: people's jaws drop open at the levels of prescription that are occurring, but often it is the case that it requires that amount to actually manage the pain for that individual but they are extraordinarily difficult. They become very aggressive; they are not receiving the drug of choice from the practitioner of choice. They are...extraordinarily complex and difficult people to manage.<sup>134</sup>

Certainly it is the view of Mr Peter Halstead, Registrar of the South Australian Pharmacy Board, that many patients will initially have legitimate reasons for seeking pain relief medications and only later will manipulate the system to support a dependency on these drugs.<sup>135</sup> Such a view is supported by the research literature that analyses the 'pathways to addiction' for prescription drugs. According to one recent American study the two most common pathways are through recreational drug abuse but more frequently through iatrogenic treatment or seeking relief for painful conditions and illnesses:

This outcome was echoed by our key informants. The physical pain pathway included physician prescriptions for physical pain or self medication for pain. Legitimate prescriptions of opioid analgesics...were used to 'treat' pain. Our key informants suggested that addiction developed over time when 'reasonable use' progressed to excessive or maladaptive use (Leukefeld et al 2007, p.517).

Many iatrogenic patients can develop complex and difficult problems associated with their drug seeking, as noted in a case study provided in a submission from the Interhospital Liaison Group, Southern Health, Dandenong Hospital:

A 59 year old lady presented to hospital for management anaemia. She was living alone, at home, having separated from her husband and was estranged from her children. She was

133 Submission of Ms Gwenda Cannard, Director, TRANX (Tranquilliser Recovery and New Existence) Inc., to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006. TRANX has since had its name changed to ReConnexion.

134 Mr Keith Evans, CEO, Drugs and Alcohol Services, South Australia, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Adelaide, 18 May 2007.

135 See comments of Mr Peter Halstead, Registrar, Pharmacy Board of South Australia, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Adelaide, 18 May 2007.



unemployed. Over the previous 3 months, she had become increasingly short of breath, had reduced exercise tolerance and had multiple episodes of hyperventilation, anxiety and tremulousness. She was found to have a low haemoglobin but when she presented for further investigations, she was found to be too intoxicated with alcohol for a gastroscopy to be performed safely.

She had a past history of: falls resulting in fractures to her left arm; suicide attempts by overdose; and social isolation. She had developed a significant alcohol dependence which she described as a response to receiving inadequate benzodiazepine dosage. A history of chronic benzodiazepine dependence emerged. She had first been prescribed barbiturates when 14 years of age, in response to symptoms of agoraphobia. Subsequently, she had used benzodiazepines continually, escalating in doses up to 24mg of alprazolam per day (equivalent to 240mg diazepam per day). When her doses were reduced, she described increasing social dysfunction and limitation of daily activities due to anxiety. She had developed a significant pattern of helpless and hopeless psychological themes and fitted into the diagnostic criteria for borderline personality disorder. There had been multiple instances where clinicians had refused to prescribe her high doses and she had experienced prolonged withdrawals. She described frequenting up to 7 General Practitioners concurrently to gain a supply of benzodiazepines. Her dissatisfaction with treatment and ongoing poor response to medications resulted in her drinking heavily for 4 years. She attended a residential detox unit for alcohol dependence but started drinking soon after leaving there.<sup>136</sup>

According to Ms Bev McIlroy, a drug and alcohol worker from south-west Victoria, one of the major problems with iatrogenic dependency is that doctors do not fully explain to patients legitimately seeking relief from pain the possible or potential consequences of taking strong analgesics at the time they are initially prescribed:

Iatrogenic dependency is something that I specifically would like to talk about, and we have a lot of experience of that...This really is a bugbear of mine and, being my age and being in the nursing profession for 35 years, you see how it has evolved. I was around in the days when Valium was introduced as a drug for Parkinson's et cetera; fantastic drug, no dependency et cetera. Well, here we are today and, in our perspective and from a treatment modality, from our point of view, it is one of the most significantly difficult drugs of dependency to deal with...People have no concept of tolerance; they have no concept of dependency. I am talking about people who are prescribed opiates for chronic pain, and benzos for whatever reason – from the young mothers through to the older baby-boomer generation that is taking their drug-taking habits into their old age...Those people are not exposed to education around tolerance and dependency and, if we could just do that, if doctors across the board had an understanding – I know they have an understanding of both of those characteristics, but they have to take the time or have someone take the time to explain them to the clients. The therapeutic value of these drugs has no relationship whatsoever to the prescribing habits.

[As a result] one of our biggest barriers is the fear associated with both benzos and prescribed opiates: the fear that someone is going to stop them using them [benzodiazepines and prescribed opiates], [the use of] which is happening quite legitimately at the moment. The fear is the major barrier to change, absolute fear, particularly with those two drugs: legally prescribed, medically required in the first instance, but managed very poorly. If I got on a soapbox about this stuff, it is the iatrogenic stuff that we would make a difference to.<sup>137</sup>

136 Submission of the Interhospital Liaison Group, Southern Health, Dandenong Hospital, Melbourne, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

137 Ms Bev McIlroy, Service Manager, Glenelg and Southern Grampians Drug Treatment Service, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Warrambbool, 29 May 2007. Dr Malcolm Hogg expressed similar concerns as to whether patients receiving pain relieving drugs whilst in hospital were sufficiently advised as to the potential problems with dependency and tolerance to the drugs administered (see Evidence of Dr Malcolm Hogg, Australian Pain Society, Australian and New Zealand College of Anaesthetists, Melbourne Health, given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007).

### *Self harm and suicidal ideation*

An account of people, predominantly women, who may use prescription drugs in an attempt to end their own lives has already been given in Chapter 2.2. This was in the context of research conducted on prescription drug abuse in the north-east Melbourne municipalities of Moreland and Darebin. During the course of that research it was found that:

Despite the taboo topic of drug overdose, and community silence on suicidal ideation, the researcher was able to make contact with a number of women who had overdosed on medications. The common themes for the majority of women contacted were a history of sexual abuse and/or family violence.<sup>138</sup>

In particular, women subject to depression and anxiety for whom benzodiazepines had been prescribed did not necessarily understand that the effect of such medications could be to exacerbate rather than relieve their illnesses:

This is not always clear to the people taking the medications, who often feel that the rise in anxiety and depression is symptomatic of their own inability to cope and not an impact of the medication itself...<sup>139</sup>

This could result in a dangerous cycle whereby long-term prescribing to alleviate problems associated with illnesses such as depression could eventually lead to patterns of suicidal ideation. Whilst such localised research is not necessarily indicative of a more widespread connection between (long-term) prescribing of benzodiazepines and suicide attempts, it is an issue that could certainly be the subject of further and more generalised research.

### *Self-medication*

People can seek pharmaceutical drugs, especially benzodiazepines and narcotic analgesics, in order to quell the pain of previous physical or emotional trauma, or treatment of an underlying drug dependency problem. With regards to the latter, Fountain and colleagues (2000) observe:

It has been suggested that some of those buying diverted prescription drugs – particularly methadone – are engaged in self treatment (Langrod, Galanter & Lowinson 1974; Spunt et al., 1986; Gossop, Battersby & Strang 1991; Dale & Jones 1992), and that the benefits of prescription drugs are therefore reaching an out-of-treatment population. However, 'self-treatment' suggests that users are mimicking the therapeutically based decisions of treatment agencies. The combinations and supratherapeutic amounts of drugs used by some who buy prescription drugs on the illicit market are not generally purchased with such therapeutic objectives, and would not be available to them in these forms and doses via legitimate treatment sources (Ruben & Morrison 1992; Seivewright & Dougal, 1993; Strang et al., 1993). Nevertheless, some users of diverted prescription drugs have assimilated the harm reduction advice emanating from drug treatment services and disseminated by the drug users' grapevine. Ironically, the knowledge that illicit drugs and injecting are dangerous probably increases the demand for the 'safer' prescription drugs for injection (Edmunds et al., 1996; Fountain et al., 1996), even though there may be additional dangers from the crushing and injecting of tablets meant only for oral use (Strang et al., 1998; Department of Health 1999) (Fountain et al 2000, p.398).

The research conducted into prescription drug abuse by people within the Darebin and Moreland communities referred to above also indicates that for many people, particularly women, benzodiazepines were indeed a major coping mechanism for dealing with pain and trauma:

138 Submission of Darebin City Council to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

139 Submission of Darebin City Council to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.



The overwhelming reasons indicated for women using benzodiazepines – in conjunction with alcohol or marijuana – was to avoid flashbacks from childhood sexual abuse, and adult pain from domestic violence:

“My own use of sleeping pills increased over a period of time because I became dependent on them to actually get to sleep. The same applied to antidepressants. My alcohol intake increased from the age of 14 up until I was 39 years old. This was due to: sexual abuse as a child; an abusive relationship; divorce; being a sole parent; often not coping with life in general. The tablets and alcohol were used to block out the hurt” – Participant in research discussion group.<sup>140</sup>

In the context of young people, the Youth Substance Abuse Service (YSAS) addressed the issue of drug seeking in order to deal with past emotional trauma in their submission to the Inquiry:

The ‘typical’ young person accessing the services provided by YSAS has experienced multiple adverse events in his or her life, apart from and preceding those associated with their alcohol and/or drug use. The majority of these young people have experienced significant levels of trauma and abuse during their childhood and adolescence. Children who have been exposed to overwhelmingly negative early life experiences suffer from a ‘re-setting’ of their arousal baseline, so that even when no threat is present they remain in a state of physiological alarm. This makes them more ‘reactive’, increasing the likelihood they will be pushed into a state of terror by quite minor stressors. These changes in arousal levels as a result of abuse and neglect play a major role in the behavioural problems associated with such young people. For these young people drugs provide an escape from unbearable feelings.<sup>141</sup>

An example of people using diverted pharmaceutical drugs to treat their own dependency problem was given by the Western Region Health Centre’s submission to the Inquiry:

[Benzodiazepines are]...commonly used by people who inject drugs as a way to self-manage a home-detoxification. Pharmaceuticals required for detox management may be acquired through the ‘black market’ or through consultation with a GP. Many people will prefer to access benzodiazepines for a home detox through the ‘black market’ for fear of discrimination and judgement from a GP, fear of being seen (and recorded by the Government) as a ‘doctor shopper’ and the ramifications of such. It must be remembered that relapse is not uncommon for a person who has been injecting drugs. This practice of self managed home detox ensures privacy for the person/s concerned.<sup>142</sup>

### *Dealing with withdrawal symptoms*

Benzodiazepines have long been used by heroin users to help manage the discomfort of opiate withdrawal. This is also described in the submission to the Inquiry by the Western Region Health Centre:

Benzodiazepines alleviate some withdrawal symptoms including insomnia and anxiety. Due to the difficulties in maintaining a consistent heroin supply, heroin withdrawal can be a regular occurrence. Therefore many people are using benzodiazepines frequently to maintain a level of drug intoxication and to prevent drug withdrawal. In these circumstances, people are topping up with benzodiazepines whenever they are having trouble accessing heroin.<sup>143</sup>

140 Cited in Submission of Darebin City Council to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

141 Submission of the Youth Substance Abuse Service (YSAS) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

142 Submission of the Western Region Health Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

143 Submission of the Western Region Health Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

### *Drug substitution*

When there are longer-term declines in the market availability of a drug, such as happened with the so-called 'heroin drought' in Australia, there can be a more large-scale and sustained shift toward substitution of pharmaceutical drugs. For example, subsequent to the onset of Australia's 'heroin drought', there was a dramatic increase in benzodiazepine use by injecting drug users surveyed as part of the Illicit Drug Reporting System (IDRS), and a spike in temazepam gel capsule prescriptions (Degenhardt et al 2005).<sup>144</sup>

The change in the Victorian drug market and the increased use of benzodiazepines is reflected in the YSAS submission to the Inquiry:

Use of benzodiazepines has increased as access to heroin has declined. There are very few pure heroin users now although that is the preferred drug. The opiate dependents use either a mix of non-prescribed buprenorphine in conjunction with benzodiazepines or prescribed methadone with benzodiazepines.<sup>145</sup>

### *Enhancement of other drug use*

Drug users often use pharmaceuticals to increase the effects of other drugs that they are taking, as Dr Mike McDonough, Western Hospital, described clearly in evidence to the Inquiry:

In particular, we know heroin users commonly use benzodiazepines in conjunction with their heroin use and sometimes inject or take benzodiazepines orally around the time of injection. This is generally to augment or facilitate or increase the opiate effect – "increase the rush", or the pleasurable effect – of the drugs. If you have been tolerant and you are dependent on a drug for a long period of time and the street purity is fluctuating a lot, another way you can boost the effect is take another drug that helps facilitate or augment the effects of the drug that you are taking. That is a common reason that heroin addicts go for benzodiazepines and they are easily available, certainly under Medicare. You can go to the local doctor and get a PBS [Pharmaceutical Benefit Scheme] prescription and it does not cost you much money, so comparative to illicit drugs they are very easily available.<sup>146</sup>

### *Use of benzodiazepines and other pharmaceutical drugs by opioid treatment clients*

Opiate dependent clients undergoing pharmacological treatment with methadone, buprenorphine, naltrexone or other medications sometimes use benzodiazepines or other pharmaceutical drugs in order to get intoxicated.

Methadone, which is used for the treatment of opiate dependence, works by flooding the opioid receptor cells in the patient's brains with a long-acting opioid. After a stable dose is reached the patient becomes tolerant to the intoxicating effect. This tolerance means they are effectively unable to get high on heroin or other opioids. This is referred to as the 'blockade' effect of methadone. As a consequence these clients must use non-opioid drugs such as benzodiazepines to get intoxicated. Consequently, some methadone clients have long been known to have high rates of current benzodiazepine use. For example Darke et al (1993) found 37 per cent of methadone maintenance clients reported benzodiazepine use in the previous month, with 11 per cent of clients using five or more pills per day. Furthermore, Swensen et al (1993) found rates of benzodiazepine use were higher for those on higher doses of methadone, yet other opioid use was higher among those at lower doses of methadone. This was presumably because at higher doses clients could not get intoxicated on opioids due to the 'blockade effect' of a high methadone dose, but could get

144 Australian research has shown that although this phenomenon was evident in Victoria it was not as noticeable in other jurisdictions (Degenhardt et al 2005).

145 Quote from Youth Substance Abuse Service Outreach Manager in a submission of the Youth Substance Abuse Service to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

146 Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 20 June 2006.



'high' on benzodiazepines. Patients on lower methadone doses, however, could still get intoxicated by taking heroin or other opioids in addition to their methadone dose. More recently, reviews of research on patients in methadone maintenance programmes reported current use of benzodiazepines ranging from 10.5 to 70.4 per cent (Weizman et al 2002).

A submission from the Western Region Health Centre described this use of benzodiazepines by treatment clients as follows:

A significant number of people on pharmacotherapies (opiate substitution therapy i.e. methadone) also take benzodiazepines. Once stable on a pharmacotherapy program the person isn't getting the sedated effect from heroin anymore, and may want to abstain from using heroin, but still psychologically seeks some form of sedation. For some people, using benzodiazepines is a way of getting intoxicated without using heroin.<sup>147</sup>

Buprenorphine has a greater affinity for the (Mu) opiate receptors in the brain than does the naltrexone molecule (Law et al 2004). Naltrexone is used as a blocking agent to prevent opioids having an effect. As a result, it appears that people on naltrexone can become intoxicated on buprenorphine, whilst they cannot on other opioids such as heroin. Consequently there have been anecdotal reports of diverted buprenorphine being used by naltrexone patients to get intoxicated.<sup>148</sup>

#### *Use as a currency by street and other users*

One of the reasons people seek pharmaceutical drugs is to sell them or trade them on the illicit market. Someone accessing prescription medicine on the pharmaceutical benefits scheme, or even a private prescription, can make a substantial sum selling his or her medicine. The Registrar of the Pharmacy Board of Victoria explained this when he gave evidence to the Inquiry:

The trouble is that morphine is worth about \$1 a milligram on the street at the moment. That means sustained release morphine tablets of 60 milligrams, a packet of 20, would be worth \$1,200, yet [people] might obtain this for \$3.70 because most of them have a pension card, so there is a big profit incentive...[People] from Horsham are alleged to go to Ballarat to see medical practitioners there, have them dispensed in Ballarat, [and] take them back to sell in Horsham.<sup>149</sup>

Some alcoholic patients who are often prescribed benzodiazepines to aid with sleep and withdrawal problems are also known to sell their medications to others in order to buy alcohol (Fountain et al 2000). For example:

We have had anecdotal reports of 'alcoholic' patients selling diazepam to get money to buy alcohol.<sup>150</sup>

Examples have been given from the United States where elderly people have either pocketed their legitimately prescribed medication or accessed prescriptions through exaggerating their symptoms and then traded the drugs for profit in order to supplement their income. One recent American study, for example, quotes a law enforcement official as follows:

Some of the biggest people selling are the 50, 60 70 year old people that are obtaining the prescriptions every month legally...these people can go to physicians get their Oxy [OxyContin®] like they should, they can then sell the prescriptions of 90 OC 80s

147 Submission of the Western Region Health Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

148 Personal communication to the consultant from Dr Noel Plumley, Senior Medical Officer, Drug and Alcohol Office, Department of Health, Western Australia, 28 July 2006.

149 Mr Steve Marty, Registrar, Pharmacy Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 19 June 2006.

150 Submission of Dr Rodger Brough, WRAD Centre in Warrnambool, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

[OxyContin®] and sell 'em to one person and make \$5000.00 cash (Leukefeld et al 2007, p.511).<sup>151</sup>

Even more alarming in some respects are anecdotal accounts of terminally ill patients trading their legitimately prescribed pain relief. Dr Mike McDonough, Western Hospital, testified to this phenomenon when he gave evidence to the Committee:

There is a problem, albeit very uncommon, but it is sad to say that some cancer patients have been found to be sources of diverted drugs. That is, they have perhaps sold and made some money from having been supplied more than perhaps they needed. There may have even been cases when there has been a death within a family, with the cancer patient leaving behind large quantities of narcotics [and someone has traded or on-sold these drugs]. So with patients who are in the pain management care of an oncologist, sometimes the way they manage their medication may need to be monitored very carefully.<sup>152</sup>

### *A preference for pharmaceutical over illicit street drugs*

It is not hard to imagine why some users would prefer pharmaceutical drugs rather than illicit drugs bought on the street.

The impurity and cost of illicit drugs means that some prefer prescription drugs to obtain these effects (Fountain et al. 1996). It has been suggested that benzodiazepines and buprenorphine (Temgesic) are consequently taking the place of heroin as the preferred drug (Sakol, Stark & Sykes 1989; Hammersley, Lavelle & Forsyth 1990; Klee et al. 1990). An additional significant attraction of prescription drugs to the purchaser is that they are manufactured in standard doses and are recognizable (Fountain et al. 2000, p.399).

Topp states that there are a number of factors that have contributed to the growth in diverted pharmaceutical markets. These include:

- A sizeable licit supply of prescription and controlled medications;
- The routine prescription of benzodiazepines and opioids to alleviate drug-related symptoms, such as anxiety, insomnia or withdrawal for people who inject illicit drugs;
- The inherent instability of illicit drug markets compared to the constant availability of pharmaceuticals;
- The potential profits from selling prescription drugs because of their relatively low pharmacy dispensed cost;
- The reduced legal risks in supplying and possessing prescription drugs compared to illicit drugs<sup>153</sup>; and
- The impact of new technology in facilitating [prescription fraud] (Topp 2006, p.6).

A reason for preferring *diverted* pharmaceuticals rather than getting them legitimately on prescription can be a desire to keep one's distance from the official treatment system, as explained by Fountain and colleagues (2000):

There are several reasons why those who are drug-dependent and buy diverted prescription drugs do not arrange their own prescriptions, including an unwillingness – especially of women with children – to submit to official attention, and that previous treatment episodes have left them disillusioned with services (McKeganey 1988; Sheehan, Oppenheimer & Taylor 1988; Stimson et al. 1995; Department of Health 1996; Powis et al., 1996) (Fountain et al 2000, p.398).

151 This point was reinforced to the Committee when it met with Dr Carl Leukefeld, one of the co-authors of this study, in Frankfort, Kentucky in August 2007.

152 Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 13 July 2006.

153 As a representative of the South Australian Police Service told the Committee in Adelaide in May 2007: 'If someone is using [illicit drugs] you know they are committing a criminal offence. If someone is misusing [pharmaceutical drugs], they may not be committing a criminal offence. That's the difference' (Superintendent Paul Dixon, Drugs Unit, South Australia Police Service, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Adelaide, 18 May 2007).



Anecdotal evidence also suggests that among certain groups in the population, particularly women, reliance on prescription drugs may have less 'stigma' attached to it than dependence on other (illicit) drugs. If such drugs are legal and particularly if they come from a legitimate source such as a general practitioner then *ipso facto* the 'respectable' people who use them cannot be 'drug addicts'. For some people this may be the self-justification for the use and abuse of these drugs.<sup>154</sup> In evidence to the Inquiry a representative of the Victorian Interhospital Liaison Group confirmed this and explained the difficulty such a belief or attitude creates in terms of treatment:

One of the issues that we see, particularly in the hospitals and it is reflected in the treatment services, is that it is across all socioeconomic strata. It is not just typical drug users. In fact, they are probably easier to treat. It is the middle-class, middle-age women who come in with benzo abuse and trying to help them see that they have a problem – they usually hang on to, 'But my doctor gave them to me' – that they are in fact addicted, and how you treat them becomes problematic because they are from a different mindset.<sup>155</sup>

Users of pharmaceutical drugs are also less likely to be subject to police attention and if a person does have prescription drugs in their possession<sup>156</sup> it may not be entirely clear to a police officer whether that person is breaking the law in doing so. Related to this, Fountain and colleagues (2000) noted:

The legality of ownership of prescription drugs facilitates the operation of market-places where they are traded. Potential buyers and sellers can linger with impunity until the point of sale. It has been reported that the police rarely discover diverted prescription drugs because distribution is contained within networks of drug users trading in personal prescriptions (Parker & Kirby, 1996) (Fountain et al 2000, p.395).

### *Prescription drug use as recreational culture*

#### **'Pharming Parties' – New youth drug use phenomenon or media beat-up?**

Drug use or abuse as part of a cultural or tribal phenomenon is well established (Moore 2002; Measham, Aldridge & Parker 2001, Drugs and Crime Prevention Committee 2004, 2006). Whether this pertains to the injection of heroin on the street, the consumption of alcohol on Friday night as a post-work relaxant, or the ingestion of ecstasy at raves and dance parties, the setting or context of drug use is as important as the drug itself (Zinberg 1984).

Bearing this in mind, claims of a relatively new phenomenon of pharmaceutical drug use by young people have appeared in the popular press in the United States. So-called 'pharming parties' are described as:

...get-togethers where prescription drugs are exchanged. These parties, while not necessarily devoted to illegal substances, are meeting places to use prescription drugs in order to become intoxicated. Such parties are generally an abuse of prescription medication, especially when involving teenagers, who often participate.

Analgesics (such as OxyContin or Vicodin), anti anxiety medicines (Valium or Xanax), or attention-deficit disorder drugs (Ritalin or Adderall) are common fare. While improper use of pain medication is dangerous, such drugs are highly prized for the level of intoxication they provide. Pills are generally acquired via online pharmacies, which don't require prescriptions. As well, participants will use legitimately prescribed medication (and may feign or exaggerate symptoms in order to be given further prescriptions); trading does occur, however (Wikipedia – the online Encyclopaedia, accessed 29 July 2006).

154 See for example, discussion in the submission of TRANX to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

155 Ms Ros Burnett, Interhospital Liaison Group, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 19 June 2006.

156 For a discussion of the law with regard to (pharmaceutical) drugs, see Chapter 3.2.

However, other media sources have questioned the extent, or existence, of the phenomenon. Online United States media critic Jack Shafer, on his website 'Slate', did an extensive piece on the media coverage. This is summarised below from the 'Join Together' site:

Media reports about parties where youths throw various prescription pills into a bowl at parties first surfaced in 2002, and were echoed in 2003 in a newsletter from the federal Center for Substance Abuse Prevention. More recently, USA Today reported that addiction counselors are "beginning to hear about similar pill-popping parties, which are part of a rapidly developing underground culture that surrounds the rising abuse of prescription drugs by teens and young adults".

But Shafer said the original story quoted no teens or other witnesses to these alleged parties, and said most subsequent stories either relied on anecdotes or were based on earlier reports. National Center on Addiction and Substance Abuse (CASA) chairman Joseph A. Califano Jr. also referenced pharming parties in 2005, when he released a report called, "Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S.". But Shafer said that CASA officials told him that Califano was not citing any research.

"CASA does not have quantitative data on the subject of pharming parties; however, we know that the trend exists based on focus groups we have conducted with teens and young adults for various CASA reports where we talk with them about prescription drugs at parties and this is the basis of Mr. Califano's quote", said CASA spokesperson Lauren Duran (Join Together 2006, accessed 21 July 2006).

The Committee received evidence about the phenomenon of pharming parties when it visited North America in July/August 2007. Drug and alcohol experts confirmed that these gatherings were certainly taking place, but according to Mr Michael Cunningham, Deputy Director of California's Department of Alcohol and Drug Programs:

[f]rankly ...we don't have a lot of firm hard core data which shows the extent to which they [pharming parties] are taking place and we don't have any real information which verifies that as a result of pharming x amount of overdoses, or x amount of deaths [have occurred]; right now it tends to be just anecdotal information.<sup>157</sup>

Representatives of the National Institute on Drug Abuse (NIDA) also told the Committee that whilst 'there isn't a lot of scientific evidence about valium parties, there's a boat load of [them] going on. There's no doubt about that'.<sup>158</sup>

Certainly pharming parties are relatively common among teenagers in Kentucky according to Dave Sallenges of Kentucky's Drug Enforcement Branch:

There is a phenomenon which is going on in the USA right now called pharming parties...it's a big problem with teenagers, they take bags of miscellaneous drugs, they call it trail mix<sup>159</sup> because of the appearance, they get these drugs out of their parents' medicine cabinets at home, they call that pharming where they go into the medicine cabinet, they get the pills out, take them to these parties, throw them in the bowl...

Another trick teenagers are picking up on, they mix an ounce of [codeine based cough syrup] with sports drinks and throw in a Jolly Rancher candy which I suppose makes it fizz or

157 Mr Michael Cunningham, Chief Deputy Director, California Department of Alcohol and Drug Programs, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Sacramento, 2 August 2007.

158 Representative of the National Institute on Drug Abuse, Meeting with Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Washington DC, 30 July 2007.

159 For an account of how the Internet can be used to download 'recipes' for the 'trail mix', see Chapter 5.3 of this Report.



something and then pour it over ice and they drink this stuff and the codeine causes them to get high...In the suburbs, primarily Louisville, we're seeing a big problem with this.<sup>160</sup>

At this stage, it is probably too early to say whether 'pharming parties' are a 'real' cultural phenomenon among young people or, at least partly, a case of media embellishment. An anecdotal look on a popular online drug user forum, frequented by Australian drug users, only found reference to the United States media stories. Nonetheless, American cultural trends and practices, particularly among youth, eventually seem to be adopted to greater or lesser degrees in this country.

## Patterns of use among recent Victorian injecting drug users

One of the best sources of data on patterns of use of benzodiazepines and pharmaceutical opioids by injecting drug users in Australia is the IDRS. Although the IDRS is limited in this regard, as noted in Chapter 2.1, as its surveys of users are limited to quantitative data, some qualitative accounts are provided in interviews with key informants.<sup>161</sup>

### *Benzodiazepines*

With regards to patterns of benzodiazepine use in Victoria, Jenkinson and O'Keefe (2006) found that the majority of key informants in 2005 noted a reduction in the injection of these drugs, with most use being oral. Whilst many informants believed that users were increasingly aware of the dangers of injecting benzodiazepines as a consequence of the substantial education programme, they also believed that between 10 and 50 per cent of the injecting drug users they had contact with were still using them intravenously. Key informants believed injecting drug users were using benzodiazepines to facilitate their abstinence from heroin, whilst others used them to 'economise' by substituting heroin with benzodiazepines to reduce their heroin intake. A number noted a continuing healthy 'street' trade and observed that clients continued to 'doctor-shop' to obtain benzodiazepines (Jenkinson & O'Keefe 2006, p.57). No data on the street price of benzodiazepines was reported.

### *Morphine*

Most of the 2005 IDRS sample preferred injection of morphine to the oral route, with 75 per cent reporting lifetime injection and 39 per cent reporting injecting it in the last six months. Frequency of use and injection of morphine had remained stable since the 2003 IDRS at five days in the last 180. Fifteen per cent of the 2005 IDRS sample (n=23) were able to comment on the price and availability of illicit morphine. Respondents reported that 100mg of morphine costs \$50 (range \$20–\$50); 100mg of illicit MS Contin® had been purchased for \$35–50 in the past six months, and 60mg for \$20–30. Fifty milligram of illicit Kapanol® had been purchased for between \$20 and \$50 with 20mg costing between \$10 and \$50 in that time. Most (65%) reported that the price had been stable in the past six months. Forty-eight per cent believed illicit morphine was 'difficult' to obtain, with the same percentage believing it was 'easy' to 'very easy' to obtain. Most obtained their illicit morphine from friends (65%) or a dealer's home (24%) (Jenkinson & O'Keefe 2006).

### *Oxycodone*

As noted in Chapter 2.1, in the 2005 IDRS, questions were asked about oxycodone for the first time. Some 17 per cent reported oxycodone use in the last six months with frequency of use appearing very low, typically being four days (out of 180) reported. OxyContin® was the main brand of oxycodone used in that period (Jenkinson & O'Keefe 2006).

<sup>160</sup> According to Mr Sallengs such practices have been popularised in rap songs of the late 1990s, where such mixtures have been referred to as 'Syrup', 'Sizzurp' and 'Purple Drank' (Mr Dave Sallengs, Manager, Drug Enforcement and Professional Practices Branch, Kentucky Cabinet for Health and Family Services, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Frankfort, Kentucky, 31 July 2007).

<sup>161</sup> See Chapter 2.1 of this Final Report for prevalence of use data in Australia and Victoria.

## Conclusion

Whilst there are little in-depth qualitative studies of non-medical users of pharmaceutical drugs, the literature reviewed above along with the submissions and other evidence provided to this Inquiry provides a sense of the reasons these drugs are used. They include: dependence occurring as a result of medical treatment (iatrogenic dependence); self medication; dealing with withdrawal symptoms; drug substitution, enhancement of other drug use; use by clients in opiate treatment; use as a currency by street users; and having a preference for pharmaceutical over street drugs.

The increasing media reports in the United States regarding 'pharming parties' by young people raise an issue that should be followed with interest.

Data from the IDRS indicates that whilst there have been changes in the way drugs such as benzodiazepines have been used, due to such things as the 'heroin drought' and the restrictions on the availability of temazepam in gel form, Victorian injectors continue to use benzodiazepines to deal with withdrawal or economise on their heroin use, as injectors have done for many years. Changes in the treatments available for opioid dependence have a flow-on effect on the availability of the drugs in the illicit market, as does the availability of drugs used to treat pain. As acknowledged by Jenkinson and O'Keefe (2006), the increase in non-medical use of pharmaceuticals in Victoria, as elsewhere, necessitates better research to guide prevention, policy and treatment responses.





## 2.4 Accessing Benzodiazepines and Opioid Analgesics: 'Doctor Shopping', Diversion and Other Illegitimate Means of Acquisition

### Introduction

People accessing pharmaceutical drugs such as benzodiazepines and narcotic analgesics for non-medical use do so in a variety of ways. These include 'doctor shopping' and theft, prescription pad fraud, theft and forgery, as well as accessing medications originally supplied legitimately to friends and family members. Illegitimate access through the Internet is also becoming a new avenue for procuring these drugs.<sup>162</sup>

In general it is difficult to know the extent of each of these methods in Australia or in Victoria, however there has been some research internationally which has tried to quantify this.

One example is the recent study of illicit opioid users in five Canadian cities (Haydon et al 2005), which found differences in the source of different prescription drugs used by this group. This is shown in Table 2.4a. Thus, benzodiazepines were most likely to be sourced from a friend (46.0%) or a doctor (31.9%), whilst OxyContin® was equally as likely to be sourced from a regular dealer (45.0%) or a friend (45.0%), followed by a doctor (40.0%). Other opioid medications were more likely to come from a friend (53.0%) or a regular dealer (42.5%).

**Table 2.4a: Source of selected prescription drugs among illicit opioid users recruited in five Canadian cities**

Drug	Regular Dealer % (count)	Irregular dealer % (count)	Doctor % (count)	Partner % (count)	Friend % (count)	Theft % (count)
Talwin & Ritalin	50.0 (21)	4.8 (2)	0	7.1 (3)	47.6 (20)	0
Benzodiazepines	8.8 (23)	16.5 (43)	27.6 (72)	3.5 (9)	46.0 (120)	0.4 (1)
Tylenol 3 or 4	12.5 (29)	15.5 (36)	31.9 (74)	3.5 (8)	36.9 (86)	0.4 (1)
Demerol	17.7 (6)	11.8 (4)	32.4 (11)	5.9 (2)	26.5 (9)	5.9 (2)
Dilaudid	37.3 (88)	14.0 (33)	8.1 (19)	3.8 (9)	42.0 (99)	0.9 (2)
Percocet/Percodan	40.9 (45)	19.1 (21)	36.4 (40)	4.5 (5)	56.4 (62)	1.8 (2)
OxyContin	45.0 (9)	20.0 (4)	40.0 (8)	15.0 (3)	45.0 (9)	0
Other opioid prescriptions*	42.5 (85)	20.5 (41)	26.0 (52)	5.0 (10)	53.0 (106)	1.5 (3)

Notes: \* e.g. morphine, codeine other than Tylenol 3 or 4, etc.

- Percentages can add up to more than 100%, indicating multiple sources of drug access.

Source: Haydon et al 2005, p.460.



**'Doctor shopping'**<sup>163</sup>

[How many doctors did I go to?] Gosh! Four a day at least. It was like I had a full-time job – 24 hours a day, seven days a week of going through the Yellow Pages. I lived out at [Eastern Suburbs] at the time and I would go as far as [Northern and Southern Suburbs]. I spread out as far as I could go and then I would repeat some sort of format to go back to those doctors and around again and again. Sometimes they would question me, and that is when you become very fearful. Once you have been caught out, it becomes terrifying: (a) you are not going to get the medication and (b) it is very confronting.<sup>164</sup>

'Doctor shopping' involves patients attending several doctors in order to obtain several prescriptions for controlled drugs so as to get a quantity of drugs greater than their therapeutic needs, which are then used for personal consumption or sold on the street market (National Center on Addiction and Substance Abuse (CASA) 2005; Pradel et al 2004).<sup>165</sup> This phenomenon is not limited to patients seeking drugs from general practitioners (GPs), as patients also attend accident and emergency departments of hospitals seeking drugs (McNabb et al 2006). There is also a smaller but nonetheless significant problem associated with people seeking to illegitimately obtain prescription drugs from dentists and other allied health professionals.<sup>166</sup>

In a qualitative study of London drug users in treatment (Fountain et al 1998) one respondent was asked what was the most prescriptions they had ever held at one time:

From four doctors: two private, one GP [general practitioner] that I was getting methadone from, and one ordinary GP, and that was for Valium and temazepam. The rest was all sorta Class A drugs. But that's a lot for one person – getting four pretty big scripts – it's a lot. You think of every addict that could do that – that's a lot of drugs (Fountain et al 1998, p.161).

**Evidence of 'doctor shopping' in Australia**

In Australia in 1997 the Health Insurance Commission (HIC), now Medicare Australia, instituted the Doctor Shopping Program in order to: (i) reduce the level of pharmaceutical misuse and thus improve the health outcomes of 'doctor shoppers'; (ii) reduce unnecessary and inappropriate medical appointments and prescriptions; and (iii) refer matters for investigation where criminal activity is involved (Australian Centre for Policing Research 2002).<sup>167</sup> In his evidence to this Inquiry Dr Malcolm Dobbin of the Victorian Drugs and Poisons Unit (DPU) explained the criteria for classifying 'doctor shoppers':

They [HIC/Medicare Australia] defined doctor shoppers as those people who saw 15 or more GPs in a year, had 30 or more Medicare consultations and appeared to obtain more PBS [Pharmaceutical Benefits Scheme] drugs than clinically necessary.<sup>168</sup>

<sup>163</sup> This section should be read in conjunction with the discussion in Section Four of this Report on how 'doctor shopping' could be addressed through prescription drug monitoring programmes.

<sup>164</sup> 'Mary', Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 20 June 2006. The name and residential location of the person who gave evidence have been changed to protect her anonymity.

<sup>165</sup> Doctor shopping is sometimes known as 'multiple scripting'. See Fountain et al 1998.

<sup>166</sup> See comments of Mr Keith Evans, Chief Executive Officer, Drug and Alcohol Services, South Australia, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Adelaide, 18 May 2007.

With regard to other health professionals, the Australian Medical Association (AMA) (Victoria) has expressed concern that the extension of prescribing rights to podiatrists may increase the amount of 'doctor shopping' taking place and that safeguards already in place to address 'doctor shopping', such as Medicare Australia's Prescription Shopping Program, will not apply to podiatrists (Submission of AMA (Victoria) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007). For further discussion of the Medicare Australia's Prescription Shopping Program, see Chapter 4.2. For further discussion on the extension of prescribing rights to podiatrists in Victoria, see Chapter 5.1.

<sup>167</sup> This programme now termed the Prescription Shopping Program under Medicare Australia and other 'doctor shopping' monitoring programmes at local and international level will be discussed at length in Section Four of this Report.

<sup>168</sup> Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, Department of Human Services, Briefing given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 29 May 2006.

Turning Point Alcohol and Drug Centre stated, however, that such a definition is problematic:

[b]ecause [the definition of] 'doctor-shoppers' excludes people who attend fewer than 15 doctors or fewer than 30 Medicare consultations, attendances of those who use a false identity or Medicare card, or obtain private prescriptions (non-PBS or RPBS [Repatriation Pharmaceutical Benefits Scheme] subsidised)....Consequently these figures may underestimate the true prevalence of acquisition of these drugs for non-medical purposes.<sup>169</sup>

As such, the statistics on 'doctor shopping' given below might be an underestimation.

The Committee acknowledges technical definitions of 'doctor shopping' such as that provided by Medicare Australia. Nonetheless, the Committee believes that the term 'doctor shopping' can be confusing. For example, it may give the erroneous impression that a patient is excluded from receiving general medical treatment from one or more doctors. Clearly patients have the right to consult a medical professional of their choice and change that doctor as they see fit. Whilst this Report does use the term 'doctor shopping' where the context requires, in most circumstances the term 'prescription shopping' is preferable.

In 1997, Australia-wide, there were 1,270 doctor shoppers per 1,000 GPs and in Victoria there were 1,447 per 1,000. Prescriptions filled by 'doctor shoppers' nationally included 59 per cent for psychotropic drugs of misuse including benzodiazepines (35%), codeine compounds (15%) and narcotic analgesics, with the remainder being medicines for other conditions, many of which appeared to be obtained on the Pharmaceutical Benefits Scheme (PBS) and then taken overseas for relatives or for sale.<sup>170</sup>

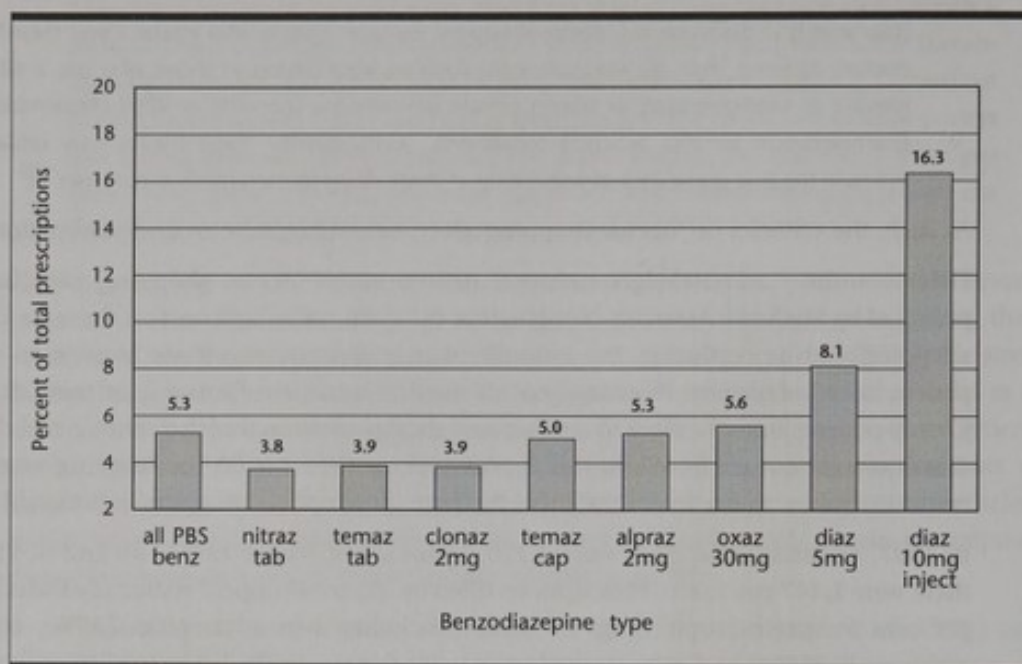
Dr. Malcolm Dobbin found that the percentage of prescriptions for benzodiazepines dispensed under the PBS, which had been obtained by the 'doctor shoppers' identified under the HIC's programme, was considerable (see Figure 2.4a).

<sup>169</sup> Submission of Turning Point Alcohol and Drug Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

<sup>170</sup> Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, Department of Human Services, Briefing given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 29 May 2006.



**Figure 2.4a: Per cent of total PBS benzodiazepine prescriptions obtained by 'doctor shoppers' in Australia, 2000**



Notes: all PBS benz = all benzodiazepines available on the Pharmaceutical Benefits Scheme  
 nitraz tab = nitrazepam tablets  
 temaz tab = temazepam tablets  
 clonaz = clonazepam  
 temaz cap = temazepam capsules  
 alpraz = alprazolam  
 oxaz = oxazepam  
 diaz = diazepam

Source: Extracted from presentation made by Dr Malcolm Dobbin to the Dugs and Crime Prevention Committee, Briefing, 29 May 2006.

Dr Malcolm Dobbin remarked to the Committee:

It is alarming. I was totally alarmed, but then when I looked at the figures for opioids I was even more alarmed. I find it astounding that this proportion of PBS drugs could be obtained by this small group of drug-seeking patients.<sup>171</sup>

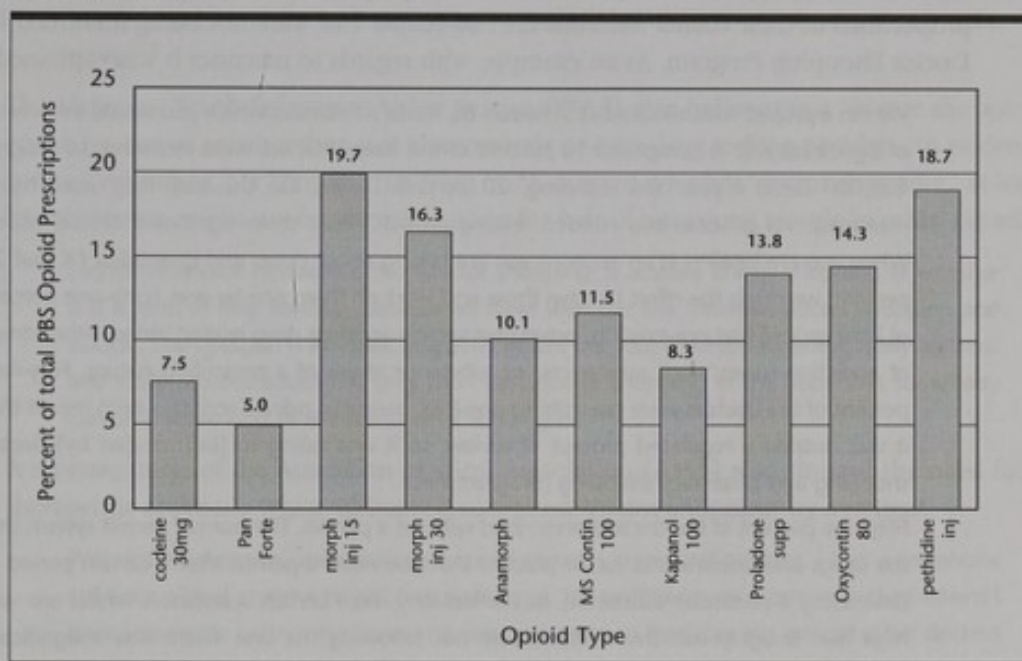
Referring to the data provided in Figure 2.4b below he noted:

You can see the morphine injections here and here, and pethidine injections, one in five or one in seven, but then the high-dose 100-milligram Ms Contin – that is, 100 milligrams of morphine – or the OxyContin 80-milligram, which is another high-dose formulation. But probably the biggest number would be the Panadeine Forte or similar products, containing 30 milligrams of codeine as well. This is a big-volume item. This probably accounts for the biggest number of diverted scripts.<sup>172</sup>

<sup>171</sup> Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, Department of Human Services, Briefing given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 29 May 2006.

<sup>172</sup> Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, Department of Human Services, Briefing given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 29 May 2006.

**Figure 2.4b: Per cent of total PBS opioid prescriptions obtained by 'doctor shoppers' in Australia, 2000**



Source: Extracted from presentation made by Dr Malcolm Dobbin to the Dugs and Crime Prevention Committee, Briefing, 29 May 2006.

Thus the Australian data indicate that 'doctor shoppers' account for significant proportions of all the prescriptions filled on the PBS for benzodiazepines and narcotic analgesics, including almost one in five prescriptions filled for injectable formulations of morphine and pethidine.

More recent statistics provided to the Committee by Medicare Australia show that in 2005-2006 there were 54,474 unique patients identified by the Prescription Shopping Programme. It should be noted, however, that this figure includes some patients who may legitimately be seeking medication for diseases such as cancer. A summary of statistics for the Prescription Shopping Service is provided in Appendix 11.

### Problems with the Doctor Shopping Program

It is unfortunate, however, that there is not a comprehensive annual collection of 'doctor shopping' statistics compiled by Medicare Australia and readily available for public research purposes. The lack of readily available data has been questioned in a number of coronial cases pertaining to deaths associated with benzodiazepines and/or opioid analgesics. For example, in the context of the benzodiazepine alprazolam,<sup>173</sup> a Tasmanian Coroner remarked earlier in 2007:

Alprazolam together with other Benzodiazepines are not the subject of any monitoring in the same way as narcotic substances. These drugs are usually prescribed on the Pharmaceutical Benefits Scheme, however Commonwealth privacy laws do not allow the sharing of this information with State authorities. There is no direct method available to identify whether a person is obtaining multiple prescriptions of such drugs from different doctors. I recommend that this issue be raised with the Commonwealth authorities in order to allow identification from their data of instances indicative of the abuse or misuse of prescribed drugs such as benzodiazepines.<sup>174</sup>

Another problem with the Doctor Shopping Program is that it only captures prescriptions within the PBS. However, other prescriptions are prescribed through private prescribers where the scripts are not registered with the PBS. One group of patients who are often prescribed large amounts of benzodiazepines or narcotic analgesics are victims of motor

<sup>173</sup> See Chapter 2.2 for a discussion of concerns pertaining to alprazolam (Xanax®).

<sup>174</sup> Coronial Findings, Tasmania. Case Number HO116/2005. Coroner, Stephen Curry. Date: 6 February 2007.



vehicle accidents, whose accident claims are managed by the Transport Accident Commission (TAC). Evidence provided to the Inquiry by the TAC suggested that significant proportions of their clients were not on PBS scripts and were not being identified by the Doctor Shopping Program. As an example, with regards to narcotics it was explained:

We ran a project which looked at Schedule 8s, those substances which you would think were of significant risk. It comprised 10 percent of the items that we were receiving, so roughly 100,000 items a year. On scanning, 20 percent looked like the way they were being managed was unusual and needed review; probably had some significant clinical issues. When you are looking at an account you are talking about doses and quantities. Of that 20 percent, we made the effort to trawl those and work on them one by one. Forty-one percent of [that group] had pre-existing, pre-motor vehicle accident drug related issues, either drugs of addiction issues, illicit substances, or substance abuse of a prescribed nature. Fifty-four percent of the doctors were prescribing non-PBS, meaning private scripts, which meant that it was outside a regulated process of review, so it was going to [be] miss[ed by] doctor shopping and pharmacy shopping [programmes].

Fifty-one percent of the doctors prescribed without a permit. The normal permit system that the drugs and poisons unit has in place is that you need a permit after a certain period of time using a particular substance, or immediately, with certain substances which are very high risk. Roughly half the doctors were not following the law. There was a significant problem with the misuse of injectable narcotics. We are talking about morphine and pethidine. There were very high quantities and circumstances where you would not normally use those substances. We do not have the capacity to assess the extent of diversion. Here we are talking about individuals who are getting high quantities of Schedule 8s. The extent of diversion we assume, we do not know.<sup>175</sup>

Martyres, Clode and Burns (2004) conducted an analysis of the Victorian Coroner's Court records linked with PBS data relating to the death of 254 persons aged 15 to 24 from heroin-related overdose between 1994 and 1999. The data showed that, in the years before they died, their 'doctor shopping' escalated with an increase in both the number of doctors seen and rates of prescriptions issued. Their 'doctor shopping' peaked in the year before they died. The researchers found that although all prescriptions increased before death, those for opioids and benzodiazepines increased more than other drugs. They concluded that whilst 'doctor shopping' is primarily viewed as an economic problem, they believe that further research into escalating drug seeking behaviour by young heroin users may provide a clinical predictor of overdose risk and an opportunity for intervention and preventing overdose fatalities (Martyres, Clode & Burns 2004).

One of the consequences of 'doctor shopping' is that it increases the amounts of pharmaceutical drugs that are available on the street illicitly, which poses problems for those clinicians servicing that population, as Dr Frei from the Interhospital Liaison Group explained:

This is how drug markets have changed in the last five years, I think. Ten years ago, if somebody said that they were on Valium or one of these benzodiazepine drugs, they would be getting them from a doctor and you would be able to confirm it with the doctor. Now there seems to be this huge street availability of these drugs. They are traded on the street and it is really difficult. Ten years ago we could have rung the doctor and the doctor would have said, 'Yes, I prescribed this person. It's a bit too much, but this is what they get', and they may not have been doctor shopping. Nowadays, they might be going to half a dozen doctors, getting them from friends or buying them from people on the street. That group is really difficult to work out. With this huge reservoir of illicit drugs being traded on the street, it is very hard to get an idea of how much somebody is using. Because a lot of these drugs cause a bit of amnesia, they might forget how much they have used. That is one of the big

<sup>175</sup> Dr Peter Harcourt, Chief Health Officer Health and Disability Strategy Programmes, Transport Accident Commission, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 19 June 2006.



difficulties. In fact, with heroin I have always found the illicit drug users easy. They say, 'This is how much heroin I use. I buy it each day', and, strangely, it is a bit easier to deal with. The licit drug users who are haphazardly buying prescription drugs on the street are really quite tricky.<sup>176</sup>

The Victorian Youth Substance Abuse Service (YSAS) also believes that 'doctor shopping' has to be viewed as other than just an economic or even drug seeking problem. In evidence to the Committee, Mr Tony Palmer from YSAS queried whether 'doctor shopping', at least in some cases, might not be viewed as a 'cry for help' from young people in crisis. He asks:

[w]hether what is normally called 'doctor shopping' is actually doctor shopping or whether it is a form of help seeking, because we have seen this link between doctor shopping and suicide. The question is whether, at a point where the young person is getting really agitated and really anxious about life, they then start doctor shopping in the hope that somebody can offer some kind of answer to what is going on.<sup>177</sup>

A representative of the Australian Medical Association (AMA) also stressed the need for a therapeutic approach when addressing suspected 'doctor shopping' by a patient:

Prescription shoppers are a major source of concern in general practice. I had a telephone call from a local pharmacist just two weeks ago. He said there was a certain patient whom I have known for quite some time who was appearing to be shopping around other doctors and was getting too many opioids. He had a legitimate lumbar back problem but he came in to me and I laid it on the line to him. I said, 'Look, you will go to one doctor. It is either me or whoever it is, nominate your doctor, but you do not go to anybody else and we will see if we can manage this pain. You seem to be increasing the need for opioids'.

Then we discussed his condition, how life was going for him and the fact that he had developed depression. He was started on antidepressant medication, and counselling was arranged for him, and now he is back to his normal prescribed medication without going doctor shopping. It is very important that there is this communication between the pharmacists and the doctors, and perhaps it probably does not occur often enough.<sup>178</sup>

The points made in the above quotes about the need to take a therapeutic approach to 'doctor shopping' in most cases are well taken. 'Doctor shopping' is not just about numbers. There are many human stories behind the Medicare Australia statistics. This is no better exemplified than through the story of Mary who has often been quoted throughout this Report. Mary supplied the Committee with a diary of her experiences as a 'doctor shopper' from early June to early July 2007. This testament titled '*Diary of an Addict*' was written *after* her original testimony before this Committee and during a time when she had recommenced taking benzodiazepines. It is an extraordinary account of how easy it is for a person determined to access these drugs through legitimate channels, even though in some cases the prescribing of these drugs was clearly inappropriate – at best inadvertent, at worst negligent or even unethical.

### **Methods used by 'doctor shoppers'**

It would seem that the methods used by 'doctor shoppers' to seek and access prescription drugs illegitimately are many and varied. This was certainly the case in one London study

176 Dr Mathew Frei, Interhospital Liaison Group, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 19 June 2006.

177 Mr Tony Palmer, Trainer and Consultant, Youth Substance Abuse Service, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 20 June 2006.

178 Dr Harry Hemily, Vice President, AMA (Victoria), Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007.

Such an approach whilst commendable seems to be at odds with the suggestion of the AMA (Victoria) that a criminal offence of 'doctor shopping' be introduced. Although it could be inferred that the AMA may consider a doctor shopping offence less appropriate in a case where a person is 'shopping' to sustain their own addiction compared to a person who is seeking to access drugs to on-sell for commercial gain only. For discussion of the AMA's proposal for a doctor shopping offence see Chapter 3.2 of this Report.



by Fountain et al (1998). The authors presented results from their qualitative study of drug users in treatment to demonstrate the strategies drug users employed to obtain surplus drugs to sell on the illicit market. A selection of them is presented here.

**Overscripting** – Here the client gets prescriptions for larger amounts of a drug than they need for themselves. Fountain et al (1998) give the example of 'Maurice':

I always keep my own juice (methadone mixture) – well, I sell a bit of it occasionally, but I need most of it myself, or I'd be sick (withdraw)...I do sell pills (benzodiazepines) when I get them for myself...I mean, when I get my temazi (temazepam) and Valium script, I just take a couple – like a couple with a hit (injection of heroin) or a couple to go to sleep with...I get 60 of each a month, and, like, on average, I take out of them half a dozen (Fountain et al 1998, p.161).

**Exaggerating their dependency** – The most frequently used strategy was for users to exaggerate the amount they used themselves. The authors note that this often put the doctor in a difficult position where benzodiazepines were concerned, because if the story of excessive use was true, abrupt cessation could precipitate a seizure.

Sally: I had no pill addiction whatsoever, but I went in there with a sob-story saying 'I'm using ten Mogadon, eight blue Valium (10 mg) a day, and buying them off the black market, and I have to thieve to get the money, and I don't want to do that any more, and I want to try and sort out my life' and so forth, and what she said was 'Out of the two drugs you're taking, I can only prescribe one of them'. So I said to myself 'Right, Mogadon is 5 mg, Valium is 10 mg – so I'll have the Valium'. And when it came to the amount, I said I was using 12 blues (10 mg Valium tablets) a day, which is 120 mg a day...it's a hell of a lot, but I said 'I've managed to cut myself down to 80 mg' and she said 'Oh, brilliant'. So therefore, I get 56 blues of 10 mg a week, and I pick them up fortnightly, which is 112 blue tablets, take a couple myself, and the rest I sell (Fountain et al 1998, p.162).

A submission to this Inquiry by a former self-termed 'addict' of prescription drugs also testified to how she would on occasion overstate the pain being suffered for her (legitimate) illness in order to obtain the drugs she craved. As she succinctly put it: 'One of the first "skills" to master when doctor-shopping is acting – and desperation for a drug is an extremely good teacher'.<sup>179</sup>

**Bargaining with prescribers** – This involved what one might call 'emotional blackmail' to say that, unless they were prescribed the pharmaceuticals, they would have to engage in sex work, or commit other crimes, in order to buy heroin to feed their habit. Where a prescriber suggested decreasing the client's dose this could be met with a threat to top up their dose by using extra from the illicit market (Fountain et al 1998).

**Gaining sympathy** – As indicated above, women spoke of using 'sob-stories' to get the drugs they wanted, or presenting a hopeful story of real effort towards change.

Lucy: You tell them what you know they want to hear...God forbid, my mother, she has died more times...she's had car accidents, she's died of cancer, and I've been grieving, 'I've got to go the funeral, I need this and this and this', and it's amazing how quick those tears dry up when you see that pen writing the script (Fountain et al. 1998, p.163).<sup>180</sup>

**Feigning addiction** – Fountain et al (1998) also found several clients who obtained benzodiazepines from a general practitioner by claiming addiction to alcohol rather than opiates.

<sup>179</sup> Submission to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, April 2006. The name of the author of this submission has been withheld to protect her anonymity.

<sup>180</sup> Conversely they may use aggressive tactics to intimidate the doctor into prescribing them drugs. See evidence of Mr Peter Muhleisen, Chief Pharmacist, Turning Point Alcohol and Drug Centre, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 9 July 2007.

**Claiming to be a temporary resident** – Presenting oneself as a visitor from out of town who has run out of medication was another strategy that worked well for clients seeking extra pharmaceuticals.

I've actually been guilty of going into a doctor's out of the blue and he has just gone 'bosh' (written out a prescription)...yeah, as a temporary resident, say from the North, and I've walked out with temazepam, diazepam, and DFs (DF118). That's on the first visit...Then you walk round the corner and do it again, and you've got your pockets full and you've earned yourself a few bob – you sell them and you've got the money to buy your own stuff (preferred drugs) (Fountain et al 1998, p.164).<sup>181</sup>

Mr Steve Marty, the Registrar of the Victorian Pharmacy Board, related to the Committee how ingenious some 'doctor shoppers' could be in this regard:

We have had occasions where a deregistered nurse photocopied a prescription for Ritalin. It was an extremely good photocopier because it looked like the writing had been with a felt-tipped pen...[She presented] these to a substantial number of pharmacies, none of whom picked up that it did not have the quantity in words, which is one of the requirements at the moment and should have raised suspicion...This woman...would go in and say, 'Can I leave my prescriptions here with you and I'll get them when I need them?' She would go in the next day or the day after when a different pharmacist was on duty and say, 'You've got my prescriptions here', so there was some assumption that she was a regular customer.

She got a lot of these prescriptions and she would go in a few days later and say, 'I'm running a sales conference in Sydney. I'm not allowed to get these dispensed up there. Could I take my repeat so I'll have enough to last me whilst I'm away?' ...She was detected because she went to a pharmacy across the other side of town but the pharmacist on duty that day had been on duty in the eastern suburbs where she had presented the day before, so she was picked up as a result of that.<sup>182</sup>

Dr Malcolm Dobbin described a similar case in his briefing to the Inquiry:

One man we have heard of is in his 40s. He has had a coronary artery bypass graft, so he has a midline sternal scar...He presents to the doctor and says, 'I've just moved from interstate...Will you be my doctor?' He spends 20 minutes or half an hour going through what he needs, and the doctor examines him. It all looks pretty genuine. He is getting his heart tablets, his cholesterol tablets, his hypertension tablets, and as the doctor is writing the script he says, 'Oh, by the way, can you put a script on there for temazepam capsules'...<sup>183</sup>

Some 'doctor shoppers' will go to extraordinary lengths to present themselves to doctors' surgeries where they are not known. One such example was given to the Committee by Mr and Mrs Brown with regard to their son Tony's attempts to access prescription drugs to support his addiction:

181 The converse may be also true, that is, if a doctor is new to an area, he or she may fall 'easy prey' to a clever 'doctor shopper'. For example, Ms Toni Riley, a pharmacist and proprietor of a number of pharmacies in Bendigo told the Committee that there seemed to be quite a significant upsurge of 'doctor shopping' and scripts for benzodiazepines written when they had new doctors in town (see comments of Ms Toni Riley, Toni Riley Pharmacies, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Bendigo, 30 May 2007).

182 Mr Steve Marty, Registrar, Pharmacy Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 19 June 2006.

183 Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, Department of Human Services, Briefing given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 29 May 2006.



He was working with his doctors in Nhill or Horsham – and he would get whatever scripts he could and if 20 milligram was not enough, well, he would go to Stawell or he would go to Hamilton or Camperdown or Warrnambool. There was just no end to it.<sup>184</sup>

#### A 'successful strategy'

One of the respondents in the London study thought that persistence usually paid off when scamming doctors: 'Just take pot luck, because at the end of the day, the doctor can only say no. The chances are you are going to get something off someone' (Fountain et al 1998, p.164). Another, who had a 20-year history of 'doctor shopping', explained the enjoyment she had from outwitting the prescribers:

I used to enjoy doing it. I believed what I was saying. I never ever got nicked...You're always scared, but sometimes that's part of the fun of it. Especially if you know someone that's already hit that doctor and you think that you can get a lot better than them and you do it; it's quite a buzz. I mean, I always felt so clever when I came out: I'd pulled it off perfectly and thought, 'What a liar I am: that poor doctor is totally taken in by this. They're trying to help me – there's nothing wrong with me, I've just gone in with this load of lies and he's believed this'. And what you have to do – the trick to it is that you have to believe it yourself when you go in that room, go through that door. You believe what you say and you're so convincing 'cos you believe every word you're saying. If you didn't do that, you know, if you faltered at all, you wouldn't get it. You've got to be convinced that it's true and that doctor will believe you. Nine out of ten will believe you (Fountain et al 1998, p.165).

Mr Steve Marty, Registrar with the Pharmacy Board of Victoria, expressed his sympathy for the difficult situation of most doctors when he gave evidence to this Inquiry:

When many medical practitioners prescribe, of course, they are relying on a truthful history being presented by the patient and, to a certain degree, you have to accept it unless you want to be in an argument or accuse the person of lying or interrogate them further. So they do need to have very good diagnostic skills, but these people also are very skilled in the way that they present information: they will have done their research, know what to say; they will know all of the symptoms sometimes better than some of the practitioners involved, I suspect. Once again, there is no central history that you could look up. GPs come under pressure, certainly from aggressive behaviour, threats to them or to patients waiting in the reception area. There have been occasions where friends have caused substantial trouble in the waiting areas and all the GP wants to do is get them out of the surgery, so [the GP] will write a prescription.<sup>185</sup>

<sup>184</sup> Evidence of Mr Brown, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Bendigo, 30 May 2007. The name used is a pseudonym to protect the confidentiality of the witness.

Norm Ferrier, a Warrnambool based pharmacist, made similar comments to the Committee. He knew of clients who, whilst domiciled in Warrnambool, travelled as far afield as Portland and Ballarat to access OxyContin® (See evidence of Mr Norm Ferrier, Pharmacist, given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Warrnambool, 29 May 2007).

<sup>185</sup> Mr Steve Marty, Registrar, Pharmacy Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 19 June 2006.

## Forged, stolen or altered prescriptions

Evidence has been given to this Inquiry from several sources testifying to the relative ease with which people can forge, alter or otherwise illegally obtain prescriptions or prescription pads.<sup>186</sup>

For example, a submission from the Pharmacy Board of Victoria to this Inquiry explained that:

Benzodiazepines have commonly appeared on forged or altered prescriptions and have been the target of pharmacy break-ins.

Forgeries can be on both handwritten prescriptions and more recently computer generated prescriptions. Similarly, alterations have been made to handwritten prescriptions, usually by increasing the quantity originally ordered by the prescriber and/or the number of repeats to be supplied.

Computer software for prescribing has been fraudulently obtained on occasion and used to generate unauthorised prescriptions and also cases where scanners using optical character recognition programs to copy a genuine computer generated prescription and then change patient details, drug, quantity and number of repeats have resulted in fraudulent supply of drugs.

Security of computers and prescription stationery is an issue for prescribers. Prescribers are required to notify the loss of prescription stationery to the Drugs and Poisons Unit of the Department of Human Services. This information is advised as a list to the Pharmacy Board each Friday which in turn publishes the list in a database on its website to assist pharmacists in checking the validity of prescriptions.<sup>187</sup>

At a Public Hearing in June 2007 Mr Steve Marty followed up this submission with an account of methods used by prescription drug forgers:

I have seen computer-generated prescriptions that are not produced by medical practitioners and I have also seen a computer-generated prescription that has been put through a scanner and then optical character recognition has been used to manipulate that and print out a new, altered prescription. It was only a fairly astute young pharmacist who picked it up. She just did not feel right about it and contacted the doctor, who said, 'I've never heard of that patient'. This is a whole new challenge.

That is on top of the problem of prescription stationery, which medical practitioners need to be acutely aware of – not only medical practitioners, but now we have a wide range of people who are authorised to prescribe and they need to be very aware that their stationery is a valuable item. I am told that a blank prescription pad can be worth up to \$10,000. They will normally steal pages. They will feign that they are going to vomit or something like that and the doctor will turn around to get a bowl or something like that and in that time, if they have left a prescription pad sitting on the desk, they will steal a few pages off. They will either sell them, write their own scripts on them and sell them or they will have them dispensed

<sup>186</sup> Forgery of prescriptions for both drugs of dependence and other forms of drugs and medicines are punishable by fines and/or imprisonment. See provisions of the *Drugs, Poisons and Controlled Substances Act 1981* discussed in Chapter 4.2 of this Final Report.

When a representative of Victoria Police gave evidence at a Public Hearing of this Inquiry she stated that:

'I think there are probably three ways in which prescription drugs are obtained: some are theft of prescription pads and forging those pads to obtain the drugs; some will be on-selling and collecting and selling through diversion; and others will be through doctor shopping or other forms of accessing that drug' (Detective Superintendent Wendy Steendam, Crime Strategy Unit, Victoria Police, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 25 June 2007).

<sup>187</sup> Submission of the Pharmacy Board of Victoria to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007. For an account of how the implementation of an electronic prescribing system may address prescription forgery and fraud, see the discussion in Chapter 5.2 of this Report.



and sell them, or with forgeries and alterations they will attempt to add items to existing prescriptions because they will look at the writing and copy it and add to it.<sup>188</sup>

The Victorian Forged Prescription Study (Lloyd, Guibert & Bell 2000) conducted for the Victorian Branch of the Pharmaceutical Society of Australia Ltd was an attempt to address the issues related to forgery of prescriptions and to assess the nature and extent of forgery in the Victorian community. The project included literature reviews, interviews and surveys of those involved in the pharmacy profession. Their survey of 772 pharmacists in Victoria found that roughly equal proportions believed forgeries to occur rarely (40%) or frequently (39%). Perception of frequent prescription forgery was greater in suburban Melbourne (46%) than in rural Victoria (18%), and was also greater among those with more years of practice (Lloyd, Guibert & Bell 2000).

In addition to making a number of recommendations as to how the problem could be addressed, Lloyd, Guibert & Bell (2000) analysed data from the Department of Human Services (DHS) database of forged prescriptions for the period January 1997 to March 1999. The DHS expects doctors to advise it if they become aware of their prescription stationery being stolen or used for forging prescriptions. At that time the authors of the study found a fairly stable rate of forgeries reported, with a slight tendency for the forgeries to be on stolen stationery, rather than adulteration of bona fide prescriptions (see Table 4.2b). The authors concluded that:

A significant number of both doctor and pharmacy practitioner groups demonstrated that they are generally not aware of the true extent of the problem of forgery, nor of their individual legal and professional responsibilities (Lloyd, Guibert & Bell 2000, p.ix).

**Table 2.4b: Distribution of prescription forgeries reported to the DHS Drugs and Poisons Unit from 1 Jan 1997 to 15 March 1999**

Year	Number of names used by forgers	Numbers of forgeries		Number of different drugs sought	Number of pharmacies at which prescriptions were uttered	Number of different doctor's stationery used	Number of doctors reporting stationery stolen
		Alterations to genuine prescription	Forged on stolen stationery				
1997	146	73	99	191	155	90	33
1998	121	76	51	124	112	49	25
1999*	41	15	28	38	38	27	8

NOTE: Until 15 March

Source: Lloyd, Guibert & Bell 2000, p.19.

Consistent with the above data, Forgione, Neuenschwander and Vermeer (2001) noted that most of the prescription forgery in the United States involved stolen, or printing of phoney, prescription pads:

The primary source of prescription forgery is the forgery of prescription pads. Prescription pads can easily be printed with phoney names, addresses, telephone numbers, and DEA [Drug Enforcement Agency] numbers. Some scammers travel around the country breaking into physicians' offices or even setting up their own offices. Others may include a cellular phone number on the prescription pad – the pharmacist then reaches an accomplice who poses as the prescribing doctor and confirms the prescription over the phone, thus relieving any concerns the pharmacist may have (Forgione, Neuenschwander & Vermeer 2001, p.66).

In his briefing to the Inquiry Dr Malcolm Dobbin described one case of 'doctor shopping' in Victoria involving stolen prescription pads used to facilitate temazepam diversion:

We have pharmacists and other inspectors who go to pharmacies and trawl through the pharmacists' records case by case, and in this case they have identified a number of forged prescriptions obtained by this particular man and woman team. The inspector identified 300 prescriptions over three months made out to this particular person and did not have any way of knowing whether there had been others forged under other names. They had been

<sup>188</sup> Mr Steve Marty, Registrar, Pharmacy Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007.

obtained from 77 different pharmacies and they were mostly done on prescription pads that had been obtained by breaking into a doctor's surgery, but they had also been taken from a doctor's desktop when the doctor was distracted. So you can see the difficulty, using our current methods, in trying to detect and prevent the dispensing of these drugs. These had been dispensed. At that time temazepam capsules were being trafficked for \$50 a prescription – a slab, as it is called, of capsules – or between \$10 and \$20 a capsule.<sup>189</sup>

In South Australia a number of measures have been put in place that make it harder to dispense a forged prescription. A submission to this Inquiry by Mr Geoff Anderson, Chief Pharmacist and Manager of South Australia Health, Drug Dependence Unit, outlined these to the Committee:

Pharmacists cannot hand over the medication until the patient has signed and dated for receipt of the drug and if the person for whom the drug is dispensed, or the agent, is not known to the pharmacist, they must provide satisfactory evidence of their identity. Signatures, with supporting identification, of the person collecting the medication assist in the identification of that person in cases of fraud.<sup>190</sup>

It is one thing, however, to have such measures in place and another to successfully prosecute prescription drug forgeries and other offences according to Mr Steve Marty:

One of the problems is that people who are taken before the courts for altering [or forging] prescriptions are treated pretty leniently because it is at the lower end of the scale. It is not an illicit substance, it is a legal substance that is being prescribed...and that is one of the difficulties we have in pharmacists perhaps reporting some of these matters. Pharmacists will [have to] give up a day's work, have to pay for a locum, go to court and see somebody get a \$100 good behaviour bond.<sup>191</sup>

In the United States it has been observed that some people seeking pharmaceutical drugs have had their own prescription pads printed at commercial print shops, as this doesn't require special credentials (Blumenschein 1997). Yet, even if there are checks to guard against this practice, with cheap and widely available high quality colour scanners, printers, photocopiers and desktop publishing software, legitimate prescriptions can also be copied, producing very professional looking fakes.<sup>192</sup>

Prescription forgery scams can be very sophisticated and hard to detect, as demonstrated by the following two notorious scams in America:

In these situations, prescription pads are printed utilizing a fictitious physician name, practice address, DEA number, state license number and phone number. When a pharmacist tries to verify the prescription by contacting the prescriber using the phone number listed on the prescription, the forger's accomplice will pick up on the other end and pretend to be the physician. In some cases the phone number listed on the prescription goes to a hired answering service that forwards the message to the phony physician who calls the pharmacist back to "verify" the prescription. Criminals using this kind of scam diverted over 60,000 dosage units of Dilaudid from 1990–1993 in Florida (Blumenschein 1997, p.186).

189 Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, Department of Human Services, Briefing given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 29 May 2006.

190 Submission of Mr Geoff Anderson, Manager, Drug Dependence Unit, South Australia Health, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria July 2007.

191 Evidence of Mr Steve Marty, Registrar, Pharmacy Board of Victoria to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007.

192 In recent years, however, some American states have rigorous measures in place to address prescription forgery. For example, in California prescribers must order tamper resistant prescription forms from state security printer companies pre-approved by the California Board of Pharmacy and the state Department of Justice. Firms selected as approved printers must submit to a stringent security vetting process before such approval is granted. Representatives of the California Board of Pharmacy told the Committee that early signs indicated that the security forms were assisting to reduce the amount of prescription forgery in California. (See for example, comments of Ms Judi Nurse, Supervising Inspector, California Board of Pharmacy, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 2 August 2007.



Prescription drug scammers have also called a physician's office, found that it was closed, and then called the physician's answering service impersonating the physician and asking to have all the physician's calls held. The individual then dropped the prescriptions for controlled substances at numerous pharmacies. After a few hours, the scammer would call the physician's answering service to check for messages. If a pharmacy did not call, the prescriptions would be picked up at that pharmacy (Forgione, Neuenschwander & Vermeer 2001, p.66).

Blumenschein (1997) concluded that altering prescriptions can be one of the easiest methods of prescription fraud. Changing the quantity prescribed or the number of repeats to be dispensed is easier if the prescriber is not careful about how they write it. For example, when quantities are written as numbers and not spelled out they can be more easily altered, or a digit added. Similarly, if the number of repeats is not specified clearly it is a relatively easy task for the forger to adjust the script for the maximum number of refills. Less commonly, a second drug can be added to a legitimate script, or the strength of a preparation can be increased. In Victoria the Drugs, Poisons and Controlled Substances Regulations 2006 do require the quantity of the prescribed medicine and the maximum number of repeats of Schedule 8 and 9 drugs to be written in both words and figures.<sup>193</sup>

In recent years, however, some American states have rigorous measures in place to address prescription forgery. For example, in California prescribers must order tamper resistant prescription forms from state security printer companies pre-approved by the California Board of Pharmacy and the state Department of Justice. Firms selected as approved printers must submit to a stringent security vetting process before such approval is granted. Representatives of the California Board of Pharmacy told the Committee that early signs indicated that the security forms were assisting to reduce the amount of prescription forgery in California. (See for example, comments of Ms Judi Nurse, Supervising Inspector, California Board of Pharmacy, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 2 August 2007).

It is unclear, however, as to why such a stipulation should not also apply to the prescribing of Schedule 4 drugs, which include most benzodiazepines.

Another strategy is when the prescription drug seeker phones the pharmacy posing as a prescriber or nurse, often after hours or on weekends when the pharmacist is least able to contact the prescriber (Blumenschein 1997, pp.186–87).

Lloyd, Guibert & Bell (2000) surveyed some 668 Victorian general practitioners regarding prescription forgery. Among this group 37 per cent perceived the practice as 'frequent', 28 per cent as 'rare' and 35 per cent 'did not know' (p.47). Overall, the authors concluded that forgery probably contributes less to net pharmaceutical drug abuse in Victoria than other methods of acquiring pharmaceuticals illegitimately. However, because it requires little skill compared to other methods (such as misrepresenting themselves to doctors), and the risk of detection is probably low, it is still frequently used (Lloyd, Guibert & Bell 2000).

## Acquisition from friends and family

Friends and family constitute a major source of prescription drugs used for non-medical purposes. A submission by the YSAS noted that 'Benzodiazepines are generally first accessed by raiding a parent's or other relative's legitimate supply'.<sup>194</sup>

A young person cited in a United States study stated:

193 See Regulation 26, Drugs, Poisons and Controlled Substances Regulations 2006.

194 Submission of the Youth Substance Abuse Service to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

I can get prescription drugs from different places and don't ever have to see a doctor...I have friends whose parents are pill addicts, and we 'borrow' from them. Other times I have friends who have ailments who get lots of pills and sell them for cheap. As long as prescription pills are taken right, they're much safer than street drugs (18-year-old male from San Francisco) (Friedman 2006, p.1448).

In a web-based survey, McCabe and Boyd (2005) surveyed 9,161 undergraduate students attending a large public midwestern research university. The respondents identified 18 sources of prescription drugs for illicit use that were classified into three broad categories: peer, family and other sources. Those who obtained prescription drugs from peer sources reported significantly higher rates of alcohol and other drug use than students who did not use prescription drugs illicitly or who sourced their drugs from their family.

Not all medications accessed through family members will be necessarily done through theft or other clandestine means. Mr Joseph Rannazzisi, the Administrator of the United States Drug Enforcement Administration (DEA), made the following observations when testifying to a congressional hearing on prescription drug abuse in July 2006:

As DEA increases its understanding of where abusers acquire prescription drugs, preliminary data suggest that the most common method in which controlled substance prescriptions are diverted may be through friends and family. For example, a person with a lawful and genuine medical need for a controlled substance may use only a portion of the prescribed amount. A family member or friend may complain of similar symptoms, and the former patient shares excess medication. Alternatively, for someone addicted to controlled substance prescription drugs or to an inquisitive youngster, the mere availability of unused controlled substance prescriptions in the house may prove to be an irresistible temptation.

The solution to this aspect of the problem lies both with the medical community and the legitimate patient population. Greater educational efforts are needed regarding quick and safe disposal of unused and unneeded medications. Prescribers need to carefully consider the potential for abuse of controlled substances and prescribe only the amount of a controlled substance required medically. Patients must also be educated about the legal and social ramifications of providing a controlled substance to a friend or family member. It is not merely illegal, but could feed, or lead to, an addiction, and place that loved one in a life threatening situation (<http://www.usdoj.gov/dea/pubs/cngrtest/ct072606.html>).

Although admittedly anecdotal, some evidence given by a representative of the Interhospital Group to this Committee suggests there may also be a culture of inter-generational acceptance of the use of prescription drugs. In other words parents, particularly mothers, may pass on their own prescription drugs to members of the family without first considering whether this is appropriate:

[p]articularly in the western and northern region where it is culturally accepted; it is almost a rite of passage for girls to start their benzo use at about 14, 16, because that is what mum and grandma and everyone had done. They do not come into treatment services because 'Why get off them?'<sup>195</sup>

Just as family members might supply their own drugs to another family member, as indicated above in the American context it is not unheard of for a family member, friend or acquaintance to divert the drugs of the person to whom they are legitimately prescribed, sometimes even after they are dead:

We have an increasing incidence of cancer hospital in the home, people who want to die at home; so community pharmacies are often called upon to dispense 120 ampoules of morphine. When the person dies, there are occasions where the grandchildren or the son or daughter decide that this might produce some alternative income or they have been stolen from home. There have been instances where patients have been assaulted after leaving

195 Ms Ros Burnett, Interhospital Liaison Group, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 19 June 2006.



pharmacies, often because the pharmacy has not been smart enough to put these into an opaque bag so that [other] people are not aware of what they are getting. If you are in the right environment and somebody sees this, it is worthwhile taking it. That is part of the difficulty.<sup>196</sup>

The non-medical use of pharmaceutical drugs such as narcotic analgesics and benzodiazepines often has a long tradition in small communities far from the major sources of heroin supply. This is the case in the two smallest heroin markets in Australia, the Northern Territory and Tasmania, where it has been suggested diverted pharmaceutical drugs, rather than heroin, have long dominated the illicit drug market. A recent article by Topp (2006) describes the role of friends and family in supplying these drugs and discusses the extent to which non-medical use of pharmaceutical drugs could be less harmful than the use of street drugs.

We know relatively little about the methods by which pharmaceuticals are diverted to the black market, although Darwin academic Dr Bridie O'Reilly suggests supply is driven mainly by small-scale diversion from legitimate prescriptions, doctor shopping and forged prescriptions, rather than through organised thefts from pharmacies or points of manufacture, or via other sources such as internet pharmacy or importation.

Dr O'Reilly says prescription drugs are relatively easy to obtain from a diffuse network of users, friends of users, dealers and suppliers, some of whom also sell other drugs, such as methamphetamine, heroin and/or cannabis. There is little, if any, involvement of organised criminal groups, and the violence and criminality that typically characterise heroin markets are absent. Dr O'Reilly cites this feature as a significant advantage of a pharmaceutical-dominated market (Topp 2006, p.7).

## The role of healthcare providers in diversion of pharmaceutical drugs

### *Inappropriate prescribing for others*

The previous discussion focused primarily on the role and actions of people who were seeking prescription drugs illegitimately. But health care providers, particularly prescribing doctors, also contribute to the problem either through inattentiveness, incompetence or even questionable ethical behaviour.

In 1980, the American Medical Association adopted a taxonomy termed 'The Four D's' – the dated, the disabled, the dishonest and the duped – to describe doctors who over-prescribed medicine (Forgione, Neuenschwander & Vermeer 2001). This taxonomy seems to provide a useful shorthand way to describe the different reasons that doctors might over-prescribe:

- Dated doctors are those who make their therapeutic decisions based on outdated, incomplete, or incorrect information;<sup>197</sup>
- Disabled physicians are those who misprescribe due to their own mental illness or own addiction problems;
- Dishonest doctors are those who use their medical license to deal drugs for their own financial benefit; and

196 Mr Steve Marty, Registrar, Pharmacy Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 19 June 2006.

197 An example of 'dated doctors' was given to the Committee by Mr Dave Sallengs, Manager, Drug Enforcement and Professional Practices Branch, Kentucky Cabinet for Health and Family Services, when the Committee met with him in Frankfort, Kentucky (31 July 2007):

'We've got doctors that should have quit practice 10 or 15 years ago, they don't need the money they just do it because they're bored and they just want something to do and unfortunately their memory's short. They are [easily duped] and they can't remember if they've prescribed stuff for this person before...The drug diverters come in and give [these doctors] stories about you treated my mother 40 years ago for this complaint and he'd write the prescription out. These are doctors who are seen as easy targets for drug diverters because they give out the pills [without too much persuasion] and keep substandard records'.

- Duped doctors are those who unintentionally prescribe drugs to a user based on false information provided by the patient (Forgione, Neuenschwander & Vermeer 2001, pp.66–68).

Some dishonest medical practitioners, termed 'script doctors', prescribe benzodiazepines, narcotics or other misused pharmaceuticals to patients who they know will abuse them, in exchange for money, sexual favours or other forms of recompense. Such doctors are in essence using their medical licence to deal drugs illegally (CASA 2005). Pharmacists or other pharmacy staff can also divert pharmaceutical drugs by forging prescriptions for drugs that they then sell illegally, or using patient and provider information from the pharmacy database to 'create' prescriptions (CASA 2005).

Whilst the above literature draws from the American experience, similar classifications have been made in Australia. For example, a submission from Mr John Galloway, Chief Pharmacist, Pharmaceutical Services Branch, Tasmanian Department of Health, outlines the various 'subgroups' of doctors from whom 'doctor shoppers' may access prescription drugs;

#### **Doctor Subgroup 1 (The regular doctor)**

These doctors form the great majority of general practitioners. We believe that their judgement is generally reasonably good. They are willing to prescribe opioids for patients with severe chronic pain. They are generally cautious about initiating opioids but they often inherit patients already on opioids who are problematic. As the practice of using opioids in chronic pain is a relatively recent change, many have had little structured training in employing opioids for this purpose or in management of drug dependency. They are often reluctant to look closely for evidence of aberrant drug use behaviour (eg. injection sites)...

#### **Doctor Subgroup 2 (The intimidated doctor)**

These doctors are sometimes elderly, or are isolated. They are pressured or threatened by patients in various ways into prescribing drugs which may be abused. They also know that they will not have a policeman [sic] nearby all of the time to protect them from aggressive patients.

#### **Doctor Subgroup 3 (The "soft" prescriber)**

These are relatively few in number. They are usually sympathetic doctors trying earnestly to do good for each patient and they believe that they are doing good. However, their judgement is essentially poor and they are easily persuaded and manipulated by patients. They sometimes volunteer to become pharmacotherapy prescribers. They sometimes attract large numbers of difficult patients who, in some cases, other doctors unfairly pass on to them. Sometimes the doses they prescribe are high.

#### **Doctor Sub-group 4 (The rogue doctor)**

Fortunately these cases are very rare. These doctors turn a blind eye and supply drugs for non-medical purposes. Their actions are essentially criminal. They may have social links with those who abuse or sell drugs, and enjoy risk taking. They are also likely to be using drugs themselves. Their activities attract attention and reports would be referred to the police and to the Medical Council for investigation.<sup>198</sup>

One of the useful aspects of the American state drug monitoring systems discussed in Section Four of this Report is their ability not only to monitor 'doctor shopping' but also to ascertain which doctors may be over-prescribing prescription medications either inadvertently, negligently or with criminal intent. This was certainly the view of many of the representatives from health and law enforcement agencies with whom the Committee met during its tour of North America. For example, Carla Watkins of the Californian

<sup>198</sup> Submission of Mr John Galloway, Chief Pharmacist and Ms Mary Sharpe, Deputy Chief Pharmacist, Pharmaceutical Services Branch, Department of Health and Human Services, Tasmania, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.



CURES (Controlled Substances Utilisation Review and Evaluation System) programme, discussed in Chapter 4.1, stated that the reports generated by CURES could 'pick up doctors':

[w]e can look at the standard report and are able to identify why is this doctor writing 1,000 tablets a month. We can then go into our medical board website, and identify what the doctor's specialty is before we start investigating the doctor.<sup>199</sup> But [if it does seem suspect behaviour] doctors end up going through the same investigatory process as [a suspect] patient...<sup>200</sup>

Similar results have been achieved with KASPER (Kentucky All Schedule Prescription Electronic Reporting) in Kentucky. Mr Dave Sallengs, Manager, Drug Enforcement and Professional Practices Branch of the Kentucky Cabinet for Health and Family Services, told the Committee that:

As a result of KASPER, in 2004 42 prescribers were sanctioned either criminally or administratively, in other words they lost their privileges to prescribe controlled substances, and some of them lost their medical license. In 2005 the number was 37 practitioners...that's a significant number as far as action is taken that results in a lawsuit.<sup>201</sup>

The above discussion relates for the most part to inappropriate behaviours of doctors in their role of prescribing drugs for *other* people. It is not unknown, however, for health care professionals *themselves* to abuse the drugs over which they may have control or access.

#### *Diversion by healthcare providers for their own use*

There has also been a longstanding recognition that doctors, nurses and pharmacists are at increased risk of using drugs for non-medical purposes, associated with their high levels of access to these drugs. A recent study of diversion cases involving healthcare workers in Cincinnati from 1992 to 2002 (Inciardi et al 2006) found that opioids followed by benzodiazepines were the drugs most often diverted, with nurses (63.4%) responsible for most of the cases, followed by physicians (8.7%), medical assistants (6.4%), pharmacists (6.0%) and nursing assistants (5.0%). Hydrocodone (20.0%) was the most widely diverted drug, followed by oxycodone (immediate release) (15.6%). OxyContin® was only mentioned in 2 per cent of cases, as apparently it was not routinely available through much of the period of the analysis, and because of media scrutiny special care was taken to restrict diversion (Inciardi et al 2006). Most of the diversions in this study appeared to be for the healthcare providers' own use.<sup>202</sup>

#### **Nurses**

Drug diversion can certainly occur in the context of nursing. In August 2007 the Committee met with Ms Carol Stanford, Probation Program Manager with the California Board of Nursing's Treatment Program for registered nurses who have problems with substance abuse. She stated that the combination of high levels of stress in the workplace and relatively easy access to prescription drugs, mostly opioids, meant that nurses, particularly those working in emergency departments, had fairly high levels of substance abuse problems compared to other professions.<sup>203</sup>

199 Such a step is necessary to exclude doctors who may legitimately be prescribing large amounts of certain drugs, for example for cancer patients or registered pharmacotherapy clients.

200 Ms Carla Watkins, Supervisor of Criminal Identification and Intelligence, CURES programme, Meeting with Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Sacramento, 3 August 2007.

201 Mr Dave Sallengs, Manager, Drug Enforcement and Professional Practices Branch, Kentucky Cabinet for Health and Family Services, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Frankfort, 31 July 2007.

202 The legal consequences of such behaviour are discussed in Chapter 3.2 of this Final Report.

203 Ms Carol Stanford, Program Director, Board of Registered Nursing, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Sacramento, 2 August 2007.

In California, a nurse may be referred to the Board of Nursing when a complaint has arisen with regard to his or her substance abusing behaviour. Self-referrals are also common, although in such cases disciplinary proceedings would not usually be conducted. Most nurses then have the opportunity to undertake a course of rehabilitation offered by the Board. The alternative may be to face disciplinary charges and possible suspension or dismissal. Ms Stanford told the Committee that for those nurses who undertake to complete the therapy and rehabilitation program it is not unusual to take up to five years to complete it.<sup>204</sup>

The most difficult cases according to Ms Stanford are those where the nurse has been caught stealing drugs off the ward. If there is clear evidence of the theft being for on-sale or diversion it is more likely to be a case for the law enforcement authorities. In cases where the theft is to sustain the nurse's own habit, a referral to the Board and entry into the rehabilitation may be more appropriate, although such a referral may also be the result of a court disposition.

Ms Stanford believes the Nursing Board Program is better and more effective than those run through the criminal justice system because it is run by nurses, for nurses.

In the Victorian context a submission to the Inquiry from the Nurses Board of Victoria noted that:

In the 2004–2005 Nurses Board of Victoria Annual Report, there were a total of 23 complaints that included the misuse/abuse of medications, including the misappropriation of medications from the workplace. However, these complaints must be considered within the context of a lack of a legislative framework that requires mandatory reporting. The Board is aware that not all incidents are reported to the Board, including some situations where the employer chooses to manage the incident within the employment relationship...The drug classes that appear to be the most prevalent in complaints received are narcotics and benzodiazepines.<sup>205</sup>

Partly as a result of these types of incidents the Victorian Nurses Health Program (VNHP) was established in 2006.

The VNHP is an independent and confidential support service for nurses and student nurses with health concerns relating to mental health, alcohol and drug issues. It is discussed further in the context of treatment services for prescription drug abuse in Chapter 7.2 of this Report.

The other area that the nursing profession sees as particularly important is the ability to access good data on usage patterns and profiles by those health professionals who may have problems with substance abuse. Whilst Heather Pickard, Director of the VNHP believes there should clearly be a correlation between medical professionals having access to prescription drugs and the rates of use and abuse by those professionals, there is little research of either a quantitative or qualitative nature that can verify such a hypothesis:

A study [was done] in Australia five years ago I think, and one of the areas that was highlighted as an indicator of risk for nurses is the access, but we have been through a lot of regulatory changes and access has changed a lot. It is really hard to benchmark whether that has made a difference or not because we have never had any figures before our existence, other than if people get caught, so we have data on how many people – nurses – actually got caught but we do not have data on how many had problems related to access.<sup>206</sup>

204 Ms Carol Stanford, Program Director, Board of Registered Nursing, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Sacramento, 2 August 2007.

205 Submission of the Nurses Board of Victoria to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

206 Ms Heather Pickard, Director, Victorian Nurses Health Program, Evidence to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 9 July 2007.



## Doctors

It is not only access to prescription drugs by medical professionals through theft or diversion that is of concern. There are also problems associated with doctors and other prescribers, prescribing themselves medications.<sup>207</sup> This is a practice that is prohibited in Victoria.<sup>208</sup>

Mr Steve Marty indicated that such a practice is clearly a cause for concern:

Self-prescribing and self-administration by health practitioners is prohibited by legislation, and yet we still see this happen often enough. Medical practitioners think, well, why shouldn't they be able to treat themselves? I would suggest that no-one can rationally treat themselves; it is not possible. You see some very skilled people who have serious abuse problems and still continue to practise and put their patients at risk. You really doubt what their mental capacity is for rationalising their own situation.<sup>209</sup>

Dr Con Constantinou, Health Manager of the Medical Practitioners Board of Victoria (MPBV), told the Committee that whilst such occurrences are rare they do happen. He explained the process that the Board uses to address 'rogue' or substance abusing doctors when he gave evidence at a Public Hearing in July 2007:

For the last two years I have been manager of the health section, which is the section of the board that monitors doctors who are impaired by health problems...

Two aspects of medicine tend to lead doctors [towards substance abuse] if they have the personality for it. One is the pressure of work, both through the study stage, and we have some medical students with such problems, in hospital work, and quite often that is where drug abuse problems begin for medical practitioners; but also in practising doctors later on – it is quite stressful work.

The second aspect is the easy access: sometimes through theft of their employer's stock, sometimes through use of the supply of S8s in the doctor's bag supply, and sometimes by diverting patients' requirements or forging prescriptions in other patients' names et cetera. Of course it is illegal for doctors to prescribe for themselves and so they are careful not to do that, not to draw attention.

In the category [of] doctors abusing drugs, the most common source of referral [to the MPBV] is their employer – usually the hospital or a multidocor practice; sometimes it is their colleagues. Because it is mandatory to report doctors who have a medical condition and whose practice could be a risk to the safety of the public, we often get reports from treating doctors as well.<sup>210</sup>

Dr Constantinou indicated that where at all possible the Board tried to take a therapeutic rather than punitive approach to the problems of a doctor who may be abusing prescription or other drugs:

We would make sure that the doctor is not working whilst they are having acute rehabilitation to get off the acute addiction. Then a condition of allowing them to go back to practising would be that they be under the care of a drug addiction consultant, with chemical monitoring of their urine or blood on a regular basis and with the results coming

<sup>207</sup> Pharmacists are also not immune to the pressures of illicitly using the medications they dispense. Mr Steve Marty, Registrar of the Pharmacy Board of Victoria, told the Committee in this regard:

'When I qualified 37 years ago, I do not believe pharmacists would have illicitly taken a medication, and yet in the last 12 months I have dealt with more pharmacists with problems than I have in my 17 years of working with the board. It is about access' (Mr Steve Marty, Registrar, Pharmacy Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 19 June 2006).

<sup>208</sup> See also the discussion in Section 3.

<sup>209</sup> Mr Steve Marty, Registrar, Pharmacy Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 19 June 2006.

<sup>210</sup> Dr Con Constantinou, Health Manager, Medical Practitioners Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 9 July 2007.

to us. There would be conditions on their working, such as they must be under supervision, they can only work a certain number of hours, they are not allowed to prescribe schedule 8 drugs and other appropriate restrictions...

Addiction always makes you say, 'I have not got a problem'. It takes a long time for that to sink through. On average we monitor doctors with drug-seeking problems for a minimum of five years because we know relapses are common. We have had doctors we have been monitoring for 10 years or more. So it varies. Some, once they have been caught once, will not do it again. But we still monitor them for five years because we know the relapse rate is so high. Although they have the training and they should have the insight, it does not mean they have the personality strength to fight the addiction. They need support, the same as any other addict.<sup>211</sup>

A key way that the Board can take a therapeutic approach is to refer the doctor to the Victorian Doctors Health Program (VDHP). Medical practitioners may also self-refer to this Program. Similar to the Nurses' Program, the VDHP is a confidential service for doctors and medical students with health concerns including stress and anxiety problems, substance use disorders, mental health disorders and other health problems.

Dr Con Constantinou told the Committee that the VDHP has been very well received and is a useful service to refer doctors to who come to the attention of the MPBV. The VDHP is discussed further in the context of treatment issues in Chapter 7.2 of this Report.

### Pharmacists

Whilst the Committee has not found any Australian data on pharmacists who may misuse or abuse prescription drugs, evidence suggests that in the United States between 40 and 65 per cent of pharmacists have used a drug illicitly at least once during their professional careers and some 20 per cent have done so at a level where they have experienced negative, health, vocational or relationship consequences (Dabney & Hollinger 2002; Hollinger & Dabney 2002).<sup>212</sup>

Dabney and Hollinger drawing from the largely American academic material argue that prescription drug abuse by pharmacists, as with other health professionals, can be divided into two generic conceptual categories - recreational abuse and therapeutic self medication. Recreational abuse is clearly facilitated or exacerbated by 'their nearly unlimited access to prescription medications and their belief in their invincibility to drug addiction (Dabney and Hollinger 2002, p.183).

## Theft of prescription drugs

### Retail theft

Benzodiazepines, narcotic opioids and other controlled drugs can be stolen from pharmacies, doctors' surgeries, dentist practices, veterinary clinics, hospitals, nursing homes and from individual patients. Theft can occur by shoplifting, robbery or burglary (CASA 2005). The Victorian Branch of the Pharmaceutical Society of Australia (Lloyd, Guibert & Bell 2000) considers that whilst thefts from pharmacies and wholesalers have long been a source of drugs for pharmaceutical drug abuse and will continue to be so, stringent security measures now in place have reduced thefts from these sources.

In his evidence to the Inquiry Dr Malcolm Dobbin noted:

211 Dr Con Constantinou, Health Manager, Medical Practitioners Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 9 July 2007.

212 The United States Drug Enforcement Administration (DEA) has published an excellent Guide for Drug Addiction in Health Care Professionals which assists healthcare professionals, friends and families to recognise the signs that may indicate a colleague, co-worker or treating healthcare professional may be diverting controlled substances to support a substance abuse problem. This guide is accessible on [http://www.deadiversion.doj.gov/pubs/brochures/drug\\_hc.htm](http://www.deadiversion.doj.gov/pubs/brochures/drug_hc.htm) and is also attached as Appendix 18.



There is breaking and entering into pharmacies, and during the time that temazepam capsules were favoured for abuse there was a spate of pharmacy thefts. I have heard a pharmacist [who was] the subject of a pharmacy break-in describe the observations of one of the shopkeepers across the road. People pulled up in a car and, with a sledgehammer smashed the door down, walked in, went to the pharmacy storage area where the drugs were stored, took all of the temazepam capsules and left the temazepam tablets, on the way out smashed a camera and took a few sunglasses and some perfume, and were gone within five minutes. There was also a series of ram raids where people stole cars, drove through the windows of pharmacies and stole temazepam capsules.<sup>213</sup>

Also referring to pharmacy burglaries during the time when temazepam capsules were available, Mr Steve Marty described how:

It used to surprise me that, on visiting pharmacies, I would look at the top shelves and say, 'You must have a wish to be broken into, because if you're going to have 12 dozen on display up there, you might as well have a sign at the front door that says, "After-hours drug supply, break glass and enter"', because that is exactly what happened. There were ram raids, where they use a car, back into the front door, smash it and get in and out within a couple of minutes. Those capsules were sold for \$5 on the street, so if they stole a couple of hundred bottles of 25, there was a big return for them.<sup>214</sup>

Anecdotal evidence suggests that as a result of Victoria's 'Temazepam Initiative'<sup>215</sup>, criminal activity directed at pharmacies, particularly armed robberies and burglaries, may have decreased. Nonetheless such incidences still occur as the following quote from Steve Marty indicates.

Narcotics, of course, are a source of armed hold-ups to pharmacies. It comes and goes. There was recently one in the Mornington Peninsula where the person demanded specific drugs. They would have done their homework to work out that that pharmacy happened to have a number of people taking Ritalin and oxycodone. They are well informed in this.<sup>216</sup>

However, it should be noted that there is very little recent data that accounts for crime directed at pharmacies. Indeed, it is of concern that the most recent data available with regard to crime directed towards pharmacies (theft, burglary, robbery and armed robbery) is for the financial year 2002-2003.<sup>217</sup> Moreover, the little data available in this area does not differentiate between drug types. For example, it is almost impossible to get information as to the level of theft of benzodiazepines or opioids as a class of drug, let alone theft of individual drug types within that class (for example alprazolam or oxycodone).

This is to be distinguished from the United States where more comprehensive and recent data with regard to the links between prescription drug abuse and criminal activity is collated (CASA 2005, RADARS 2007). For example, CASA reports that in the United States, concern about theft of drugs from pharmacies is increasing and in recent years OxyContin® has been the goal of the bulk of pharmacy robberies across that country (CASA 2005).

213 Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, Department of Human Services, Briefing given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 29 May 2006.

214 Mr Steve Marty, Registrar, Pharmacy Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 19 June 2006.

215 See discussion in Chapter 2.2.

216 Mr Steve Marty, Registrar, Pharmacy Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 19 June 2006.

217 This includes data from the Pharmacy Guild Insurance Group and LEAP data from Victoria Police as reproduced in NDLERF 2007.

### ***Theft from pharmaceutical companies and wholesalers***

The Australian Centre for Policing Research (2002) in their report *The diversion of pharmaceutical drugs onto the illicit drug market* noted that whilst the value of pharmaceutical drugs creates the possibility of diversion at the wholesale or retail level, the degree of monitoring that occurs over all levels of the supply chain for Schedule 8 drugs (but not for lower scheduled drugs) meant it was less likely that large-scale diversion from the supply chain would occur. The Victorian Branch of the Pharmaceutical Society of Australia shares this view (Lloyd, Guibert & Bell 2000).

However, this does not mean that pharmaceutical theft at wholesale level does not occur in Victoria. Senior representatives of the pharmaceutical industry gave evidence to the Committee that whilst relatively uncommon such theft did occur:

[t]he pharmaceutical industry: is somewhat unique in that the black market value of many of the products is significantly higher than its commercial value. This disparity and the increasing gap between the illicit demand for these products and its easy supply is a major factor in the derivation of much of Sigma's security risk....We have everything the chemist shop has but in a lot more aggregation. We can get leakage from outside if we are not careful. We get it through internal theft, burglary, material substitution...armed robbery...

As a general rule we spend a lot of money to prevent the unlawful acquisition of these sorts of products.<sup>218</sup>

In the United States, CASA (2005) has indicated that there are a number of opportunities in the supply chain for diversion to occur. Drugs may be stolen from wholesalers and sometimes exchanged for counterfeit drugs. Drugs can change hands several times along the supply chain before reaching the end user. Further, an 1,800 per cent increase in media stories on wholesale supply theft in the United States (Brushwood & Kimberlin 2004) indicates a substantial problem in that country, if not in our own.

### **Access by those engaging in criminal activity**

Some patients engage in organised criminal schemes to acquire pharmaceutical drugs to re-sell on the illicit market. For example, Forgione, Neuenschwander and Vermeer described a scheme in Chicago which:

employed 'professional' cancer patients. When doctors were confronted with a quadriplegic or cancer patient, they tended to write the requested prescription out of empathy for the alleged 'patient.' [The group] collected Dilaudid [hydromorphone] prescriptions...diverting more than 60,000 tablets (Forgione, Neuenschwander & Vermeer 2001, p.66).

One startling anecdote was related to the Committee by a nurse practising in a drug and alcohol clinic in Bendigo. It reveals the somewhat ingenious tactics a 'professional' prescription drug diverter may use in accessing and trading these drugs:

I got a very detailed report once from a client about his services to a local neighbourhood community that were mostly single mothers. The single mothers were sourcing the benzos, and he got paid in drugs. That was his currency for what he needed. He did not need to use them himself but he sold them on. So these women were legitimately getting their benzos from their doctor because they are single mothers, they are stressed, they are looking after children and whatever and they have stress and anxiety or goodness knows what or cannot sleep and are freely getting quite significant amounts of benzos.<sup>219</sup>

A comparable story was told to the Committee pertaining to experiences in another Victorian provincial city. Dr David Richards, a drug and alcohol clinician from

218 Mr Peter Thomas, National Security Manager, Sigma Pharmaceuticals, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Pharmaceutical Company Forum, Melbourne, 16 July 2007.

219 Ms Cheryl Sobczyk, Clinical Nurse Manager, Bendigo Community Health Services, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Bendigo, 30 May 2007.



Warrnambool, related the following account of various methods used to divert and trade prescription drugs in that town:

Anecdotally, I hear stories of groups watching pharmacies and approaching people – not always without threat – when they have left the pharmacy, with offers for the medication that they might have picked up. I have heard stories of significant violence against people who have refused to sell. Initially that was a couple of pharmacies – one in Portland and one in Colac – where it was happening, but it is becoming more general, and that is a worry. ...

I also often tell my colleagues of an experience that I had, many years ago now, when a delightful little old lady who was a patient of mine in general practice in another part of the state started to have some falls. I suggested to her that perhaps we would reduce her dose of temazepam at night and she said, 'But, doctor, I only take one', and I said, 'But I'm giving you a prescription for two a night'. She said, 'Yes, but there's a nice man who comes and does my shopping and cuts my grass, and I give him one of those'.

Equally, we have a current problem with a patient here who is dying. She is a young woman with a young family, who is dying of a malignant disease. She is in a significant amount of pain and she is selling oxycodone.<sup>220</sup>

### Access via the Internet

Access to prescription pharmaceuticals such as benzodiazepines and narcotic analgesics over the Internet is a relatively recent phenomenon.<sup>221</sup> There is a growing body of evidence showing that internationally and in Australia:

- 1) Large numbers of Internet sites exist online and provide these drugs, many without the need for a prescription;
- 2) Many of these sites can be easily found by using standard web browsers and simple search terms;
- 3) Other sites show how diverted pharmaceuticals can be doctored for misuse (see, for example, Cone 2006);
- 4) There is case study and research evidence that both internationally and in Australia drug users are accessing these drugs online;
- 5) It is probable that Internet access will become a growing source of access for pharmaceutical drugs for at least a sample of illicit drug users; and
- 6) Evidence from the United States shows that the Internet poses problems for authorities wanting to restrict access to these drugs for non-medical use, as the following quote from CASA highlights:

Illegal Internet pharmacies have introduced a new avenue through which unscrupulous buyers and users can purchase controlled substances for unlawful purposes. These pharmacies – many of them based outside the U.S. – sell a variety of prescription medications including controlled drugs. Some of these pharmacies provide consumers with prescription drugs without a physical examination by a physician. The consumer fills out an online questionnaire that is reportedly evaluated by a physician affiliated with the online pharmacy. Without ever meeting the patient face-to-face, the physician approves the questionnaire and then authorizes the Internet pharmacy to send the drug to the patient. Tens of thousands of 'prescriptions' are written each year for controlled and non-controlled prescription drugs through such internet pharmacies, none of which require medical records, examinations, lab tests or follow-ups. Some of these 'rogue' internet pharmacies provide such online consultations free of charge; others refer customers to 'script' doctors who are willing to write prescriptions for cash. Finally, some internet pharmacies dispense prescription drugs without even the pretense of having a physician's prescription (CASA 2005, pp.63–64).

<sup>220</sup> Dr David Richards, Addiction Medicine Physician, Western Region Alcohol and Drug Centre, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Warrnambool, 29 May 2007.

<sup>221</sup> This will be discussed in Chapter 5.3.

An earlier paper in the *Medical Journal of Australia* by St George, Emanuel and Middleton (2004) provided a case example of an Australian patient who did access Schedule 8 drugs online:

A 20-year-old patient was referred for management of anxiety and polydrug misuse. The patient related that anyone could be a misuser and pusher of drugs without relying on illicit suppliers of such drugs or 'doctor shopping'. A click of a mouse could supply whatever drug a patient wanted from online pharmacy services available 24 hours a day. These sites are easy to use and often require little more than a credit card number to gain access to a wide range of prescription drugs, such as diazepam, alprazolam, temazepam, methylphenidate, morphine and codeine. The patient had a 2-year history of using large amounts of zolpidem, temazepam, alprazolam and diazepam with alcohol, as well as regular use of marijuana. These medications were originally obtained by doctor shopping for prescriptions. However, while researching these medications on the Internet, our patient discovered the online pharmacies that dispensed prescription medication without a script. Zolpidem, oxycodone and methylphenidate were all ordered by the patient from online pharmacies based in Mexico and Thailand. He 'surf'ed the Internet for the site with the cheapest drugs and found one that sold 100 zolpidem, his drug of choice, for US\$70.00, with a delivery charge of US\$5.50. He was able to order quantities of 100, 200 or 500 tablets. It took 2 weeks for the discreetly packaged drugs to arrive at the patient's door. The patient volunteered this information during therapy for drug addiction and was quick to see the negative implications. After a period of counselling about the causes of medication misuse, he was motivated to cease further ordering and willing to undergo drug detoxification (St George, Emanuel & Middleton 2004, p.118).

Commenting on the above article in a *Medical Journal of Australia* editorial, Gijsbers and Whelan (2004) asked:

What should we now do? We need more data, and cases like that described by St George et al help to alert health professionals in the field to this new drug source. The suggestions put forward by St George and colleagues have merit, but, without more data, their alarm may be premature. In the past, drug control on the supply side, especially of illicit drugs, has produced disappointing results (Gijsbers & Whelan 2004, p.103).

Mr Steve Marty shared this concern in his evidence given to the Inquiry:

There is meant to be 100 per cent X-ray scanning of mail and parcels into Australia, but th[ey] cannot possibly detect [all mail and small parcels] at the border, particularly when Customs are looking for larger things, such as container loads of pseudoephedrine that have happened in the last couple of years. Picking up a bottle of something for an individual is fairly low on the pecking order and it is very difficult to open every single pack and identify the contents.<sup>222</sup>

Regarding Internet pharmacies in Australia, Mr Marty was more confident about the controls in place:

There are Internet pharmacies in Australia. We look at those websites, along with the police. Sometimes they test purchase on those. Most of them in Australia do not do it too badly...all the ones that I have looked at in fact say quite clearly up-front, 'You must have a prescription'...It is a problem from overseas: for someone to legally be in possession, they need to have a prescription from a medical practitioner registered in the state in which they are resident. That allows them to be in lawful possession.<sup>223</sup>

222 Mr Steve Marty, Registrar, Pharmacy Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 19 June 2006.

223 Mr Steve Marty, Registrar, Pharmacy Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 19 June 2006.



For further discussion of Internet and mail order access to prescription drugs, see Chapter 5.3 of this Final Report.

## Summary

Although there is a lack of local studies of methods of accessing pharmaceutical drugs for non-medical use, there is enough in the international published literature and the accounts of local clinicians, regulators and others to at least gain a basic understanding of the methods used. This section has provided accounts of 'doctor shopping'; the use of forged, stolen or altered prescriptions; acquisition from friends and family; diversion by pharmacy staff and other health care workers; retail theft; theft from pharmaceutical suppliers and wholesalers; access from criminals and other drug users; and finally the emerging trend of access via the Internet. However, without in-depth qualitative accounts at a local level of how these activities fit in with the broader experience of people's lives, educational, policy, regulatory and treatment responses to pharmaceutical drug misuse will be inadequate.

## Case example: The non-medical use of OxyContin<sup>®224</sup> in the United States – Lessons for Australia?

The issue of non-medical use of pharmaceutical drugs has been more prominent in the public consciousness in the United States than it has been in Australia. This is largely due to the widespread misuse of OxyContin<sup>®</sup>, a formulation of oxycodone which is prescribed for pain relief. The development and impact of 'OxyContin<sup>®</sup>' has been the subject of a number of United States government reports (eg. CASA 2005; United States General Accounting Office 2003) and media stories (eg. Tough 2001).<sup>225</sup> The widespread prescription of this opioid drug for treatment of non-cancer pain has been implicated in the increasing misuse of the drug in that country.<sup>226</sup> But as will be discussed in Section Seven a change in 'pain culture' and its treatment is also noticeable in Australia.

### *The development of OxyContin<sup>®</sup>*

In 1995 OxyContin<sup>®</sup> (Purdue Pharma) was approved by the Food and Drug Administration (FDA) in the United States as a sustained-release preparation of oxycodone. As OxyContin<sup>®</sup> is formulated to be released over a 12-hour period it was thought to have much lower abuse risk than immediate-release oxycodone (CASA 2005; Cicero, Inciardi & Munoz 2005).

OxyContin<sup>®</sup> was preceded by Purdue's older product, MS Contin, a morphine-based product that was approved in 1984 for pain of a similar intensity and duration and was promoted during its early years for the treatment of cancer pain (United States General Accounting Office 2003).

However in 2000, widespread reports of OxyContin<sup>®</sup> abuse surfaced (Heye et al 2002; Cicero, Inciardi & Munoz 2005). The problem was initially most serious in Maine and in the Appalachian states of Kentucky, Virginia and West Virginia. Its abuse was described as 'epidemic' in these areas (CASA 2005; United States General Accounting Office 2003).

<sup>224</sup> OxyContin<sup>®</sup> is a narcotic analgesic – see Chapter 1.2, Table 1.2c.

<sup>225</sup> The issue of OxyContin<sup>®</sup> in the media has been at times somewhat controversial. Tough's analysis of OxyContin<sup>®</sup> use and abuse in the Appalachian regions of the USA is a good case in point (Tough 2001). Couched in the style of investigative journalism for which the *New York Times* is renowned, it was a hard hitting and evocative portrait of the insidious nature of prescription drug addiction. But this and other reports have had their detractors. For example, Trevor Butterworth on behalf of the Statistical Assessment Service is particularly scathing of media coverage of OxyContin<sup>®</sup> abuse in the USA. He states that: 'By portraying OxyContin as a home grown weapon of mass destruction, the media have inflicted enormous damage to the medical community's attempts to treat chronic pain in millions of Americans' He continues in the context of the Tough article:

'In sum, it is hard to see what the [New York] Times got right in its coverage of OxyContin<sup>®</sup> abuse. Like the supposed existence of WMD's [Weapons of Mass Destruction], the apparent epidemic of OxyContin<sup>®</sup> abuse in America has led to a war. And it's a war that America will lose, if people in pain cannot go to their local physician and get treatment they need to make life bearable. The Times apologised for their exaggerating the threat of WMD in Iraq; it can do the same with OxyContin<sup>®</sup>' (Butterworth 2004, pp.6–7).

<sup>226</sup> The rate of legitimate prescription and use of OxyContin<sup>®</sup> in Australia is showing a similar trend (see Chapter 2.1).



Mainstream media started reporting OxyContin® abuse in early 2000. This coverage, according to some commentators, led to a great increase of OxyContin® mentions on the Internet. In the view of Heye et al the Internet more than any other means has served to accelerate the 'education' of abusers with regard to OxyContin® and other prescription drugs (Heye et al 2002).<sup>227</sup>

Illicit drug users had learned that by crushing the tablet the sustained release coating could be disabled and then the drug could be snorted, swallowed or dissolved in water for injection, producing an instant euphoria. As a result, OxyContin® became a popular alternative to street heroin, being termed 'poor man's heroin' or 'hillbilly heroin' (Katz & Hays 2004).<sup>228</sup> In Kentucky, as elsewhere, there were notorious cases of doctors over-prescribing OxyContin®. For example, one Harlan County urologist was sentenced to 20 years in federal prison after being convicted for improperly dispensing the drug. He was seeing up to 133 patients in a day and charging them a fee of \$65 each, for an OxyContin® prescription (Tunnell 2005).

After learning about the initial reports of abuse and diversion of OxyContin in Maine in 2000, Purdue formed a response team made up of its top executives and physicians to initiate meetings with federal and state officials in Maine to gain an understanding of the scope of the problem and to devise strategies for preventing abuse and diversion. After these meetings, Purdue distributed brochures to health care professionals that described several steps that could be taken to prevent prescription drug abuse and diversion (United States General Accounting Office 2003, p.10).

By 2001, OxyContin® was the most frequently prescribed non-generic narcotic medication for the treatment of moderate-to-severe pain in the United States (United States General Accounting Office 2003). The statistics on OxyContin® prescription in the United States are presented in Chapter 2.1.

According to Katz and Hays (2004), since its introduction into the marketplace in 1995 there have been media reports of OxyContin® abuse contributing to overdose deaths, and as of 2002 there were 450 OxyContin®-related overdose deaths reported. By 2002 some 50 to 90 per cent of new methadone patients in Kentucky, Virginia, West Virginia and Pennsylvania were identifying OxyContin® as their primary drug of abuse. Yet there were also criticisms of the media portrayals of OxyContin® misuse and deaths – some claiming that mentions of OxyContin® in emergency room presentations in the United States increased in response to media stories which amounted 'to easy-to-follow instructions on the correct abuse procedure' (Butterworth 2004).

Irrespective of the mechanisms involved, the evidence is that OxyContin® abuse has spread throughout the United States, and one of the factors further fuelling its widespread diversion has been its street value of 10 times its legitimate cost (CASA 2005). Recent data collected from a project funded by Purdue Pharma for the development of an abuse surveillance programme, termed the Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS®)<sup>229</sup> system, concluded that prescription drug abuse was prevalent across the country, with OxyContin® being rated by key informants as the most prevalent drug of abuse (Cicero, Inciardi & Munoz 2005).

Of particular concern in the United States has been the seeming prevalence of abuse of OxyContin® among adolescents and young people, as indicated in the data presented in Chapter 2.1. Katz and Hays have reviewed several case reports of OxyContin® use among American teenagers. For example, a survey at a rural Michigan high school showed that 98% of students had heard of OxyContin® and 9.5% had regularly tried it, often sourcing

227 In particular the Internet has been 'instructive' in showing abusers how to subvert the time-release mechanism of the OxyContin formula (Heye et al 2002).

228 Although some commentators have viewed OxyContin® as a 'gateway' drug to heroin, particularly for young people. See Siegal et al 2003 and discussion in Chapter 2.2 of this Report.

229 The RADARS system is discussed further in the context of prescription drug monitoring programmes below.



it from friends and/or family, usually clandestinely.<sup>230</sup> Seventy-two percent of the survey participants indicated that it was 'not at all hard to get OxyContin®' (Katz & Hays 2004, p.231). Of particular concern to the authors was that the abuse of opioid medications by young people may not only result in serious addictions to those drugs but also may lead to later heroin use – the so called 'gateway drug effect' (Katz & Siegal 2004; see also Siegal et al 2003).<sup>231</sup>

### *The marketing of OxyContin®*

Whilst the pharmaceutical company Purdue Pharma has been praised for its efforts to combat prescription drug diversion through programmes such as RADARS, conversely, Purdue has also received substantial criticism in both the media (eg. Tough 2001) and United States Government agency reports (eg. United States General Accounting Office 2003), for what has been described as its aggressive marketing of OxyContin® in that country:

Purdue conducted an extensive campaign to market and promote OxyContin that focused on encouraging physicians, including those in primary care specialties, to prescribe the drug for non-cancer as well as cancer pain. To implement its OxyContin campaign, Purdue significantly increased its sales force and used multiple promotional approaches. OxyContin sales and prescriptions grew rapidly following its market introduction, with the growth in prescriptions for non-cancer pain outpacing the growth in prescriptions for cancer pain. DEA [Drug Enforcement Agency] has expressed concern that Purdue marketed OxyContin for a wide variety of conditions to physicians who may not have been adequately trained in pain management. Purdue has been cited twice by FDA for OxyContin advertisements in medical journals that violated the FD&C Act. FDA has also taken similar actions against manufacturers of two of the three comparable schedule II controlled substances we examined, to ensure that their marketing and promotion were truthful, balanced, and accurately communicated. In addition, Purdue provided two promotional videos to physicians that, according to FDA, appear to have made unsubstantiated claims and minimized the risks of OxyContin. The first video was available for about 3 years without being submitted to FDA for review (United States General Accounting Office 2003, pp.16–17).

The United States General Accounting Office (2003) also points out that:

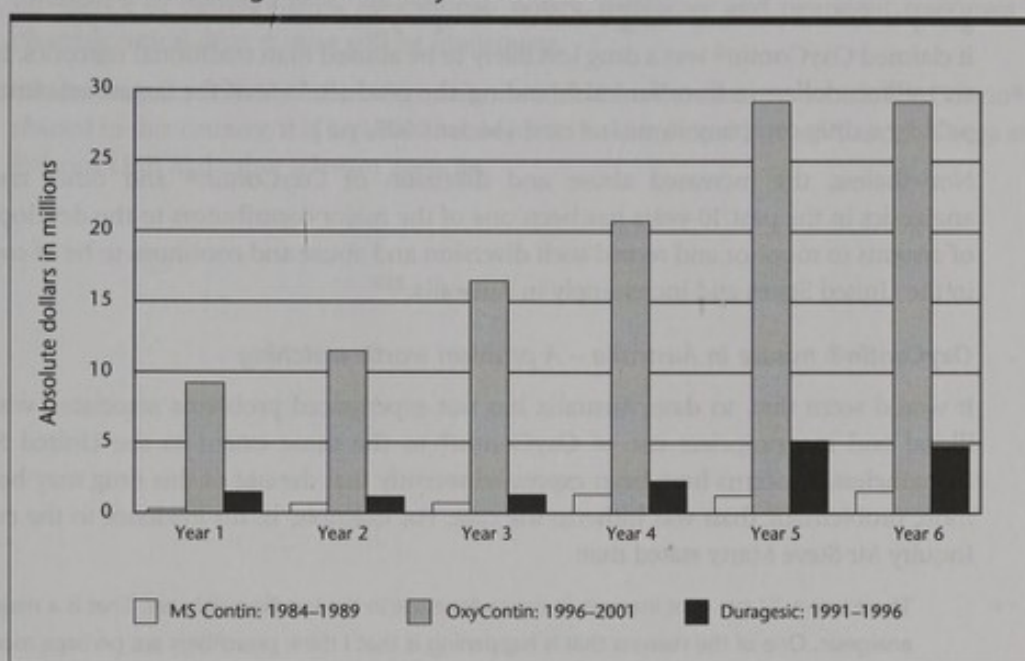
According to DEA's analysis of IMS Health data, Purdue spent approximately 6 to 12 times more on promotional efforts during OxyContin's first 6 years on the market than it had spent on its older product, MS Contin, during its first 6 years, or than had been spent by Janssen Pharmaceutical Products, L.P., for one of OxyContin's drug competitors, Duragesic (United States General Accounting Office 2003, p.21).

230 Of particular concern to the authors was that the adolescents in their study began using OxyContin® in mid teens, an age range at low risk for heroin or other opioid use. Moreover a high proportion of the teenagers in their sample accessed the drug from parents who were using it for pain management: 'In many of the patients we have seen, parental [use] or dependence on opioids was a significant risk factor for adolescent abuse' (Katz & Hays 2004, p.233).

231 The phenomenon of prescription drugs being 'gateway drugs' is discussed in Chapter 2.2.

Figure 2.4c below illustrates this comparative promotional expenditure.

**Figure 2.4c: Promotional spending for OxyContin® and two other analgesics in the United States during their first six years of sales**



Note: Dollars are 2002 adjusted.

Source: United States General Accounting Office 2003, p.22.

Originally the FDA in the United States permitted Purdue Pharma to imply in its labelling that OxyContin® had a lower abuse potential than other opioids because of its 12-hour time-release mechanism. However, according to CASA (2005), because the time-release mechanism can be subverted, as described above, OxyContin® seems to have a greater abuse potential than other opioid drugs. The original safety warning on the label, since revised in the light of FDA requirements, instructed users 'not to crush the pills as when crushed, toxic levels of the drug could be released'. In CASA's view, 'This labelling may have suggested to drug abusers how to abuse the drug' (CASA 2005, p.21). Moreover, it has been observed that:

The press coverage of the diversion and abuse of OxyContin has helped shape the public's perception of the magnitude of the overall problem of controlled prescription drug diversion and abuse in the U.S. and has raised considerable awareness. In response to public outcry and pressure from the DEA and FDA, Purdue Pharma adjusted some of its marketing practices, launched an educational campaign and, together with the FDA, implemented a risk management plan – aimed at detecting and preventing diversion and abuse – for the drug (CASA 2005, p.21).

According to CASA (2005) the company also employed websites to inform consumers and others about pain and associated matters. One of these sites, established in 1997, was called 'Partners Against Pain'. This site aims to provide consumers with information about options for management and treatment of pain. This was in part to remedy an earlier situation where it had been argued that Purdue Pharma had heavily promoted OxyContin® to general practitioners 'who often had little training in treating serious pain or in recognising signs of drug abuse' (Meier 2007, p.2). Notwithstanding such efforts, the DEA criticised Purdue Pharma for not adding an antagonist agent to OxyContin® to prevent its abuse, as has been done with buprenorphine in Australia (Suboxone) and with Talwin® decades ago in the United States (CASA 2005). Purdue claims to be working to change the formulation of OxyContin® to make it less able to be abused (Tough 2001). Whilst attempts to develop narcotic analgesics with minimal abuse potential are laudable



(Compton & Volkow 2006), at this stage no further information is available on Purdue's progress in this regard.<sup>232</sup>

In May 2007 Purdue Pharma and three of its current and former Chief Executives pleaded guilty to federal criminal charges that the company had misled doctors and patients when it claimed OxyContin® was a drug less likely to be abused than traditional narcotics. It paid six million dollars in fines for 'misbranding' the product, 'one of the largest amounts ever paid by a drug company in such a case' (Meier 2007, p.1).

Nonetheless, the increased abuse and diversion of OxyContin® and other narcotic analgesics in the past 10 years has been one of the major contributors to the development of systems to monitor and record such diversion and abuse and continues to be of concern in the United States and increasingly in Australia.<sup>233</sup>

### *OxyContin® misuse in Australia – A problem worth watching*

It would seem that, to date, Australia has not experienced problems associated with the illegal and inappropriate use of OxyContin® to the same extent as the United States. Nonetheless, concerns have been expressed recently that the use of this drug may become more problematic than was hitherto the case. For example, in his evidence to the current Inquiry Mr Steve Marty stated that:

There was a 24 per cent increase in oxycodone use in the last financial year. That is a major analgesic. One of the reasons that is happening is that I think prescribers are perhaps more confident to [prescribe] narcotics than they might have been. In previous years, they thought of this as being a last resort.<sup>234</sup>

In 2005, due to anecdotal reports about increasing use of illicit oxycodone among injecting drug users, questions specifically about oxycodone were added to the survey of Australian injecting drug issues conducted annually as part of the illicit Drug Reporting System (IDRS) (Stafford, Degenhardt, Black et al 2006). In 2005, 15 per cent of Victorian injecting drug users surveyed as part of the IDRS said they had injected oxycodone in the previous six months, with OxyContin® being the most commonly used product (Jenkinson & O'Keefe 2006). In 2006, 24 per cent of Victorian injecting drug users said they had injected illicit oxycodone in the previous six months (O'Brien et al 2007).

The activities of drug users, treatment providers, regulators, pharmaceutical companies and the media in the example of OxyContin® misuse in America is one that should inform the response to non-medical use of this and other pharmaceutical drugs in this country.

## **Conclusion**

This chapter provided an overview of how people who use benzodiazepines and narcotic analgesics for non-medical purposes access these drugs. Consideration of the way these drugs are accessed reveals the challenges posed to regulators, professional associations, the private sector and individual health professionals.

Compared to other drug problems in Australia, there is a dearth of information on the culture of non-medical use of pharmaceutical drugs. Whilst the international literature, drug trends monitoring provided by the IDRS, and submissions provided to this Inquiry

<sup>232</sup> There have been a number of legal actions filed in United States courts against the company:

'According to Purdue, as of early October 2003, over 300 lawsuits concerning OxyContin were pending against Purdue, and 50 additional lawsuits had been dismissed. The cases involve many allegations, including, for example, that Purdue used improper sales tactics and over-promoted OxyContin causing the drug to be inappropriately prescribed by physicians, and that Purdue took inadequate actions to prevent addiction, abuse and diversion of the drug. The lawsuits have been brought in 25 states and the District of Columbia in both federal and state courts' (United States General Accounting Office 2003, p.10).

<sup>233</sup> Statistics on the growth of OxyContin® prescriptions in Australia (and the United States) are presented in Chapter 2.1. In Australia OxyContin® is produced and marketed by Mundipharma Pty Ltd, an associate company of Purdue. See [www.mundipharma.com.au](http://www.mundipharma.com.au).

<sup>234</sup> Mr Steve Marty, Registrar, Pharmacy Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 19 June 2006.







## PART B:

# Strategies to Reduce Misuse of Prescription Drugs

## Section Three: Regulatory and Legal Issues

### 3.1 Legal and Regulatory Aspects of Pharmaceutical Drug Use

The structures of drug regulation that exist today – drug laws, drug regulatory agencies, drug evaluation boards, quality control (QC) laboratories, drug information centres, etc. – have evolved over time. During this process, the scope of legislative and regulatory powers has been gradually expanded, in response both to the ever-increasing complexity of an increasingly sophisticated pharmaceutical sector, and to the perceived needs of society. In some countries the enactment of comprehensive drug laws was a result of crisis-led change, when public demand led to the adoption of more restrictive legislation to provide stronger safeguards for the public. Drug regulation is therefore a public policy response to the perceived needs of society. Consequently, drug laws need to be updated to keep pace with changes and challenges in their environment (World Health Organization (WHO) 2002, pp.1–2).

This chapter predominantly concerns Commonwealth regulation of prescription drugs and controlled substances. It looks at the role of the Therapeutic Goods Administration (TGA), the process of *scheduling* drugs and drug licences. It also looks briefly at the regulations and processes surrounding their advertising, labelling, and storage and recording mechanisms. A key aspect of this section is a discussion of the *Review of Drugs, Poisons and Controlled Substances Legislation* (hereinafter called The Galbally Review).<sup>235</sup>

It should be noted at the outset that this is a very complex area of regulation that is frequently subject to change and review. The review of pharmaceutical drug regulation in

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235 The review of the Drugs, Poisons and Controlled Substances legislation (The Galbally Review) was undertaken in 2000 and will be discussed later in this chapter.



this Report is by necessity basic, drawing only upon the most essential features of the current framework.<sup>236</sup>

The second part of the chapter very briefly gives an overview of the various controls that have been put in place at state level to ensure that drugs such as benzodiazepines are used only for the purposes for which they were produced. Most discussion with regard to the state system for permits, authorities and controls, however, is more conveniently located in Chapter 3.2 in the section that pertains to the monitoring of prescription drugs and state review of prescribing and dispensation practices.

This chapter in conjunction with the material in Section Four provides the legal background and context for the discussion in Chapter 5.1 pertaining to the interventions and programmes used by pharmacists, medical practitioners and regulatory bodies to combat abuse of pharmaceutical drugs in Victoria.

### **Commonwealth and state regulation of pharmaceutical drugs in Australia**

The system of drug regulation in Australia today is comprehensive, yet complex. This section traces the evolution of drug regulation in Australia and Victoria, the current modes of control and suggested recommendations for reform. It also examines the regulatory framework that governs the way in which pharmaceutical drugs enter the market. This system is for the most part jointly administered through Commonwealth and state authorities. The various and overlapping responsibilities between Commonwealth and state/territory authorities and the laws they administer is presented in Table 3.1a.

<sup>236</sup> For example, the combined length of the *Therapeutic Goods Act 1989* and its associated regulations is over 600 pages, not including associated guidelines, appendices, codes and other related documents.

**Table 3.1a: Commonwealth and state responsibilities for medicines and drugs control in Australia**

<b>Commonwealth</b>	
<u>Law or Instrument</u>	<u>Remarks</u>
<ul style="list-style-type: none"> <li>Commonwealth Constitution</li> <li>Section 51 (i) Interstate Trade</li> <li>Section 51 (xx) Corporations</li> <li>Section 51 (xiiiA) Pharmaceutical benefits</li> <li>Section 51 (xxix) External affairs</li> </ul>	<p>Gives the Commonwealth exclusive powers to regulate in the field of drug control where the actions cross jurisdictional boundaries and fall within relevant listed powers under Section 51.</p> <p>Other regulatory interventions or models must be adopted by reference or through mirror legislation into state law.</p>
<ul style="list-style-type: none"> <li><i>Therapeutic Goods Act 1989</i></li> </ul>	The <i>Therapeutic Goods Act</i> established the Therapeutic Goods Administration (TGA), which governs the listing process for most drugs and medicines in Australia, the licensing of drugs manufacturers and administers the laws and policies with regards to advertising, labelling and packaging of medicines and other drugs and poisons at a national level.
<ul style="list-style-type: none"> <li>Therapeutic Goods Regulations 1990</li> </ul>	Supplements the <i>Therapeutic Goods Act</i> with more detailed administration procedures and processes
<ul style="list-style-type: none"> <li>Therapeutic Goods Orders</li> </ul>	Orders made by the Minister under section 10 of the <i>Therapeutic Goods Act</i> . These orders specify the standards or directives for therapeutic goods.
<ul style="list-style-type: none"> <li>Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP)</li> </ul>	The SUSDP is drawn up by the National Drugs and Poisons Schedule Committee and is issued by the Australian Health Ministers' Advisory Council (AHMAC). It is adopted by reference or mirror legislation into state and territory legislation.
<ul style="list-style-type: none"> <li>Therapeutic Goods Advertising Code (TGAC) 2006</li> </ul>	The Code ensures the marketing and advertising of therapeutic goods to consumers is conducted in a manner that promotes the quality use of therapeutic goods.
<ul style="list-style-type: none"> <li>Various Therapeutic Goods Administration Committees</li> </ul>	See Figure 6.2 for a list of these supplementary committees and agencies and their functions.
<b>Victoria</b>	
<u>Law or Instrument</u>	<u>Remarks</u>
<ul style="list-style-type: none"> <li><i>Therapeutic Goods (Victoria) Act 1994</i></li> </ul>	State 'mirror' legislation that complements and adopts most of the provisions of the <i>Therapeutic Goods Act 1989</i> (Commonwealth). In particular, it incorporates procedures with regard to listing and registration and evaluation of therapeutic goods in Victoria.
<ul style="list-style-type: none"> <li>Drugs Poisons and Controlled Substances Act (DPCSA) 1981               <ul style="list-style-type: none"> <li>- Division One</li> <li>- Divisions Four and Ten</li> <li>- Part Five</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Poisons List and Poisons Code adopts Commonwealth standards with regard to drug scheduling.</li> <li>Administers and governs issuing of permits and licences to prescribe, dispense or administer scheduled drugs of dependence. Generally regulates prescribing and administration of Schedule 4, 8 and 9 poisons including prescription medicine offences.</li> <li>Provides for criminal law offences and penalties with regard to drugs of dependence.</li> </ul>
<ul style="list-style-type: none"> <li>Drugs Poisons and Controlled Substances Act Regulations 2006</li> </ul>	Supplements the DPCSA with more detailed prescription regulations controlling the administration of drugs and poisons in Victoria.
<ul style="list-style-type: none"> <li><i>Road Safety Act 1986</i> – Section 49 (i) (ba)</li> </ul>	Provides for an offence of driving a motor vehicle while being drug impaired (includes prescription drugs).
<ul style="list-style-type: none"> <li><i>Road Safety (Drug Driving) Act 2003</i></li> </ul>	Provides for random breath testing of suspected drug drivers comparable to alcohol breath testing. Currently only applies to certain illicit drugs.



The legislative regulation of pharmaceutical drugs, poisons and controlled substances reflects a concern that a system where there are no controls over these drugs would lead to consumers being at risk:

As the use of such substances grew, and as concern over their misuse developed, official controls were increasingly introduced (Galbally 2000b, p.151).

Before examining the legal mechanisms pertaining to Australian drug regulation in detail it is necessary to place such a review in its historical and philosophical context.

### *History of drug regulation in Australia*

For most of us living nowadays in developed societies, a prescription system is a taken-for-granted part of the social order. Yet for the most part, the prescription system as we have specified it is less than a century old as a mandatory system or even as a normative mode of practice. In Britain prior to 1913, prescriptions in the modern sense existed, but they were relatively unimportant. Instead there were two largely separate systems of provision of medications. Those who could afford to see a physician received their medicines directly from their doctor, with the doctors doing 90% of the dispensing themselves (Berridge & Edwards, 1981:115). Meanwhile, the poor purchased medicines from pharmacists or druggists without a doctor's prescription (Room 2007, pp.2–3).

It is thought that the first legislative control of drugs and poisons in England (and by extension the Australian colonies) was through the *Arsenic Act 1851* (Jones 2000).<sup>237</sup> Over the next 100 years a series of pharmacy, drug regulation and poisons Acts were enacted in the Australian states federated in 1901. But as Robin Room indicates in the quote above, any systematic regulation of prescribing and pharmacy was rudimentary prior to the twentieth century. At that time in both Britain and Australia a range of legislative instruments increasingly regulated at local level the manufacture, distribution, sale and quality of medicines, drugs and other pharmaceutical goods.<sup>238</sup>

In Australia, prior to the Second World War any controls over the distribution and retailing of drugs were primarily the responsibility of state governments and there was only limited concern with drug evaluation (Industry Commission 1996a, p.42).<sup>239</sup> The first committee to advise on the evaluation of pharmaceutical drugs was established by the State of Victoria in 1948 (WHO 2002). This Committee, however, could only review those products sold within the state boundaries of Victoria.

In the 1950s the National Biological Standards Laboratory introduced limited drug evaluation procedures at the Commonwealth level.<sup>240</sup> Tests were undertaken to ensure therapeutic goods complied with applicable standards in the United Kingdom.<sup>241</sup>

237 In the mid 19th century, death from poisoning was a major cause of mortality. Arsenic was often implicated as the causative agent. As a result, in Britain the then newly incorporated Pharmaceutical Society, together with the doctors, lobbied for the government to introduce legislation on this subject (Jones 2000):

'The Arsenic Act of 1851 resulted and was the first measure introduced in an attempt to control the sale of any poisonous substance. A record of the transaction was to be made in a book which both vendor and purchaser would sign. The Act applied only to arsenic. Sales were not restricted to premises occupied by the newly emerging chemists and druggists and it appeared that any trader could sell it, provided a record was kept' (2000, p.938).

The Arsenic Act in turn led soon after to the *Pharmacy Act of 1868* and the colonial Australian equivalents.

238 For a general account of the history of pharmacy and pharmaceutical regulation in Australia, see Miller 2005. For a review of the history of drug regulation from a British perspective generally, see Griffin and Shah 2006.

239 Whilst the Commonwealth Department of Health was established in 1921, most health-related regulation was the province of the states until the early 1950s. In 1953 the *Therapeutic Substances Act* was enacted giving the federal government control over imported therapeutic substances, drugs of addiction and the interstate trade of these substances (Hirshorn & Monk 2006, p.653).

240 The relevant constitutional authority giving the Commonwealth legal powers over pharmaceutical drug regulation (across state borders) is found in Section 51 of the Commonwealth Constitution, particularly S 51(1) [inter state trade]; S 51 (xx) [corporations]; S 51 (xiiiA) [pharmaceutical benefits] and S 51 (xxix) [external affairs].

241 Particularly those standards based on the *British Pharmacopoeia*, the definitive source of pharmaceutical standards. This source is still used and incorporated by reference as the definitive standard in Australian Commonwealth and state legislation.

Arguably, however, the most important event that led to more stringent systems of pharmaceutical control both in Australia and worldwide was the thalidomide crisis of the early 1960s.<sup>242</sup> As a result of the crisis, the Australian Drug Evaluation Committee (ADEC) was established in 1963:

The thalidomide experience had brought home to Australian health officials that there were not only benefits but [also] potential risks from the use of therapeutic compounds...The role of the Committee in the genesis of Australia's drug regulatory system was pivotal. It was as a result of the recommendations of the Committee that standards for submission of data for people wishing to import medicines into Australia were introduced. The Committee also sought to ensure that companies were required to provide information about risks, as well as benefits, in promotional material for health professionals and very early in its life established a voluntary adverse drug reaction reporting scheme (TGA 2003, p.1).<sup>243</sup>

Since 1963 a range of Commonwealth bodies, agencies and committees, many with state jurisdictional representation, have been established to coordinate and oversee drug evaluation and controls in Australia. A list of these bodies is shown as Table 3.1b.<sup>244</sup>

**Table 3.1b: Committees and agencies associated with drug regulation**

The Australian Health Ministers' Advisory Council (AHMAC). Membership comprises the Head (plus one other senior officer) of each of the Australian Government, state and territory and New Zealand health authorities, and the Australian Government Department of Veterans' Affairs. AHMAC approves the Standard Uniform Schedule for Drugs and Poisons.

The National Coordinating Committee on Therapeutic Goods (NCCTG) comprises representatives from Commonwealth and state health authorities and makes recommendations to the Australian Health Ministers' Advisory Council.

The Australian Register of Therapeutic Goods (ARTG) was established under the *Therapeutic Goods Act 1989*. The ARTG is a computer database of therapeutic goods. Therapeutic goods are divided into two major classes: medicines and medical devices. Unless exempt, therapeutic goods must be entered as either 'registered' goods or 'listed' goods before they may be supplied in or exported from Australia.

The Australian Drug Evaluation Committee (ADEC) is the statutory body under the *Therapeutic Goods Act 1989* that advises the Minister and the Secretary of the Department of Health and Ageing (DoHA) on which products are to be entered onto the ARTG.

The Therapeutic Goods Administration (TGA) is a Division of the DoHA. It provides administrative support to ADEC and acts as the national therapeutic goods control authority.

The Medicines Evaluation Committee (MEC) is an expert committee that provides advice to the Secretary of the DoHA on the registration of over-the-counter or non-prescription drugs (other than traditional medicines).

The Complementary Medicines Evaluation Committee (CMEC) is an expert committee that provides advice to the Secretary of the DoHA on the registration of non-prescription traditional medicines.

The Adverse Drug Reactions Advisory Committee (ADRAC), a sub-committee of ADEC, monitors the safety of therapeutic drugs when released on the market.

The National Drugs and Poisons Schedule Committee (NDPSC) recommends scheduling restrictions for adoption by the states. It consists of Commonwealth, state and territory government representatives and technical expert members. It reports to AHMAC, and is supported administratively by the DoHA.

242 The use of the sedative drug thalidomide partly to address nausea and 'morning sickness' during pregnancy resulted in the birth of children with body abnormalities and malformations on an unprecedented and worldwide scale. The drug was withdrawn from use in most countries by the end of 1961. For a general discussion of the thalidomide crisis, see Griffin and Shah 2006; Clow 2003; and Porter 2006.

243 This later evolved into a formal subcommittee of the TGA, the Adverse Drug Reactions Committee. See discussion below.

244 This is by no means an exhaustive list but it does outline the most important of the Commonwealth and joint Commonwealth and state/territory bodies.



The establishment of the National Coordination Committee on Therapeutic Goods in the 1970s in conjunction with the National Drugs and Poisons Schedule Committee (NDPSC) was particularly important in creating a mechanism for achieving some degree of uniformity in therapeutic goods legislation across Australian jurisdictions.<sup>245</sup>

Arguably the most important change to the joint Commonwealth–State regulatory system in recent years was the enactment of the *Therapeutic Goods Act 1989*. This Act, its subsequent amendments, and the body primarily responsible for its administration, the TGA,<sup>246</sup> form the basis for regulatory control of drugs and therapeutic substances in Australia.<sup>247</sup>

The augmentation of stricter drug control policies is a classic case of ‘crisis led change’ (WHO 2002, p.37). Increasingly, and certainly since the thalidomide crisis, effective drug regulation has also had an international profile with the WHO and other international agencies providing support to supplement national regulatory efforts.<sup>248</sup> Drug control, particularly with regard to narcotics, has been increasingly standardised with the creation of international treaties and instruments to facilitate cross-border drug controls and, in some cases, regulate prescription medicines.<sup>249</sup> For example, additional restrictions for prescribing, dispensing and administration will apply to certain drugs over and above those of other prescription drugs, subject to United Nations conventions.<sup>250</sup> Closer to home the creation of the Trans Tasman Treaty Agreement establishing a single regulatory agency for therapeutic products that will cover both New Zealand and Australia and its states is a good example of a bilateral agreement on standardising drug policy in a particular region.<sup>251</sup>

245 Although, as the Galbally Review has commented, this has not always been successful. Differences between state legislation and between some state legislation and the Commonwealth model remain to this day, although these will diminish as the recommendations of the Review are gradually implemented (Galbally 2000a, 2000b). See also discussion below.

246 The TGA has had an interesting history. It has been transformed from originally being a government funded to a self-funded agency. Since the 1980s fees and charges for the evaluation of applications have increasingly become the source of income of the administration.

247 As will be discussed later in this chapter, the jurisdictional and legal basis by which the provisions of this Commonwealth legislation is incorporated into state and territory law is complex and beyond the scope of this chapter. Suffice to say that some states may incorporate the whole Act or parts thereof by reference into its own legislation, whilst others such as Victoria may pass mirroring legislation. Whatever method is chosen, for the most part drug regulation is remarkably similar across the states and between the states and the Commonwealth. The Galbally Review of drug regulation legislation has, however, recommended central and uniform model Commonwealth drug legislation that, if the states adopt, may mean them ceding some of their powers. See discussion later in this chapter.

248 Particularly in developing countries. As with so many areas of health policy, regulation and development it is the countries of the industrialised west that have the most well developed drug regulation systems. Despite the efforts of international agencies, ‘Generally, in most developing countries, drug regulation is very weak and the safety, efficacy and quality of imported or locally manufactured drugs cannot therefore be assured’ (WHO 2002, p.11).

For an interesting comparative account of global drug regulation systems see the report *Effective Drug Regulation: A Multi-country Study* (WHO 2002). This study of 10 countries (including Australia) from a variety of geographic regions, cultural and socio-economic backgrounds compares and assesses drug regulation performance and efficiency in these countries using a standardised methodology ‘to document the results so that other countries may learn from them’ (WHO 2002, p.11).

249 In particular Australia is a signatory to the Single Convention on Narcotic Drugs 1961, the Psychotropic Substances Convention 1972 and the Illicit Trafficking of Narcotic Drugs and Psychotropic Substances Convention 1988. Australia has also developed formal processes through the *Therapeutic Goods Act* and regulations to adopt international guidelines on drug control such as those of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Australia also has membership of international bodies devoted to developing best practice drug regulation policies such as the Pharmaceutical Inspection Convention. From the producer side, Australian pharmaceutical companies may be members of international peak bodies and lobby groups such as the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). The internationalisation of drug policy, whilst an interesting and important topic, is beyond the scope of this chapter (see generally Griffin & O’Grady 2006).

250 Usually listed as Schedule 8 drugs in Australia. See discussion below.

251 The ultimate aim of the agreement is to work towards the complete harmonisation of the regulatory system for therapeutic goods in both countries. The single regulatory agency is expected to commence operations in late 2006. In 2005 Australia also entered into a trade agreement with the United States with regard to the free trade of medicines and pharmaceutical drugs. The development of the Australia–United States Free Trade Agreement (AUSTFA) has not been without controversy, particularly with regard to the effects it may have on the Pharmaceutical Benefits Scheme (PBS) and the National Medicines Policy. Such a topic, however, is beyond the scope of this Inquiry. For further discussion, see Faunce et al 2005. For an interesting discussion of the comparative systems of drug regulation in Australia as compared to the United States, see the transcript of the *Health Report* (12 June 2006). In this discussion between Australian and American health academics it was generally agreed that the Australian TGA is far less influenced by the pharmaceutical industry than its American equivalent, the Food and Drug Administration.



### The objects of drug regulation

In drug regulation, the government acts as the guardian of the public by controlling private powers for public purposes. Ensuring the safety, efficacy and quality of drugs available to the public is the main aim of drug regulation...Drug regulation is the totality of all measures – legal, administrative and technical – which governments take to ensure the safety, efficacy and quality of drugs, as well as the relevance and accuracy of product information. Public health and safety concerns have obliged governments to intervene in the activities of the pharmaceutical sector.

Guaranteeing the safety, efficacy and quality of drugs available to the public is the main goal of drug regulation and encompasses a variety of functions. Key functions include licensing of premises, persons and practices; inspection of manufacturing facilities and distribution channels; product assessment and registration (marketing authorisation); adverse drug reaction monitoring; control of drug promotion and advertising. Each of these functions targets a different aspect of pharmaceutical activities, but all of them must be undertaken simultaneously to ensure effective consumer protection (WHO 2002, pp.4–5, 7–8).

Since the turn of the twentieth century an extraordinary development in the range, number and effectiveness of pharmaceutical products has taken place. Most of these drugs, including benzodiazepines, have provided great benefits to society. The downside, however, has been the increase in the number of toxic, impure, untested, substandard and counterfeit drugs on national and international markets and the terrible consequences of these that may occur (WHO 2002).<sup>252</sup>

Given these developments, the primary objective of drug regulation is to redress 'the market failure arising from the *asymmetry of information* (knowledge and understanding) of the risks and hazards associated with consumer access to and use of poisons' (Galbally 2000a, p.15). As such, it is appropriate in certain circumstances to restrict the free market in the production and trade of such goods in the interest of public health.<sup>253</sup>

However, different countries and political systems, even within the industrialised democracies, promote different levels of drug regulation. For example, in some countries herbal, naturopathic and vitamin products may be strictly regulated whilst they may not be in others, including Australia. In some countries self-regulation of pharmaceutical production through the use of codes of practice may be common, at least with some types of drug, whilst other countries may require more stringent regulation through government boards of control. Some nations may manufacture and distribute drugs and others, including Australia, may leave manufacturing to private pharmaceutical companies subject to them complying with government mandated quality controls. Finally, different systems of regulation will place different emphasis on the role of the private sector in the regulatory process generally. Australia, for example, is one of the few countries in which pharmaceutical company and consumer group representatives have a formal place 'at the table' of government advisory committees such as those under the auspices of the TGA. Indeed, according to the WHO, Australia is the only country that allows pharmaceutical

252 Most discussion of drug regulation recognises, however, that a balance needs to be maintained between safeguarding the public health by stringently evaluating and licensing drugs and yet at the same time promoting public health by making potentially valuable drugs available without unnecessary delay. Indeed the Baume Review, established in 1991, aimed at better balancing the interests of speedy assessment and availability of pharmaceuticals and safety issues, particularly in the context of HIV/AIDS-related drugs. As a result, the concept of 'timely availability' (of drugs) was added to the objectives of the *Therapeutic Goods Act* (see Baume 1991; Industry Commission 1996a).

253 Even where this may conflict with national competition policy. The *National Review of Drugs, Poisons and Controlled Substances Legislation* (the Galbally Review) commissioned to examine national and state drug regulation, legislation and practices in light of the National Competition Policy recognised that drugs and poisons, whilst often highly valuable to the community, 'can and do result in harm and that this would be expected to worsen under unrestrained deregulation' (Galbally 2000a, p.ix). The Review concluded: 'the total potential for harm warrants acceptance of reduced competition and higher costs in some circumstances' (Galbally 2000a, p.ix). For further discussion of the Galbally Review, see later in this chapter.



industry representatives to deliberate on committees that have power to consider evaluation or registration applications.<sup>254</sup>

The regulatory system for pharmaceutical drugs (including prescription drugs) in Australia is generally seen as one of the better global models of regulation (WHO 2002). Moreover, the need for regulation of pharmaceutical products to ensure the safety and efficacy of therapeutic goods has generally been accepted, and indeed promoted, by the health sector, consumers and the pharmaceutical industry alike (Industry Commission 1996a). A discussion of this system is the subject of the next section of this chapter.

### ***Drug regulation in the modern era: The Therapeutic Goods Act 1989 and associated legislation***

#### **Other legislation and policies affecting drug regulation**

It should be stated from the outset, that whilst the focus of this section is appropriately on the operations of the *Therapeutic Goods Act 1989* and complementary state legislation, the overall system of drug regulation in Australia is affected by a number of other legislative and policy provisions extraneous to this specific legislation. These will be canvassed briefly before proceeding to a detailed discussion of the *Therapeutic Goods Act*.

From a legislative perspective a range of Acts and regulations also have bearing on the overall issue of drug regulation. These may include laws with regard to customs and imports,<sup>255</sup> consumer protection legislation,<sup>256</sup> trade agreements,<sup>257</sup> agricultural and veterinary laws,<sup>258</sup> criminal legislation,<sup>259</sup> occupational health and safety,<sup>260</sup> and regulations pertaining to food standards.<sup>261</sup> Such legislation may also be duplicated or supported, at least in part by state and territory equivalents.

#### ***The Pharmaceutical Benefits Scheme (PBS)***

In addition to legislation, drug regulation may be affected by a variety of national and state policies. One of the most important of these is the federal Pharmaceutical Benefits Scheme (PBS). The PBS is the national scheme whereby certain listed prescription or hospital-administered medicines are subsidised by the state. The PBS is predominantly concerned

254 The World Health Organization for example discusses the importance of both consumer and industry bodies in the development of drug regulation policy in Australia. Bodies such as the Consumers Health Forum (particularly since the advent of HIV/AIDS), Medicines Australia, the peak body for Australia pharmaceutical companies, and professional peak bodies such as the Pharmacy Guild of Australia and the various Royal Colleges of Medicines all play an important role in contributing to the policy debate on drug regulation in Australia (WHO 2002). The Australian Pharmaceutical Advisory Council (APAC) is a good example of a body that has input from many people, including medical, industry and consumer representatives, with the aim of advising the Commonwealth Minister of Health on pharmaceutical policy and regulation. For further information on APAC, see their website at <http://www.health.gov.au/internet/wcms/Publishing.nsf/Content/nmp-advisory-apac.htm>

255 *Customs Act 1901* and associated regulations.

256 *Trade Practices Act 1974*.

257 For example, the *Trans Tasman Mutual Recognition Act 1997*. See also the *US Free Trade Agreement Implementation Act 2004*.

258 *Agricultural and Veterinary Chemicals Code Act 1994*.

259 *Narcotic Drugs Act 1975*.

260 At state level the adverse effects of drug use, including prescription drug use, are covered in the *Occupational Health and Safety Act 2004* (Vic). Correspondence to this Inquiry by Mr John Lenders, the Victorian Minister for WorkCover, states that whilst the Victorian WorkCover Authority has not specifically covered activities or programmes relating to prescription drugs, the general principles of the OHS Act require:

- Employers to provide and maintain a working environment that is safe and without risks to health and safety
- Employers and self-employed persons to ensure that persons other than employees are not exposed to risks to their own health arising from the undertaking of the employer or self-employed person
- Employees to take reasonable care for their own health and safety and that of others (for example, ensuring that they are not by use of drugs, affected in a way that may put themselves or others at risk).

These requirements may from time to time result in employers promoting or implementing programmes such as prevention, education, counselling and rehabilitation initiatives to address drug issues in the workplace as part of an overall OHS strategy. Conceivably such a strategy could include materials with regard to prescription drug abuse and particularly the consequences for worker fatigue and safety issues' (see correspondence of Mr John Lenders, Minister for WorkCover, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006).

261 *Australia New Zealand Food Authority Amendment Act 2001*.

with the timely access by Australians to low cost medicines rather than their regulation.<sup>262</sup> As such, a detailed discussion of the scheme is beyond the scope of this chapter. What is of relevance, however, is the fact that some of the federal and state safeguards with regard to the use and abuse of prescription drugs apply only to PBS listed drugs. In other words, there may be situations in which a person accesses drugs outside of the PBS, for example by private payment, and thereby bypasses some of the safeguards built into the system to prevent 'doctor or prescription shopping', an issue discussed in Chapter 2.4.

#### *The National Medicines Policy*

The National Medicines Policy is another federal policy that impacts upon drug regulation. Although extending beyond prescription medicines to complementary healthcare and over-the-counter products, the overarching aims of the policy implemented in 2000 are based on the following objectives:

- Timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- Medicines meeting appropriate standards of quality, safety and efficacy;
- Quality use of medicines; and
- Maintaining a responsible and viable medicines industry (Department of Health and Ageing (DoHA) 1999, p.1).

It is the third arm of the National Medicines Policy that is particularly relevant to the issue of drug regulation. The Quality Use of Medicines Program is concerned that the quality, safety and efficacy of medicines available in Australia should be of the highest possible standard. Whilst agencies such as the TGA are responsible through the mechanisms outlined below for the quality of the drugs released in Australia, their correct prescription, dispensation, use and administration is promoted through a range of means. These include education campaigns aimed at doctors, nurses, pharmacists and consumers; formal agreements between government and providers such as the Community Pharmacy Agreements;<sup>263</sup> and the professional codes of practice of groups such as the College of General Practitioners, the various state Pharmacy Boards,<sup>264</sup> and the Codes of Practice governing the Australian pharmaceutical industry, particularly that of the industry's peak body, Medicines Australia. These are matters that are more suitably developed in Section Six of this Report.

#### **The Therapeutic Goods Act 1989**

The *Therapeutic Goods Act* (hereinafter the Act) is the basis of modern drug regulation in this country and through some complicated legal mechanisms by extension to the states.

When enacted in 1989 the Act and its regulations were instrumental in giving the Commonwealth more clearly delineated regulative authority over pharmaceutical and other drugs. As Hirshorn and Monk state, the Act applies to:

- All corporations who supply or manufacture medicines for supply (regardless of where) in Australia
- Unincorporated parties who supply or manufacture medicines for supply in Australia outside their own state or territory
- All parties (whether incorporated or unincorporated) who supply medicines under the Pharmaceutical Benefits Scheme (PBS)

<sup>262</sup> For a comprehensive account of Australia's PBS, see Duckett 2004.

<sup>263</sup> Since 1990 the Commonwealth of Australia and the Pharmacy Guild of Australia (PGA) have entered into five-year Community Pharmacy Agreements. Whilst the agreements primarily set out the remuneration scales for pharmacists dispensing under the PBS, the current (Fourth) Community Pharmacy Agreement also makes arrangements for the provision and funding of professional pharmacy programmes including services enabling pharmacists to better educate and instruct their customers with regard to the medications they have been prescribed. See *Fact Sheet Community Pharmacy Agreements* at <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/pharmacy-4cpafact>

<sup>264</sup> For a discussion of the important role these professional bodies play in the administration of prescription and other drugs, see Chapter 5.1.



- All parties (whether incorporated or unincorporated) who import or export medicines (2006, p.655).

Complementary state or territory legislation is necessary in those circumstances where activities fall solely within the boundaries of the state or in areas where state governments have sole responsibility.<sup>265</sup>

The increasing 'nationalisation' of drug regulation and policy recognises the changing circumstances over time whereby originally:

- Protecting public health was viewed as a state responsibility, not a matter for national policy.
- There was no Commonwealth legislation established for evaluating products.
- Emphasis was on substances, and is now more on products. Often the substance was the product, whereas now the same substance can be used in different products, in different strengths, combined with other ingredients, in different packaging, and intended for different uses.
- Consumer access was limited to the physical presence at retail outlets, whereas now there is increased access through distance supply mechanisms, such as the Internet.
- Comparatively fewer substances and less diverse products were available than are now, especially those intended for aged care (Galbally 2000b, p.28).

The objectives of the controls under the Act are based on the assumption that consumers have little knowledge about therapeutic drug substances. According to Galbally:

[n]ot only are consumers not fully informed about the consequences of their choices but...often it would be difficult for them to independently gain an adequate knowledge and understanding of:

- The substances and products needed to treat particular conditions;
- The risks associated with particular substances;
- The way in which products containing the substances need to be used safely and to achieve optimal health benefits;
- The potential interactions with other medicines or foods;
- Contraindications with certain medical conditions; and
- Poisonous substances that may be very dangerous if used inappropriately, whether intentionally or unintentionally (Galbally 2000a, p.13).<sup>266</sup>

Under the Act, controls include but are not restricted to the main areas of the scheduling, licensing, advertising,<sup>267</sup> labelling<sup>268</sup> and record keeping of certain drugs<sup>269</sup> and pharmaceutical products.<sup>270</sup>

265 As the Galbally Review commented, local government plays very little if no role in the regulatory aspects of drug or medicines control (Galbally 2000b, p.152).

266 The Galbally Review recommended that the types of objectives for both the general regulatory drug framework and scheduled medicine controls in particular be specifically set out in Commonwealth and state legislation. See in particular Recommendations 1 and 3 of the Review (Galbally 2000a, p.xiv).

267 See discussion below.

268 The labelling of medicines in Australia must conform to directives and regulations of the TGA. In particular, the directive Therapeutic Goods Order 69 *General Requirements for Labels for Medicines* specifies that information must provide the names and quantities of active ingredients, expiry dates, identification of inactive ingredients and label size, to mention a few. Labels must also conform to the requirements of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) and associated schedules, particularly the requirements for schedule signal headings. For further discussion of labelling requirements see Hirshorn and Monk 2006, p.681.

Another way of addressing the issue of information asymmetry between producers and consumers is through the use of Product Information (for health professionals) and Consumer Medicine Information (for consumers). For a discussion of these requirements, see Hirshorn and Monk 2006, pp.666–667 and the discussion in Chapter 6.1 of this Report.

269 The *Therapeutic Goods Act 1989* also governs the control of certain 'medical devices' such as an instrument, appliance or article to be used *inter alia* for the diagnosis, prevention, monitoring, treatment or alleviation of disease, the control of conception and the investigation, replacement or modification of the anatomy or of a physiological process. See *Therapeutic Goods Act 1989*, Section 41BD.

270 There are also provisions with regard to counterfeit goods and tampering of goods, gene technology, product recalls, and criminal and civil offences and penalties imposed for infringement of the Act and regulations. A discussion of these provisions is beyond the scope of this chapter.

### Drug listing and registration

The Drug Safety and Evaluation Branch of the TGA evaluates prescription medicines for inclusion on the Australian Register of Therapeutic Goods.<sup>271</sup> A sponsor makes an application to TGA to have his or her substance listed on the register as either a *listed* or a *registered* good if it is to be imported, exported, manufactured or supplied in or from Australia. Registered products include medicines listed as having a higher level of risk and include all prescription and many non-prescription medicines.<sup>272</sup> Listed products are unscheduled medicines or other products that are usually available for self-selection and self-treatment by consumers, and/or those products considered to be of relative low risk.<sup>273</sup>

Complementary medicines (traditional, alternative or naturopathic substances) are usually listed products, although they may be registered depending on their ingredients and the claims made for them.<sup>274</sup>

The registration and evaluation process for registered drugs is complex and beyond the scope of this Report, suffice to state that sponsors must supply detailed evidence to substantiate any claims made about their products.<sup>275</sup>

### Drug scheduling

In Australia access to drugs, poisons and medicines is governed by a scale of schedules that form part of the *Therapeutic Goods Act* and for the most part are adopted, gazetted or mirrored in state legislation. The Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) contains the decisions of the NDPSC whose task once a drug has been evaluated is to place the drug in the relevant schedule according to its level of toxicity, purpose of use, potency, danger it may pose to children, potential for abuse, need for the substance and the report or recommendations of the evaluator. The schedules generally specify who may sell or supply the drug, who may possess or administer it, the amount that may be supplied or the format in which it is presented. Access is progressively restricted 'where [the consumer's] general knowledge and the label information are not sufficient to overcome the consumer's lack of knowledge' (Galbally 2000b, p.18). The Standard is amended and consolidated annually, incorporating the decisions of the NDPSC, and is published four times a year. Table 3.1c gives an annotated summary of the relevant schedules.

271 Therapeutic Goods are defined in Section 3 of the Act. Products that might fit either the definition of a food or a medicine are referred to a joint TGA/Food Standards Committee (External Preference Panel on Interim Matters) to make a recommendation as to whether it is more properly classified as a food or a medicine.

272 Those classified as Schedule 4 or 8 (high risk) or Schedules 2 or 3 (lower risk pharmacy products) on the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) (see below).

273 Listed medicines are unscheduled. Whilst they still need to be assessed by the TGA for quality and safety, the TGA relies on the information provided by their sponsors as to their efficacy rather than conducting individual trials on these products.

274 See Section 52F of the *Therapeutic Goods Act 1989* and Schedule 14 of the *Therapeutic Goods Regulations 1990*. A discussion of complementary and self-selected medicines is beyond the scope of this chapter. Self-selected and over-the-counter medicines are governed by the Australian Regulatory Guidelines for OTC Medicines (ARGOM) administered by the TGA. A Complementary Medicines Evaluation Committee has also been established under the TGA. It is interesting to note, however, that Victoria is the only state that has an official schedule (Schedule 1) for traditional Chinese medicines. See *Drugs, Poisons and Controlled Substances Act 1981*.

275 For a discussion of the registration and evaluation process, see Hirshorn and Monk 2006, pp.659ff. Details of the process are also contained in the Australian Regulatory Guidelines for Prescription Medicines (ARGPM) available on the TGA website ([www.tga.gov.au](http://www.tga.gov.au)). Many of the forms, formats and processes used by the European Union to present and assess drug evaluation applications have also been adopted by the TGA.



**Table 3.1c: List of scheduled drugs adapted from the standard for the uniform scheduling of drugs and poisons**

- **Schedule 1** [In Victoria only] Traditional Chinese medicines and substances to be administered by accredited practitioners.
- **Schedule 2** includes substances that are considered to be able to be used safely when available from a pharmacy where professional advice is available. These substances include analgesics (eg. paracetamol) and antifungal preparations.
- **Schedule 3** products require the supervision of a pharmacist in their supply to advise the consumer on their safe and effective use. Substances covered in *Schedule 3* include some medicines to relieve the symptoms of asthma and some antihistamines.
- **Schedule 4** products require the intervention of a doctor, veterinarian or other authorised prescriber to diagnose the condition and prescribe the most effective treatment for that patient. These products include medicines to treat conditions such as infections (antibiotics), heart disease and depression. Once prescribed, these medicines can only be obtained from a pharmacy.
- **Schedule 5** includes substances with a low potential for causing harm, the extent of which can be reduced through using appropriate packaging with simple warnings and safety directions on the label.
- **Schedule 6** contains substances with a moderate potential for causing harm, the extent of which can be reduced through distinctive packaging with strong warnings and safety directions on the label.
- **Schedule 7** includes substances with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling and use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession storage or use may apply.
- **Schedule 8** covers products where, in addition to the *Schedule 4* controls, further access restrictions are placed on the prescribing of large quantities, prescribing for long-term treatment or in treating drug addiction. These substances include narcotics (eg. morphine) and drugs to treat attention deficit disorder (eg. methylphenidate).
- **Schedule 9** includes substances that are generally designated as illegal substances that are subject to abuse; the use, possession and supply of which is prohibited.

Source: Adapted from Galbally 2000a, pp.21–22.

The objectives of scheduling are to reduce the level of accidental or intentional poisonings through inappropriate access to the drugs, provide expert intervention so as to redress information asymmetry between consumers and the pharmaceutical industry and provide a system whereby the diversion of medicines for inappropriate, unsafe or criminal use are minimised.<sup>276</sup>

The number of schedules signifies increasingly stricter controls. Each evaluated drug is assessed according to the factors of the various schedules in a 'cascading principle' whereby a drug is first assessed against the criteria in a higher schedule and if insufficient of these factors are pertinent it is assessed against a lower schedule and so on (TGA 2005a, p.4). The schedules are divided into those pertaining to medicines (Schedules 2, 3, 4 and 8), those relating to poisons (Schedules 5, 6 and 7) and Schedule 9, which covers prohibited substances. With regard to medicines, there are five major levels of access:<sup>277</sup>

- ◆ **No schedule** – Open access or self-selection by consumers through supermarkets, pharmacies or health food stores.<sup>278</sup>
- ◆ **Schedule 2 (S2)** – Supply restricted to pharmacies (but personal supervision of a pharmacist in the sale not necessary).<sup>279</sup>

<sup>276</sup> A classic example is the rescheduling of larger packs of the drug pseudoephedrine from Schedule 2 to Schedule 4 as a measure to reduce the drug being diverted into illicit amphetamines. Despite directions from state Pharmacy Boards, some pharmacists were inadequately exercising appropriate professional standards by continuing to keep the drug on open display facilitating theft and diversion. By moving the drug into the higher schedule it became mandatory to have the drug removed from open display. For a discussion of this issue see the Drugs and Crime Prevention Committee, *Final Report, Inquiry into Amphetamine and 'Party Drug' Use in Victoria* (2004).

<sup>277</sup> As indicated, Schedule 5, 6 and 7 concern household and industrial poisons and as such are not relevant in the context of this Inquiry. Schedule 9 contains controlled substances such as heroin that are available only for approved clinical or research purposes.

<sup>278</sup> Some of the factors to be taken into account in deciding a medicine does not need to be scheduled include: that it is for the use of minor ailments that can be diagnosed or managed by the consumer; the safe use of the medicine is well established; the risk profile of the medicine is low and well defined; and the medicine is unlikely to produce dependency (see TGA 2005a).

<sup>279</sup> In some circumstances, usually in rural and remote communities where there is no pharmacist in close proximity, a poisons licence holder may supply Schedule 2 poisons (see DPCSA Division 8). The Galbally Review discussed whether Schedules 2 and 3 should be merged into one single schedule for over-the-counter medicines, but ultimately decided against recommending this, subject to ongoing monitoring of the current system.

- ◆ **Schedule 3 (S3)** – Supply restricted to sale being supervised by qualified pharmacist.<sup>280</sup>
- ◆ **Schedule 4 (S4)** – Supply only with prescription by a medical professional (doctor or where relevant dentist, optometrist or veterinarian).
- ◆ **Schedule 8 (S8)** – Supply only with prescription and subject to other controls such as prior approval or grant of permit by government agency and/or restriction on repeats. Such a permit, for example, may be required for drugs such as morphine, methadone or the stimulant methylphenidate (Ritalin). This schedule recognises that whilst these drugs have legitimate therapeutic uses, they also have potential for abuse and/or addiction.<sup>281</sup> In some circumstances Schedule 8 drugs may only be prescribed by certain medical specialists (such as an oncologist).

For the purposes of this Inquiry, Schedules 4 and 8 are of the most relevance.

The rationale behind prescription only schedules (Schedules 4 and 8) is to ensure that:

- The condition from which the consumer is suffering is diagnosed correctly;
- The most appropriate treatment is prescribed; and
- The consumer has sufficient information and understanding necessary to enable him or her to use the medicine safely and effectively (Galbally 2000a, p.27).

Schedule 8 drugs in particular can be highly toxic when used inappropriately, are generally prescribed for serious and often terminal illnesses such as cancer, and have a very high potential for being abused or causing dependence.

The SUSDP also contain appendices that supplement the schedules by establishing additional controls for certain drugs.<sup>282</sup> These may include controls with regard to storage,<sup>283</sup> handling, transport, recording, packaging, first aid, safety directions, advertising and labelling, or to whom and under what conditions they may be sold.<sup>284</sup>

Products that are already scheduled may also be rescheduled on application from state health authorities, requests from industry or professional associations, a reference from the TGA or self-initiated by the NDPSC. Rescheduling usually occurs when there is a need for maintaining consistency with comparable products under a different schedule or there has been a perception that the risk profile of the product has either been increased or decreased (thus necessitating a move to a higher or lower schedule).<sup>285</sup> The Galbally Review noted that in recent years there has been a marked trend for devolution of prescription medicines to lower levels of control, thus increasing consumer access:

This has seen a number of medicines move from Schedule 4 to Schedule 2 or Schedule 3, but rather fewer go to open sale, thus not significantly changing the number of OTC [over-the-counter] medicines available to the open market (Galbally 2000b, pp.46–47).

<sup>280</sup> The idea being that the pharmacist will give professional advice on the administration of the medicine. See discussion below.

<sup>281</sup> In Victoria this is done by the Drugs and Poisons Unit (DPU) of the Victorian DHS, see discussion below. 'Pre-authorisation' also is required from Medicare Australia for medical professionals to prescribe Schedule 8 drugs in excess of the PBS quantity or repeat levels.

<sup>282</sup> See Appendix D, for example, places stringent restrictions on the administration of S8 drugs.

<sup>283</sup> As would be expected the drugs and medicines in the higher schedules, particularly Schedule 4 and 8 drugs that can be diverted for illicit use, have more rigorous requirements with regard to their storage, display and record keeping provisions. See Therapeutic Goods Regulations 1990 and Drugs, Poisons and Controlled Substances Regulations 2006. For some controlled substances, particularly narcotics, stringent record keeping provisions must be observed pursuant to Australia's obligations under international drug treaties. For example, the *Narcotic Drugs Act 1975* requires records to be maintained and reports sent to the International Narcotics Control Board on narcotic drugs consumption.

<sup>284</sup> The extent to which the states adopt the appendices is variable. This area is where there is probably the least uniformity. For example, in some states company representatives are not permitted to carry pharmaceutical samples for prospective supply, in other states they may do so if licensed. Provisions with regard to storage and display of S2 drugs also vary from state to state.

<sup>285</sup> Drugs that have apparently resulted in adverse conditions or reactions post-marketing and scheduling are investigated or monitored by the Adverse Drug Reactions Committee (ADRAC), a subcommittee of the TGA.



*What impact does drug scheduling and rescheduling have?**Potential for increase in healthcare costs and doctors' workloads*

Restricting or controlling medicines with high misuse potential by rescheduling them to less accessible categories may, at first glance, appear to be a logical and straightforward action that will reduce misuse. However, such procedures are not without contention, and there may be costs and other unintended consequences. For example, in the United States, attempts to control the misuse of hydrocodone compounds (a group of narcotic analgesics, including Vicodin®) by rescheduling this widely prescribed medicine has resulted in some concerns:

Opponents to rescheduling hydrocodone argue that it will make the drug less accessible to patients because they will be required to visit their physician more frequently to obtain a new prescription rather than simply refilling their existing prescription. They argue that doctors will be overloaded with patient visits, increasing pain-related healthcare costs (National Center on Addiction and Substance Abuse (CASA) 2005, p.77).

*Reduction in injection misuse of certain drugs*

An Australian discussion paper proposed that drugs of concern could be designated 'authority-required prescriptions' (Dobbin 2001). The author cited examples from other countries where, in an attempt to reduce the misuse of temazepam capsules, such restrictions have been imposed, reducing the number of prescriptions. Indeed, as discussed in Chapter 2.2, in Australia the PBS Schedule was adjusted in exactly this manner, specifically because of concerns about the increasing incidence of harms arising from the unlawful and unintended use of temazepam capsules for injection. Controls were implemented so that, from May 2002, temazepam 10mg capsules in a 25-pack were designated as 'authority-required prescriptions'. Medical practitioners and pharmacists were provided with information on the rationale of this initiative when this change in practice occurred:

On 1 May 2002, temazepam 10mg capsules (25 capsule pack size) will become an 'authority required' pharmaceutical benefit.

Its new listing comes with a cautionary note for doctors that significant adverse health outcomes are associated with injecting temazepam in capsule form, and that wherever possible, tablets should be prescribed in preference to capsules...

Doctors will need to confirm capsules are being prescribed to manage insomnia in an individual who has not responded to treatment for this condition in the tablet form...

The Pharmaceutical Benefits Advisory Committee (PBAC) recommended this higher listing following advice from the Australian Pharmaceutical Advisory Council that the intravenous use of temazepam capsules was increasing due to a heroin shortage (Health Insurance Commission 2004, p.1).

The rationale for such a strategy was that the rescheduling of temazepam might encourage doctors to prescribe other benzodiazepines or tablets, thereby potentially decreasing the highly risky use of capsules and potentially limiting diversion and misuse. On the other hand, the Pharmacy Board of Victoria was concerned that such changes could potentially create demand in other areas. Commenting on the apparent increase in drug-seeking patients targeting 20mg temazepam capsules, the Pharmacy Board commented:

It is also thought that the absence of 20mg temazepam tablets and the fact that this medication is not a PBS item may have contributed to this success as the drug-seeking patient does not need to emphasise the need for the capsule formulation and can more readily request a larger dose than usual quantity on the basis of economy (Pharmacy Board of Victoria 2003, p.7).

Nevertheless, the change in practice in Australia *did* result in a net reduction in the prescription of capsules under the PBS – from 185,404 prescriptions a month in January 2001 to 1,859 prescriptions a month in November 2003. In 2004 the pharmaceutical producers withdrew temazepam capsules from the Australian market because of concern about the abuse potential (Dobbin 2006a).

The City of Melbourne gave a local example of the impact of this change in practice:

According to workers based at Living Room, the use of injecting gel capsules by their clients has dramatically declined and is now virtually non-existent since the Federal Government withdrew Temazepam gel-based capsules from the Pharmaceutical Benefits Scheme.

Furthermore, the advocacy carried out by the Victorian Department of Human Services Drugs policy unit around the harms associated with Temazepam gel-based capsules has seen pharmaceutical companies and manufacturers withdraw gel capsules from the Australian market.<sup>286</sup>

#### *Misuse of another drug*

Similarly, concern about widespread misuse of flunitrazepam (for example, Rohypnol) resulted in the NDPSC rescheduling the medicine in 1998, from a Schedule 4 to a Schedule 8 medication, resulting in a decrease in accessibility and use of the drug (Australian Illicit Drug Report 1997–98). A representative of the pharmaceutical industry who was involved in the NDPSC process for rescheduling flunitrazepam indicated to the Committee that both the general process of rescheduling drugs and the specific action of rescheduling flunitrazepam was neither straightforward nor would it necessarily result in unequivocal benefits:

You might ask yourselves what has happened since then [the rescheduling of the drug and the discontinuance of producing and marketing Rohypnol by Roche]. There has been transference of the preferred agent for misuse, both in the polydrug user situation and in the date rape situation...the misuse has been transferred to another Roche benzodiazepine, which is Rivotril. That is the brand name, and its generic or active substance name is clonazepam. It is very similar in appearance to the old Rohypnol two-milligram tablets, but Rivotril is used for the treatment of epilepsy.<sup>287</sup>

#### *Debate on appropriateness of scheduling*

The Committee also received interesting evidence with regard to scheduling from Dr Mike Tedeschi, a drug and alcohol clinician from the Canberra Hospital and academic with the Australian National University Medical School. In Dr Tedeschi's view, if anything the trend is towards 'down scheduling' of drugs in Australia. In other words, physicians and pharmaceutical companies who are aggrieved by the red tape associated with higher degrees of regulation put direct and indirect pressure on the TGA, PBS and state regulatory bodies to place drugs in lower schedules or at least not reclassify them to a higher one. Dr Tedeschi told the Committee that:

An easy way of controlling the problem would be to legislate to put these drugs in a different schedule and the drug and alcohol profession would...be very keen for there to be more restrictions legislatively on these drugs [But]... there would be an outcry from any number of interest groups. ...Similarly there's any number of drugs in Australia on the PBS that are classified as authority drugs so to access them under the PBS you have to fulfil certain requirements but if anything at the moment the pressure is on the PBS to relax authority requirement, there's a lot of pressure on the PBS not to put new drugs [on authority] and in fact on August 1st they're taking 54 drugs off for authority due to a backlash...It's a really

286 Submission of the City of Melbourne to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

287 Ms Susan Alexander, Head of Regulatory Affairs and Head of Operations, Roche Products, on behalf of Medicines Australia, in conversation with the Drugs and Crime Prevention Committee (via telephone), 20 July 2006. It should be noted that Ms Alexander was speaking primarily in her role as a representative of Medicines Australia, the peak industry body for pharmaceutical companies in Australia.



difficult problem because they're schedule 4 drugs and no one is inclined to say that these should be schedule 8 – [to do so] you're looking at education of doctors and trying to change the culture of prescribing...<sup>288</sup>

A number of submissions to this Inquiry made the point that whilst the scheduling system overall was flexible and worked relatively well, it was thought that on occasion some drugs had been wrongly placed in an inappropriate schedule.<sup>289</sup> For example, as raised in Chapter 2.2, there have been increasing concerns expressed by some clinicians that the benzodiazepine alprazolam (Xanax®) should be reclassified from Schedule 4 to Schedule 8. As was stated in that chapter this has been done in one jurisdiction – Tasmania.

With regard to rescheduling the benzodiazepine alprazolam, it is worth in this context repeating the views of one group of Melbourne medical clinicians:

The overwhelming consensus among alcohol and drug clinicians is that alprazolam is one of the most widely abused of the benzodiazepines, and that management of withdrawal of patients using alprazolam is particularly difficult.

While recognising that the scheduling of medications is currently administered at Commonwealth level, it is appropriate that the idea of rescheduling be raised in this document. Given the extent of abuse of alprazolam and the risks of withdrawal and overdose associated with this benzodiazepine, a change in schedule to S8 (alongside drugs like morphine and oxycodone) would be a positive public health measure. This change in regulation would increase the controls on alprazolam prescribing, may restrict duration of prescribing of this drug and could raise prescriber awareness of the risks of alprazolam.<sup>290</sup>

Some submissions have gone further and argued that most if not all benzodiazepines should be subject to Schedule 8 controls and/or a permit or authority system currently applicable to other drugs of addiction.<sup>291</sup> This is certainly the view of State Coroner, Mr Graeme Johnstone who has made recommendations to this effect in a number of coronial cases, including the following recommendation taken from a case in 2000:

[I recommend that] The Victorian Health Department consider urgently rescheduling all benzodiazepines to come under the operation of Schedule 8 of the Drugs, Poisons and Controlled Substances Act 1981.<sup>292</sup>

This was a view that Mr Johnstone reiterated his support for when he gave evidence to the Committee in August 2007.<sup>293</sup>

288 Dr Mike Tedeschi, ANU Medical School, Canberra Hospital, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 16 May 2007.

289 The Registrar of the Pharmacy Board of Victoria, Mr Steve Marty, made a different criticism of the scheduling process. In Mr Marty's view: 'Manufacturers appear to have too much influence on the scheduling process and not enough health practitioners with broad knowledge of regulatory issues are included in the process' (Mr Steve Marty, Registrar, Pharmacy Board of Victoria, Comments included in a Submission of the Essendon Community Legal Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2007).

290 Submission from Interhospital Liaison Group to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006. This proposal to reschedule some benzodiazepines, including alprazolam, was viewed with approval by Dr Mike Moynihan, President of the Rural Doctors Association of Victoria, when he gave evidence to the Committee on 18 June 2007. It also was a view shared by some of the witnesses with whom the Committee met in Canada, including Janet Currie and Susanne Murphy of the Psychiatric Medication Awareness Group (PMAG) of British Columbia (Vancouver, 24 July 2007).

291 See for example, Submission of Salvation Army Crisis Services to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, April 2006.

Mr Ange Vassallo, the partner of a woman with a long history of benzodiazepine addiction, also testified to the Committee that he was strongly of the belief that *all* benzodiazepines be rescheduled to Schedule 8, as he believed there is sufficient evidence that this class of drugs could be equally as harmful as the opioids when misused. (Evidence given by Mr Ange Vassallo to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007).

292 Mr Graeme Johnstone, State Coroner of Victoria, Recommendation 18, Case No 19990281, 13 April 2000.

293 Mr Graeme Johnstone, State Coroner of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 20 August 2007.

One drug and alcohol worker from south-west Victoria agreed with this recommendation but also told the Committee that even if it was not possible to reschedule benzodiazepines to Schedule 8, she did think they needed to be more stringently controlled through the existing permit or authority system.<sup>294</sup>

I would like to see permits for benzos. Permits for anyone on benzos for any longer than a designated therapeutic time, and that would have to be agreed upon...Therapeutic value should be able to be measured, like you have to have permits for S8s after a certain period of time...

[Moreover], if you are seeking a permit for benzos, you would then have to have a care plan in place, like you do now with S8s. Have your care plan. For example with benzodiazepines [you should ask], What else are you doing for this person to reduce their anxiety?<sup>295</sup>

Support for a broad reclassification of benzodiazepines to Schedule 8 has also come from Dr Con Constantinou, a representative of the Medical Practitioners Board of Victoria:

I think benzodiazepines should be Schedule 8. Of course there are ways around the Schedule 8, which is why we have the problem with the opiates, but it does make it a lot harder. It also would bring home to doctors that the benzos are not a joke; they are really serious drugs. That would help in lessening the amount prescribed. I understand the amounts being prescribed have lessened over the last three or four years, and there has been a concerted drive to inform doctors about this. I think the more we do along those lines the more welcome it will be.<sup>296</sup>

#### *Other strategies preferred to rescheduling*

On the other hand, whilst not voicing opposition to strategies such as rescheduling, a submission of the Australian Medical Association (AMA) drew attention to the lack of evidence of the effectiveness of such approaches:

...we accept that on occasions, such as the rescheduling of some benzodiazepines (flunitrazepam), and change in PBS prescription requirements (temazepam capsules), it is justifiable on public health and public safety grounds for this to occur. However, I note that on published evidence (Breen et al MJA 2004; 181(6): 300-304) a significant positive outcome has yet to be realised.<sup>297</sup>

The Pharmaceutical Society of Australia (PSA) also 'remains unconvinced' that rescheduling is a total solution to the problem. When the Committee met with officers of the PSA in Canberra they stated that in some circumstances it was not so much the schedule in which a drug was placed that was important as much as improving the practices of health care professionals with regard to prescribing, administering and dispensing these drugs. Ms Kerry Deans, CEO, stated that this was the case with benzodiazepines:

I personally can't see what benefit [rescheduling benzodiazepines] offers...

There's a lot more paperwork required around schedule 8 for everybody, particularly pharmacists in terms of receiving the stock balancing, the amount, storing it. I'm not sure – sure that a benzodiazepine in schedule 8 is going to prompt any different thinking about what's appropriate...I assume that in scheduling it you'd want to achieve a change in

294 See Chapter 3.2 for a discussion of the state permit system operating in Victoria.

295 Ms Bev McIlroy, Service Manager, Glenelg and Southern Grampians Drug Treatment Service, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Form, Warrnambool, 29 May 2007. Support for an extension of the permit system to cover benzodiazepines if rescheduling was not feasible also was given by the Victorian Alcohol and Drug Association (VAADA). (See Evidence of Mr Sam Biondo, Executive Officer, VAADA, given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 25 June 2007).

296 Dr Con Constantinou, Health Manager, Medical Practitioners Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 9 July 2007.

297 Submission of the Australian Medical Association to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.



behaviour by somebody and I think you've got to ask, does that schedule decision change that and I'm not sure a benzodiazepine rescheduling to 8 that you would get any different thinking around it. It doesn't for example restrict who can prescribe it.<sup>298</sup>

Ms Deans' colleague Dr Kay Sorimachi agreed, stressing that the emphasis should focus on the prescribing practices of health professionals and the training they may require to make good clinical decisions with regard to supplying these drugs, rather than on regulation per se:

You should do more in terms of the way in which they're prescribed and reviewing perhaps prescribing habits or, just the usage patterns, if you like, both in the community and in the persons' homes and there are all sorts of settings where they might be used inappropriately without too much regard for how long they have been in use or whatever, it's still of benefit to that person.<sup>299</sup>

The above discussion is not intended to support or negate the rescheduling of medicines as a strategy to reduce access to medicines that are being misused. Rather, it highlights the need to base decisions on available evidence, to invest in developing evidence where this is currently insufficient, and to monitor carefully the impact of any regulations or changes in procedures, adjusting them as indicated. Rescheduling is one aspect of this debate that requires measured consideration.

### Licensing

In addition to the scheduling process, the other major regulatory safeguard to ensure the safety and efficacy of drugs and medicines in Australia is through the licensing system. The *Therapeutic Goods Act 1989*, its regulations and Customs laws make provision for the issuing, renewal, suspension and revocation of licences for drug manufacture, importation, export and wholesaling. Whilst the licensing schemes under the Act:

do not provide any numerical restrictions on who can participate in the market, they do require operators to have specific knowledge, skills and character to deal with medicines and poisons safely and effectively. They aim to prevent traders, without these attributes, gaining access to the market or, in some cases, provide for removing 'problem traders' from the market (Galbally 2000a, p.15).

For the most part, the licensing system and associated safeguards, including strong codes of practice promoted by industry,<sup>300</sup> stringent quality control and assurance systems with which manufacturers must comply,<sup>301</sup> and a comprehensive system for inspections of manufacturers and distributors premises by TGA officers,<sup>302</sup> are viewed as ensuring best practice in drugs and medicines control in Australia. There have been few cases, for example, of rogue unlicensed persons engaging in the pharmaceutical trade in Australia (WHO 2002, p.63).<sup>303</sup>

298 Other than the fact that a doctor who prescribes Schedule 8 drugs must get a permit to do so from the relevant state authority, see Chapter 3.2.

Evidence of Ms Kerry Deans, CEO, Pharmaceutical Society of Australia, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Canberra, 17 May 2007.

299 Dr Kay Sorimachi, Director of Policy Development, Pharmaceutical Society of Australia, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Canberra, 17 May 2007.

Similarly, although not a prescription drug per se, the PSA does not believe the rescheduling of large packets of pseudoephedrine to Schedule 4 will stem the illicit diversion and trade in this substance in the long term. Other measures such as the Project Stop programme, discussed in Chapter 4.3, in their view has better potential to address this issue. (See submission of the Pharmaceutical Society of Australia (Victorian Branch) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

300 See for example the Code of Practice of *Medicines Australia* at [www.medicinesaustralia.com.au](http://www.medicinesaustralia.com.au)

301 See Section 36 *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulations 1990* (Part 4).

302 See Section 48 *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulations 1990*.

303 For example, the WHO Review of comparative drug regulation systems found that the percentage of violations against Good Manufacturing Practice (GMP) standards in medicine manufacturing plants varied from 1 per cent in Australia to 60 per cent in Uganda and an extraordinary 83 per cent in Estonia (WHO 2002, p.73).



Given these benefits associated with licensing, the Galbally Review was of the view that whilst the licensing system does act in restraint of trade in the sense that it restricts those who may enter and operate in the market, the overall benefits in terms of protecting public health and safety justify the restrictions, which should be maintained.<sup>304</sup>

### Advertising

The *Therapeutic Goods Act* and associated state legislation basically prohibits the advertising of Schedule 4 (prescription), Schedule 8 (controlled substances) and some Schedule 3 (sales supervised by pharmacist) medicines. Such controls are directed towards the consumer. Where advertising is permitted, as is the case with some Schedule 2 and 3 medicines, the Therapeutic Goods Advertising Code<sup>305</sup> governs the acceptability and monitoring of such advertisements.

The rationale for the prohibition on advertising to consumers was explained in the Final Report of the Galbally Review:

The underlying objectives of the restrictions on advertising relate to concerns that consumers – and particularly those in vulnerable positions because of serious health conditions – would not be in a position to assess the sort of claims that might be expected to appear in advertisements for many scheduled medicines (Galbally 2000a, p.50).

For the most part, advertising or promotion of drugs and medicines to qualified health care professionals is permitted, whether this is in medical journals, trade magazines or by pharmaceutical company representatives. The advertising of such products to medical professionals and the use of sales representatives to promote and give doctors free products (sampling)<sup>306</sup> is also governed by the provisions of the Medicines Australia Code of Conduct, to which most pharmaceutical companies operating in Australia are signatories. A criticism has been made, however, that whilst Medicines Australia does a good job of reviewing inappropriate marketing and imposes hefty fines on its members who may transgress the Code, it does little or no pre-emptive surveillance of the advertisements (*Health Report* 2006).

The Galbally Review examined alternatives to the prohibitions on advertising of pharmaceutical products such as reliance on generic trade practices or consumer protection legislation. Again, it was felt that as this legislation is applied 'post-market' the damage might be done before any corrective action is taken (2000a, p.53). Therefore, apart from some relatively minor exceptions,<sup>307</sup> the Review did not support a relaxation of advertising restrictions.

### Accessing drugs on the Internet

One issue pertaining to both advertising of and access to drugs and medicines that has raised concerns in recent years is the use of the Internet and e-commerce. Whilst the current advertising restrictions of the *Therapeutic Goods Act* and its associated regulations and codes apply to all advertising, including the Internet, that is broadcast or otherwise disseminated in Australia, neither the Commonwealth or state governments have sufficient capacity to regulate 'spam' advertising that originates overseas. Unfettered access to drugs

304 Although the Galbally Review did recognise there may be some justification in abolishing or at least liberalising some of the restrictions associated with drug licensing for drugs and poisons placed in the lower risk schedules.

305 See Part 2 and Part 6 (Division 2) of the Therapeutic Goods Regulations 1990. The most recent version of the Code was tabled in July 2006 and can be accessed at the TGA website – [www.tga.gov.au](http://www.tga.gov.au)

306 For a discussion of issues surrounding the practice of sampling, see Galbally 2000b, pp.94ff. This is one of the areas where state laws may differ. In Victoria, for example, pharmaceutical company representatives are not permitted to carry sample products when they meet on promotional visits with health care professionals. In some other states this may be permitted. The Review recommended that the regulation of sampling be removed from state jurisdiction and become subject to a national Code of Conduct administered by the Australian Pharmaceutical Manufacturers Association (now Medicines Australia) (see Galbally 2000a, pp.xixff).

307 For a discussion of these exceptions, see Galbally 2000a, pp.65ff. The Review recommended that advertising regulation become the sole province of the Commonwealth. This would, however, require complementary state legislation in cases where the advertising is purely intra-state (for example by a sole trading pharmacist). For a more general discussion of the regulation of pharmaceutical advertising see Hirshorn and Monk 2006, pp.682ff.



and medicines over the Internet poses dangers on two main levels. Firstly, there may be doubts as to the purity and safety of the drugs in question. Secondly, even if the drugs are therapeutically 'safe', without the intervention of a qualified third party such as a doctor or pharmacist to advise on their usage consumers may either wilfully or through ignorance take these medicines incorrectly and unsafely. As the Galbally Review noted: 'This is an international problem and one which the Commonwealth Government and the governments of other countries are attempting to resolve' (Galbally 2000a, p.50).<sup>308</sup>

A related issue is that of Internet prescriptions. As noted in Chapter 5.3, although the use of mail order or Internet prescriptions and delivery of medicines may be advantageous for consumers in remote and rural parts of Australia where medical practices and pharmacists are sparsely located, concerns have been expressed that face-to-face counselling is not provided. Interestingly, however, consumer groups in submissions to the Galbally Review supported the use of mail order and Internet 'pharmacy' for the cheaper costs they provided. This was also one of the reasons that pharmacy groups were opposed to their proliferation (see Galbally 2000b). Pharmacists are also concerned about the dangers of 'medical misadventure' associated with laypersons buying medicines via the Internet. In a submission to this Inquiry the Pharmacy Board of Victoria expressed their concern that the 'public is not given sufficient awareness of the dangers of buying medicines online'. Whilst the Board considers the TGA website to contain a good alert system with regard to online 'spam' advertising of medicines, few people would be aware of this service.<sup>309</sup>

Because of the arguably growing importance of the Internet as a mechanism for accessing illegal prescription drugs, this issue is discussed at length in Chapter 5.3 of this Report.

### The Galbally Review

The National Competition Policy *Review of Drugs, Poisons and Controlled Substances Legislation* (The Galbally Review) was conducted in 2000 and examined the restrictions on medicines and poisons supply imposed in national and state/territory legislation. The major issues it examined related to impositions on who can develop and supply drugs and medicines (particularly through scheduling, prescribing and licensing) and restrictions on how the goods can be supplied.<sup>310</sup> The ultimate object of the Review was to assess whether the benefits of the controls to the community as a whole outweighed the costs imposed on certain sectors (such as producers). The Review considered a number of alternatives to regulatory control including self-regulation, co-regulation particularly in association with professional standards developed by health professionals and codes of practice with industry groups, better education and training, and generic regulation through placing more reliance on general legislation such as consumer protection Acts<sup>311</sup> (Galbally 2000a). On balance the Review decided that the benefits of maintaining regulation did indeed outweigh any associated costs and for the most part should remain. Certainly the Review believed that the major features of the regulation system such as licensing and scheduling should remain.<sup>312</sup> In June 2005 the Council of Australian Governments unanimously approved the Galbally Review's Final Report and the response of the Australian Health Ministers' Advisory Council to its recommendations. The transitional arrangements for a change to a new system are currently being undertaken.

308 See also the discussion in Chapter 5.3.

309 Submission of Pharmacy Board of Victoria to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

310 A detailed discussion of the Review is beyond the scope of this chapter. For the Review's Terms of Reference, see Appendix A1 in Galbally 2000a, pp.103ff.

311 It was thought relying on consumer protection legislation was an inadequate safeguard, as usually such laws operate only 'after the event' (Galbally 2000b, p.128).

312 The Review was prepared to deregulate some areas of therapeutic goods control, particularly in the area of advertising of drugs and medicines in the lower schedules. See the Review's Recommendations in Galbally 2000a, pp.xiv-xxiv.



One of the key concerns of the Review was that there is a need for greater uniformity of drug control and regulation across Australia. This concern was echoed in a later Report of the WHO. Discussing countries with federal systems of government, it stated that:

Where drug regulatory responsibilities are divided, there is no unity of command over drug regulatory functions. The missing links resulting from fragmentation and delegation can undermine the overall effectiveness of regulation. Drug regulatory structures should be designed in such a way that there is a central co-ordinating body with overall responsibility and accountability for all aspects of drug regulation for the whole country (WHO 2002, p.3).<sup>313</sup>

The Galbally Review found that a lack of uniformity could result in the following jurisdictional problems:

- there are increased costs for business, of multiple standards required for labelling, storage, handling etc;
- the costs of establishing what the standards are in all the jurisdictions in which a company wishes to operate;
- there are inhibitions and problems for those health professionals moving across borders, especially for those practising near state borders;
- there are confusions and frustrations for consumers in a mobile society (associated with migration and travel) in identifying and using drugs and poisons safely and effectively; and
- there are costs for government of duplication of regulatory agencies in designing and monitoring standards and inefficiencies in administering those controls (Galbally 2000b, p.29).

Respondents to the Review, particularly those from the pharmaceutical industry, argued that a lack of uniformity across the country increased the costs of compliance.<sup>314</sup> On the other hand, medical consultants indicated to the Review that a lack of uniformity could create problems in prescribing and dispensing for people taking medications in different jurisdictions (Galbally 2000b). This was a particular problem for those practising in border regions such as Albury–Wodonga.

To address the issues of uniformity the Review recommended that all the states adopt, where they have not already done so, the provisions of the *Therapeutic Goods Act 1989* including scheduling decisions made under the SUSDP by reference into their state legislation. Eventually the Commonwealth will be working towards establishing uniform national model legislation in this area for adoption by states and territories.<sup>315</sup>

313 One of the few weaknesses noted of the Australian regulatory system according to the WHO was that its federal system of government means that the TGA 'does not have the authority to assess and control the drug distribution system for the whole country' (WHO 2002, p.126).

314 Although happening relatively seldom, in some cases an over-the-counter medicine might be scheduled S2 in one state and S3 in another, requiring separate labelling, packaging, different training programmes for pharmacists and their staff etc. Correspondence to this Inquiry by pharmaceutical company Mundipharma (August 2006) noted that pharmaceutical drug regulation should ideally be conducted on a purely national basis in Australia. It stated:

'Individual actions being taken by the various regulatory bodies – whilst all well considered and intentioned in isolation – demonstrate the fractured nature of the various approaches to these issues across Australia. Again, Mundipharma believes it is important to have, wherever possible, a nationally coordinated response to these matters in order to ensure ready access to S8 pain medication, whilst minimising opportunities for abuse and diversion. The power of a national approach, harnessing knowledge and expertise of all available stakeholders, to "get it right first time" should not be underestimated.

Frequent incremental changes to state and federal legislation governing the control of S8 prescription products cause significant confusion amongst those health professionals required to abide by these controls, and consequent significant difficulty in complying. While the laws may be good, lack of strict compliance by the various parties to the process weaken their effect and create opportunities for abuse and diversion of "controlled" prescription products.

Additionally, such a national response could address the important concern of a number of Australia's State Health Authorities of limited ability to detect and intervene in prescription drug abuse and diversion occurring across State borders.'

315 There was some resistance to this proposal during the Review consultation stage. The Australian Health Ministers' Working Party's response to the Review recommendations accepted this recommendation in principle but felt that further consultation is required (Australian Health Ministers Advisory Council 2003).



Other than problems associated with a lack of uniformity, which for the most part have now been resolved or are in the process of being changed,<sup>316</sup> it is generally agreed that the scheduling process and associated regulatory procedures work well in Australia. The problems lie, according to some commentators, not in the process but in the decisions that are made under its provisions, for example whether a particular drug is marketed at the appropriate level of access.

Other concerns expressed with regard to Australia's system of drug regulation since the Galbally Review report was published include that insufficient attention is paid on occasion to post-marketing surveillance of drugs, the regulation of medical devices and the advertising of drugs and medicines.<sup>317</sup> These are all important issues but beyond the scope of this Report. The next major section of this chapter switches from a discussion of the macro levels of regulation largely administered through the Commonwealth to a closer examination of the oversight of drugs and medicines, prescribed, dispensed and administered at local level.

## **The regulation and administration of pharmaceutical drugs and medicines in Victoria**

As the previous discussion indicates, the prescription and supply of medicines is somewhat a 'closed shop' that overrides the rules of competition policy, requiring as it does a qualified medical professional to mandate the possession of the drug and a qualified pharmacist to supply it. As such, a system of rules and guidelines has been developed at state level to ensure the best management of medicines and their administration in Victoria.

### ***Legal control of drugs and medicines in Victoria***

Most of the key features of the Commonwealth Therapeutic drugs legislation, at least as they relate to prescription medicines, have been incorporated into Victorian law. This has traditionally been done in a number of ways, outlined below.

#### **The Therapeutic Goods (Victoria) Act 1994**

First, the state *Therapeutic Goods (Victoria) Act 1994* (hereinafter TGVA 1994) implements, through mirror legislation, a system of therapeutic goods control complementary to those in the Commonwealth *Therapeutic Goods Act 1989*.<sup>318</sup> Thus, for example, Victorian sponsors and manufacturers<sup>319</sup> of therapeutic goods must comply with the listing and registration procedures of the Australian Register of Therapeutic Goods (ARTG) and with the applicable Commonwealth standards for the production or supply of the goods.<sup>320</sup> Evaluation of therapeutic goods applications in Victoria follows the same procedures as laid down at

316 For a detailed account of how the recommendations of the Galbally Review will be put into practice, including a new proposed model for the scheduling of medicines, see TGA 2005a and TGA 2005b. The proposed new model has accepted one of the recommendations of the Review to divide the current scheduling committee into two. From late 2006 a Medicines Scheduling Committee (MSC) and a Poisons Scheduling Committee (PSC) will operate under a joint agency framework. The MSC will give advice on matters pertaining to Schedules 2, 3, 4, 8 (medicines) and 9 (prohibited substances). The PSC will give expert advice on poisons, household, agricultural and industrial chemicals (Schedules 5, 6, and 7). The content of the standard will in other respects remain essentially the same. Another recommended change to the system that has been accepted is the proposal to conduct the scheduling process at the same time, wherever possible, as the product evaluation/assessment rather than separately, as is currently the case. Such a change, it is argued, will result in great benefits in terms of time and cost savings. See generally Galbally 2000a.

317 This has also been a criticism made in the United States. A recent Report by the Institute of Medicine (IOM) was critical of the fact that the Food and Drug Administration (FDA) does not currently require post-marketing surveillance for prescription drugs. The IOM report specifically recommended that the FDA have the ability to require post-market risk assessment and risk management programs to monitor and ensure ongoing drug safety (Institute of Medicine 2006).

318 The Commonwealth Therapeutic Goods Regulations 1990 in turn recognises the *Therapeutic Goods (Victoria) Act 1994* (Vic) (TGVA) as the corresponding state law for the purposes of the federal act. See Section 3(1) *Therapeutic Goods Act 1989* (Cth) and Section 3 *Therapeutic Goods Regulations 1990* (Cth).

319 TGVA 1994 Part 3.

320 TGVA 1994, Part 2.

Commonwealth level<sup>321</sup> and the words and phrases used in the Commonwealth Act are expressly adopted with the same meanings in the state legislation.<sup>322</sup>

### The Poisons Code and List

The second major method by which the features of the Commonwealth regulatory system are incorporated into Victorian law is through the operation of the Poisons Code.

The Poisons Code operates subject to the provisions of Section 12 and 12A of the *Drugs, Poisons and Controlled Substances Act* (DPCSA). The Code includes a Poisons List and when adopted by the state Minister for Health incorporates any of the Commonwealth standards with regard to the advertising, labelling, storing or packaging of poisons and controlled substances.

The Poisons List in effect includes by reference Schedules 2–9 of the Commonwealth standard and an additional Schedule 1 pertaining to traditional Chinese medicines that is exclusive to Victoria. Provision is also made in the Victorian Act for any of the Commonwealth *Therapeutic Goods Act* appendices; any of the decisions or interpretations under the SUDSP; and any of the exemptions made under the Commonwealth standard or schedules to be incorporated by reference into the Victorian Poisons List. In effect this means that for most purposes the schedules and the drugs are the same at Commonwealth and state level.<sup>323</sup>

Victorian health law and practice also refers to 'drugs of dependence'. This term is used to describe all Schedule 8 drugs plus those Schedule 4 drugs that may be subject to abuse and illicit trading. Benzodiazepines are included as 'drugs of dependence'.<sup>324</sup>

Regulations made under the DPCSA also allow the Minister and where relevant the Secretary to the DHS Victoria (hereinafter the Secretary) to approve changes and make decisions that affect the operation of the schedules and the drugs contained in the Poisons List. The DPCSA regulations have only recently been significantly overhauled. They are discussed further in Chapter 3.2 of this Report in the context of state review and oversight of prescribing controlled substances.<sup>325</sup>

Finally, the operation of the DPCSA is also subject to the advice of the Poisons Advisory Committee. This Committee, comprising of the Secretary and a number of expert members,<sup>326</sup> advises inter alia the Minister on matters pertaining to the Poisons Code, Poisons List and issues with regard to the regulation and administration of drugs and poisons generally within Victoria.<sup>327</sup>

### Licences, permits and warrants

Under the DPCSA a variety of licences, permits and warrants that are relevant to the regulation and administration of drugs and poisons (including prescription medicines) may be issued, refused renewed or revoked by the Secretary.<sup>328</sup> The licensing and permit system is the main way in which controls are maintained over the manufacture, sale and supply of scheduled drugs in the state. In conjunction with the regulations and the

321 TGVA 1994, Section 27. For example, as in the *Therapeutic Goods Act 1989*, the Victorian legislation includes the British Pharmacopoeia as the definitive standard reference with regard to the evaluation of drugs and medicines (see TGVA Section 67).

322 TGVA 1994, Section 4.

323 It remains to be seen whether this will change in the future. As discussed earlier in this chapter it may be that some time in the future Commonwealth law will cover the field if the states and territories cede their powers and a uniform national system based on federal legislation becomes a reality.

324 It should be noted that the Act and regulations discuss scheduled *poisons* (for example Schedule 8 poison). In the context of this chapter, however, the discussion more generally refers to scheduled *drugs*, to distinguish them from the more commonly understood reference to a poison (for example, household or industrial poison).

325 See *Drugs, Poisons and Controlled Substances Regulations 2006*. In particular, see Division One, Section 5 for a list of those persons deemed authorised to have Schedule 4, 8 and 9 drugs in their possession.

326 Including medical practitioners, pharmacologists, pharmacists and police representatives. See Section 15 DPCSA.

327 See Section 17 DPCSA for the functions of the Committee.

328 See generally DPCSA Division Four.



directives of the Secretary,<sup>329</sup> the licence system is applicable to manufacturers, wholesalers, retailers, medical practitioners, pharmacists and other healthcare professionals.<sup>330</sup> Discussion with regard to the Victorian permits and licensing system is found in Chapter 4.3 in the section pertaining to state prescription drug monitoring.

It should be noted, however, that the Victorian Department of Human Services is currently reviewing the operation of the prescription drug licensing and permit system. A Departmental *Discussion Paper* has been prepared outlining some gaps and problems in current legislation and practice. It is envisaged that any possible changes to the system arising from this *Discussion Paper* will be introduced in 2008.

329 For example, under Regulation 6 of the Drugs, Poisons and Controlled Substances Regulations 2006, the Secretary has the power to approve the authorisation of certain scheduled drugs (including Schedule 4, 8 and 9 poisons) to certain classes of people. Recently the Secretary has authorised general approval for: registered optometrists to possess and administer a variety of Schedule 4 drugs including anaesthetics; qualified Australian ski patrollers to possess and administer certain Schedule 4 drugs in emergency situations; and hospital midwives to possess and administer single doses of pethidine or morphine to women in labour. For details of these and other approvals, see DHS Victoria 2006f, *Approved by the Secretary*, circular, located at DHS Victoria (Drugs and Poisons Unit), website – [www.health.vic.gov.au/dpu/approve.htm](http://www.health.vic.gov.au/dpu/approve.htm) (Accessed 3 July 2006).

330 See Section 20 DPCSA. Under this section, for example, a licence holder may manufacture and sell or supply by wholesaler any Schedule 8 or 9 drug, with the specific exception of heroin. The granting of permits to medical practitioners or nurse practitioners to prescribe drugs of dependence (Schedule 8 and in some cases Schedule 9) is specifically located in Section 34 of the Act.

## 3.2 Criminal and other Laws Pertaining to the Abuse of Prescription and other Pharmaceutical Drugs

Within Victoria a number of criminal and quasi-criminal offence provisions apply when otherwise licit drugs such as benzodiazepines are used illicitly. Such offences include illegal possession, manufacture and trafficking of drugs of dependence, including but not restricted to prescription and pharmaceutical drugs such as benzodiazepines and opioid analgesics.<sup>331</sup> There are also specific offences under the *Drugs, Poisons and Controlled Substances Act 1981* (DPCSA 1981) that pertain to the illegal use of prescription drugs.

### General laws pertaining to criminal possession and trafficking

Whilst the criminal law as it relates to drugs is primarily the responsibility of the states and territories, it is to some degree influenced by international conventions and national laws.<sup>332</sup> Commonwealth criminal law pertaining to drugs, including prescription drugs (mainly opioid analgesics such as morphine, oxycodone etc), predominantly concerns the illegal import and export of drugs and particularly 'narcotic goods'. These provisions are found in Section 233B of the *Customs Act 1901* and its associated schedules.<sup>333</sup>

### Victorian law

The Victorian DPCSA 1981 covers drug offences occurring within the jurisdictional boundaries of Victoria. These include offences pertaining to:

- ◆ Use
- ◆ Possession
- ◆ Cultivation<sup>334</sup>
- ◆ Trafficking.

331 An issue of great importance in this respect is the diversion of pharmaceutical drugs such as pseudoephedrine and precursor chemicals to manufacture amphetamines such as 'speed'. However, as the Drugs and Crime Prevention Committee of the 55th Parliament has comprehensively canvassed the issues pertaining to this practice in its Inquiry into Amphetamine and 'Party Drug' Use, it will not revisit this issue in this Report other than to state that since that Inquiry was conducted large packs of pseudoephedrine based pharmaceuticals have been rescheduled to Schedule 4 (Prescription only medicine). The interested reader is also referred to the *Final Report (2004)* of that Inquiry for further details of pseudoephedrine diversion and amphetamine manufacture. See also the *Drugs, Poisons and Controlled Substances Act* (Sections 71C and 71D) for recent proposed changes to the laws relating to amphetamine and designer drug manufacture from precursor chemicals.

332 The most relevant treaties are:

- The United Nations Single Convention on Narcotic Drugs (1961);
- The United Nations Convention on Psychotropic Substances (1971); and
- The United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988).

For a discussion of the international aspects of drug law and how these conventions have been incorporated into domestic law see Drugs and Crime Prevention Committee, *Inquiry into Amphetamine and 'Party Drug' Use in Victoria – Final Report*, May 2004.

333 The drugs subject to criminal penalties for trafficking are found in Schedule 6. For further discussion of Commonwealth criminal law in this context, see Drugs and Crime Prevention Committee, *Inquiry into Amphetamine and 'Party Drug' Use in Victoria – Final Report*, May 2004. See also Winford 2006 for a good general account of the law.

334 Cultivation is clearly irrelevant for the purposes of this chapter, as it relates predominantly to cannabis.



## Use

The use of a drug of dependence<sup>335</sup> other than cannabis provides for a maximum penalty of 5 penalty units or imprisonment of one year or both (Section 75(b) DPCSA 1981). The offence of using a drug of dependence in practice mainly applies to illicit drugs such as heroin rather than prescription drugs, although certainly opioid analgesics such as morphine can be used illicitly.

A variety of diversion programmes are available for people charged with non-violent drugs offences who can show that they have a 'drug problem'. These include the Court Referral and Evaluation for Drug Intervention and Treatment Program and Drug Treatment Orders under the new Drug Court. A discussion of these programmes is beyond the scope of this Report (for further information, see Winford 2006).

## Possession

Possession is an indictable offence under Section 73 of the Act. Winford explains the relevant law as follows:

Under common law, a person is in possession of a drug if he or she has physical control or custody of the drug to the exclusion of others not acting with the person. The prosecution must prove knowledge by the person of the presence of the drug and an intention by the person to possess the drug. In many cases, custody of a drug may supply sufficient evidence of possession, including the necessary mental element. This is because the inference of knowledge may often be drawn from the surrounding circumstances.

As well as its common law meaning, possession has an extended meaning under the Drugs, Poisons and Controlled Substances Act 1981; Section 5 states that a person is in possession of drugs if he or she is in possession of drugs that are:

- On any land or premises occupied by the person; or
- Used, enjoyed or controlled by the person in any place whatsoever, unless the person satisfies the court to the contrary (Winford 2006, p.119).

With the exception of cannabis, the penalties relating to possession of a drug that is not related to trafficking is \$3,000 and/or one year's imprisonment or both (Section 73(1)(b)).

## Trafficking

The law of trafficking is complex. In simple terms, if the prosecution proves that following matters:

- the accused was in possession
- of a drug listed in Schedule 11 of the DPCSA 1981
- of a quantity that is a *trafficable quantity*,
- this will be *prima facie* evidence of the crime of trafficking.

A trafficable amount is determined by reference to a prescribed weight listed for that drug in Schedule 11 of the DPCSA 1981. Under Section 70(1) of the Act, the definition of trafficking has been extended to include preparing or manufacturing a drug of dependence for trafficking, in addition to sale or possession for sale of the drug. Of particular importance is the fact that at state level the trafficable amount of the drug (in powder form) is no longer weighed as pure amounts: 'The relevant weight is now the weight of the whole mixture, including substances other than the drug' (Winford 2006, p.122). Drugs that *are* weighed in pure amounts, which would include most prescription drugs, are listed in Part One of Schedule 11. A trafficable amount in methadone, for example, is listed as 2 grams

<sup>335</sup> For the purposes of these offences, 'drug of dependence' is defined by reference to the drugs listed in Schedule 11 of the DPCSA 1981. This is not to be confused with the drug schedules that have been incorporated by reference into the Act from the Commonwealth standard. Thus a Schedule 8 drug such as morphine will also appear in Schedule 11 for the purposes of being a drug of dependence that can be the subject of criminal charges such as trafficking.

pure weight. Trafficable amounts of diazepam and temazepam are 2 and 3 grams respectively.

In addition to trafficable quantities, a person may also be convicted of the more serious crime of trafficking in a *commercial quantity*. Commercial quantities and large commercial quantities for drugs of dependence are also found in Schedule 11 of the Act. The current commercial quantity of methadone, for example, is 2 kilograms (pure amount).

Trafficking offences of non-commercial amounts attract a maximum penalty of 15 years imprisonment. This sentence increases to 20 years imprisonment when the person is convicted of trafficking to a person under the age of 18.

A conviction for trafficking in a commercial quantity results in a maximum penalty of 25 years imprisonment. If the person is convicted of trafficking in a large commercial quantity, the penalties are even more severe – possible life imprisonment and in addition up to a \$500,000 fine.

### ***Laws regarding theft and associated offences***

Clearly, the criminal law provisions with regard to theft, burglary, robbery, fraud and associated offences will also be applicable where prescription drugs have been illegitimately obtained.<sup>336</sup> The circumstances where this may be relevant range from 'ram-raids' or break-ins on pharmacies to obtain drugs,<sup>337</sup> theft of prescription pads from medical surgeries or doctors' bags, or theft of medicines and drugs by people working in the healthcare field. Fraudulent means have also been used to obtain computer software to generate unauthorised prescriptions. Similarly, scanners have been used to obtain a genuine computer generated prescription upon which the patient details, drug, quantity and/or number of repeats may be fraudulently changed to receive unauthorised drugs.<sup>338</sup>

### ***Prescription drug offences***

Whilst prescription drugs are included in the general drug laws that apply to possession and trafficking, there are also some criminal offences that apply specifically to these drugs because they are only available when prescribed by a qualified medical practitioner or supplied by a qualified pharmacist. The two major offence types are forgery of prescriptions or knowingly presenting forged prescriptions in order to illegitimately obtain drugs, and obtaining drugs through fraud or false pretences. Offences of forgery of prescriptions are found in Section 77 for drugs of dependence and Section 36A for other prescription drugs.<sup>339</sup> Obtaining drugs through fraud or false pretences provisions are found in Sections 78 (drugs of dependence) and 36B (other prescription drugs) of the DPCSA.<sup>340</sup> The major

336 Victorian criminal laws with regard to theft and associated offences are primarily found in the *Crimes Act 1958*. The major offences that are relevant in this context are Section 74 (Theft), Section 75 (Robbery), Section 75A (Armed Robbery), Section 76 (Burglary), Section 77 (Aggravated Burglary) and Section 81 (Obtaining Property by Deception).

337 A relatively common occurrence when temazepam liquid-filled capsule products were on the general list of the PBS. Since those products were taken off the market, the drugs most subject to theft and burglary are pseudoephedrine based products. See Submission of Pharmacy Board of Victoria to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

338 See Submission of Pharmacy Board of Victoria to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

Theoretically, a person could be charged under Section 83A of the *Crimes Act 1958* (Falsification of Documents) for such conduct, but it is more likely that they would be charged under the specific forgery of prescription provisions of the DPCSA outlined earlier in this chapter.

339 This area of the law is somewhat unclear and confusing. Section 36A is stated to apply to Schedule 8, 9 and 4 poisons that are not drugs of dependence. Section 77 covers all other cases (that is, forgeries of prescriptions for drugs of dependence being drugs listed in DPCSA Schedule 11). Whilst there are certainly drugs such as antibiotics that may fall within Schedule 4 and are not drugs of dependence, most Schedule 8 drugs are drugs of dependence and as such are included in Schedule 11 of the DPCSA which classifies drugs of dependence for the purposes of trafficking and criminal possession (see below). In effect this seems to make Section 36A largely superfluous, at least as it pertains to Schedule 8 and 9 poisons.

340 Similarly, whilst Section 36B is applicable to obtaining Schedule 4, 8 or 9 poisons through false representations or to cases where a person is in possession of such drugs without appropriate authority it is particularly stated not to apply to drugs of dependence. Again, as most if not all Schedule 8 and 9 drugs are drugs of dependence it is unclear as to how Section 36B applies in these circumstances.



difference between the offences that apply to drugs of dependence (Sections 77 and 78) are that a person found in contravention of these offences is liable to a sentence of imprisonment whereas a fine only will apply to the offences that apply to other prescription drugs (Sections 36A and 36B).

### Is a particular offence for 'doctor shoppers' required?

One final point that should be made in the context of prescription offences relates to those people who 'fake' their symptoms when presenting to a doctor or other medical professional in order to illegitimately obtain a prescription for their drug of choice ('doctor shopping').<sup>341</sup> The Turning Point Alcohol and Drug Centre noted that:

Symptoms have reportedly often been faked in order to obtain the drugs. Of those faking symptoms in Victoria, insomnia (57%), anxiety (42%) and opiate dependence (31%) were the most commonly reported symptoms used to obtain benzodiazepines and/or opioids (Victorian Department of Human Services 2002a).<sup>342</sup>

Some states of the United States have penalised such behaviour through the creation of specific criminal law statutory offences targeting 'doctor shopping'. For example in Hawaii it is unlawful:

[f]or any person knowingly or intentionally to visit more than one practitioner and withhold information regarding previous visits for the purpose of obtaining one or more controlled substance prescriptions for quantities that:

- (1) Exceed what any single practitioner would have prescribed or dispensed for the time period and legitimate medical purpose represented; and
- (2) Would constitute an offense pursuant [to law].<sup>343</sup>

Similar provisions can be found *inter alia* in the statute books of Kentucky, California, Connecticut, Florida, Georgia and Maine, Nevada, New Hampshire, South Carolina and Utah.<sup>344</sup>

A submission from the Australian Medical Association (Victoria) (AMA (Vic)) to this Inquiry stated that, as behaviour such as the faking of medical symptoms is currently not subject to any legal consequences, 'The Committee [DCPC] might consider whether a civil or indeed a criminal penalty might act as a deterrent to this behaviour'.<sup>345</sup> The AMA (Vic) raised this matter again when representatives gave evidence to the Committee in June 2007.<sup>346</sup>

It is likely there would be myriad legal, ethical and practical problems in implementing such a law in Victoria. Australia's position is to be distinguished from that of the United States, which appears, at least in the jurisdictions the Committee visited, to take a more

341 For a discussion of the issue of 'doctor shopping', see Chapter 2.4.

342 Submission of Turning Point Alcohol and Drug Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

343 Hawaii Revised Statutes 329-46(1).

344 For further details of state doctor shopping provisions in the USA, see National Alliance for Model State Drug Laws 2006b.

345 Submission of the Australian Medical Association (AMA) (Victoria) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

346 See Evidence of representatives of the AMA (Vic) given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007.

punitive law enforcement approach to 'doctor shopping' compared to the therapeutic orientation of Australian interventions.<sup>347</sup>

In particular, what is concerning about some of the American provisions on 'doctor shopping' is that theoretically it would seem they do not distinguish between the person who is generally addicted to prescription drugs and 'doctor shops' as a means of feeding that addiction and the person who may do it in order to trade the drugs or otherwise profit through his or her fraud. In the former case it is arguable that therapeutic measures are best employed to deal with that person's problem. In the latter case, as discussed earlier in this chapter, there are already sufficient legal provisions in place in Victoria to address behaviour which is purely criminal in nature.

Another problem associated with 'doctor shopping' offences, at least as they have been formulated in America, is that they rely on medical practitioners giving testimony to sustain and prove the charges. In Kentucky, 'doctor shopping' offences are classified as Class D felonies punishable by five years incarceration.<sup>348</sup> When the Committee met with officials from the Kentucky Cabinet for Family and Health Services, the problems associated with doctors giving evidence against 'doctor shoppers' were raised:

We did a meeting once in one part of the state and there was a doctor at the meeting and I knew him and he was sullen. I said have you got a problem with KASPER [Monitoring system] and he said no, not with KASPER. 'What I don't like is having to go to court and testify when they get a doctor shopping case. It shouldn't be up to me.'

And I said 'Doctor shopping is lying to you, how can we prove that they're lying to you if you won't testify?' He never thought of it that way, he thought that they were harassing him by making him testify. Doctors don't like that but it's the only way that you can get them involved. Once they're involved they're usually pretty good about it.<sup>349</sup>

One official did comment however, that prosecuting 'doctor shopping' cases were easier once an automated monitoring system such as KASPER (Kentucky All Schedule Prescription Electronic Reporting) had been put in place and a specialist and dedicated enforcement agency was established to police the 'doctor shopping' laws:

When we first got KASPER my agency was probably the only agency that on a consistent basis worked on doctor shopper cases because before KASPER those were hard cases to work. Your regular police agencies in the state didn't have the manpower or the resources

347 This is exemplified in California where 'doctor shoppers' are dealt with by the Bureau of Narcotic Enforcement (BNE) after having been tracked through the CURES program (see Chapter 4.1). Ms Judi Nurse, Inspector with the California Board of Pharmacy, expressed her views on the more criminally minded 'doctor shoppers' when the Committee met with her in Sacramento in August 2007:

'I'm not a police officer and I only have jurisdiction over the people that are licensed, so the wholesale direct distributors, the pharmacists or pharmacies. I don't have any jurisdiction of the actual doctor shoppers themselves. They need to be referred to local law enforcement. Having said that, we have real trouble with local law enforcement dealing with doctor shopping for the most part. The Bureau of Narcotic Enforcement most effectively deals with those individuals.

You find somebody that's going to 200 doctors a month, 20 doctors a month, how many doctors a month and you try to track that person down and you try to deal with what's going on; you may either find a person who is a runner and who is nothing but a dope dealer and that person just needs to go to jail and be incarcerated' (Ms Judi Nurse, Supervising Inspector, California Board of Pharmacy, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Sacramento, California, 2 August 2007).

348 The Kentucky Revised Statutes define and penalise the following acts as 'doctor shopping':

Knowingly misrepresenting or withholding information from a practitioner;  
Providing a false name or address;  
Knowingly making a false statement;  
Falsely representing to be authorised to obtain controlled substances;  
Presenting a prescription that was obtained in violation of the above;  
Affixing a false or forged label to a controlled substance receptacle (Kentucky Revised Statutes, Section 218A.140).

349 Mr Dave Sallings, Manager, Drug Enforcement and Professional Practices Branch, Kentucky Cabinet for Health and Family Services, Meeting with Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Frankfort, Kentucky, 31 July 2007.



to do it and [before the automated KASPER system was established] it took us an average of 156 days for a doctor shopper case because [it was all manual].<sup>350</sup>

Despite their support for the creation of a 'doctor shopping' offence, the representatives of AMA (Vic) who gave evidence to the Committee also were equivocal about the fact that doctors may have to go to court and give evidence should such an offence be developed. Whilst the Vice-president of the AMA (Vic) acknowledged that doctors would be 'not too happy' about testifying in court he thought the offence was needed on the basis that it would ultimately be in the interest of their patients and the healthcare system generally:

I would argue that the service or the system being protected by addressing doctor shopping [is in the interest of] the patient. If someone is actually going around collecting prescriptions to make money, what they are doing is defrauding the PBS [Pharmaceutical Benefits Scheme]. They are defrauding the Commonwealth. We are pawns in that piece of fraud, and we can play a role in mitigating the ability to defraud as doctors because we are trying to filter out who is genuine and who is not – we always do that anyway. But ultimately the fraud is being held against the PBS, not against us as doctors.<sup>351</sup>

Notwithstanding these considered views as to the need for a 'doctor shopping' offence, the Committee believes further research and investigation is required before such a recommendation could be adopted. Moreover, the Committee is firmly of the view that any interventions to address 'doctor shopping' should, as will be discussed in Section Four, be therapeutic and health oriented in focus rather than punitive and reliant on law enforcement only.

In the meantime, it may be that the Victorian AMA's alternative recommendation of providing 'a focus on patient education as to the harms of the misuse of prescription and over-the-counter pharmaceuticals'<sup>352</sup> may be more suitable at this stage.

#### *Drug driving and road trauma offences*

A particular problem associated with prescription drugs is the potential for their effects to have harmful consequences if the person taking them is driving or in control of a motor vehicle.<sup>353</sup>

In a submission to this Inquiry, VicRoads stated that road trauma caused by drug-impaired driving is a worldwide problem and that all impairing drugs including prescription drugs have a 'dose related accident risk relationship'. The submission from VicRoads refers to a report published in 2003 by the United States Highway Traffic Safety Administration. This report:

[r]eviewed the literature on the effects of a wide range of drugs on driving performance. The classes of drugs considered were narcotics, central nervous system (CNS) depressants, CNS stimulants, cannabis, antidepressants, antihistamines, and other drugs that have been investigated in a few individual studies.

The report concluded that with respect to the acute effects of drugs, the following drug classes have a high potential for significant impairment of driving and driving-related performance: narcotics, long-life benzodiazepines in therapeutic doses, short-life

350 Mr Dave Sallings, Manager, Drug Enforcement and Professional Practices Branch, Kentucky Cabinet for Health and Family Services, Meeting with Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Frankfort, Kentucky, 31 July 2007.

351 Dr Harry Hemley, Vice-President, AMA (Victoria), Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007.

352 Submission of Australian Medical Association (Victoria) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

353 For a discussion of the particular harms and injuries associated with prescription drugs and driving, see Chapter 2.2.

benzodiazepines in high doses, barbiturates, 1st generation H1 antihistamines, and some antidepressants...<sup>354</sup>

In summary, VicRoads comments that this report and other research literature indicates that:

[m]ost benzodiazepines can cause significant impairment of driving and driving-related tasks, especially at high dosages. However, it has been argued that therapeutic dosages create impairments that may be less hazardous to driving than the illnesses they are treating.<sup>355</sup>

Similarly, in a review of driving under the influence of drugs law in New South Wales, Godfrey and Phillips state that the five drug groups commonly seen in drug-impaired drivers are:

- Alcohol
- Cannabis
- Opiates and opiate derivatives
- Benzodiazepines; and
- Stimulants (2003, p.16).

Notwithstanding such concerns, it is only relatively recently that Australian legislatures have enacted laws and procedures that penalise motorists who drive with either any or a specified amount of illicit (and licit pharmaceutical) drugs in their system in ways comparable to driving under the influence of alcohol provisions (see Godfrey & Phillips 2003).

Currently in Victoria there are two major ways in which a person impaired with a drug other than or in addition to alcohol may be charged with a driving offence. These are described as follows.

#### **Driving or being in charge of a motor vehicle whilst drug impaired<sup>356</sup>**

This charge is used when a driver has one or more drugs in his or her system, the driver's behaviour consequent to a drug assessment test is consistent with 'drug related behaviour' and that behaviour could result in the driver being unable to drive properly.<sup>357</sup>

The *Road Safety (as amended) Act 1986* specifies the procedure to identify impaired drivers and gives Victoria Police the power to take blood for suspected drug impairment cases.<sup>358</sup> Ordinarily, a police officer will have first tested a driver suspected of driving whilst impaired for blood alcohol levels by a standard breath test. If the blood alcohol reading is significant the driver will usually be charged with an alcohol-related offence. If no or low alcohol readings are obtained, police may continue to test the driver for drug impairment. VicRoads explains the procedure as follows:

The basic steps involve a Roadside Opinion by Police, a Standard Impairment Assessment (SIA) by a trained assessor, a blood sample for confirmation, and expert evaluation of behavioural and toxicological evidence.

The Standard Impairment Assessment is based on established psychomotor tests. If the Impairment Assessor concluded that the driver might be impaired due to drug use, the driver may be required to provide a blood sample for analysis for the presence of drugs.<sup>359</sup>

354 Submission of VicRoads to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

355 Submission of VicRoads to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

356 Section 49(1)(ba) *Road Safety Act 1986*.

357 Section 49(3A) *Road Safety Act 1986*.

358 A person may be additionally charged in relevant circumstances for refusing to undergo a drug impairment assessment (Section 49(1)(ca)) and/or providing a blood or urine sample after a drug impairment assessment (Section 49(1)(ea)).

359 Submission of VicRoads to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.



Drivers have a defence to this charge if they can establish that the drug in question was a legitimately prescribed drug. The relevant law states:

If on an analysis carried out in accordance with this Part, no drug other than a permissible non-prescription drug or a prescription drug was found present in the person's body, it is a defence [to the charge]...for the person charged to prove that-

- (a) he or she did not know and could not reasonably have known that the permissible or the prescription drug, or the combination of those drugs, so found would impair driving if consumed or used in accordance with advice given to him or her by a registered medical practitioner, a dentist or a pharmacist in relation to the drug or combination of drugs; and
- (b) he or she consumed or used that drug or combination of drugs in accordance with that advice.<sup>360</sup>

Convictions for driving whilst drug impaired carry a minimum licence disqualification of 12 months (first offence) or two years for a second or subsequent offence.

A submission from the Victoria Police to this Inquiry states that it generally believes the new laws and testing procedures for drug driving impairment under Section 49 of the *Road Safety Act* have resulted in positive outcomes. In particular, the testing procedures 'provide police with an effective mechanism to identify and remove high risk drivers from the road and a considerable increase in the awareness of drug driving as a significant road safety concern'.<sup>361</sup> Victoria Police also note that the procedures have been implemented without difficulty, although there is a significant operational time commitment involved in both training officers with regard to the new specialised procedures and the time involved for the processing of suspected offending drivers.<sup>362</sup>

Overall, Victoria Police considers that:

The legislation has proved to be extremely successful as a mechanism for police to identify and remove drug impaired drivers from the road. Of the 324 drivers prosecuted under the legislation to 30 June 2004 only 3 cases did not result in conviction. A further 35 drivers were detected and identified as being impaired for reasons other than [illegitimate] drug use (medical conditions) and were referred for administrative driver licence review.<sup>363</sup>

### **Road Safety (Drug Driving) Act 2003**

In Victoria the *Road Safety (Drug Driving) Act 2003* has amended the parent *Road Safety Act* to include drugs, in addition to alcohol, for the purposes of random breath testing and the provision of drug driving infringement penalties.

The rationale behind such an enactment was clearly the dangers associated with drug driving and the increasing incidence of drug-related motor accidents in recent years.

Drug is now defined in the parent Act as:

a substance that is a drug for the purposes of this Act by virtue of a declaration under subsection (3) or any other substance (other than alcohol) which, when consumed or used by a person, deprives that person (temporarily or permanently) of any of his or her normal mental or physical faculties.<sup>364</sup>

<sup>360</sup> Section 49 (3B) *Road Safety Act 1986*.

<sup>361</sup> Correspondence from Victoria Police (Traffic Alcohol Section) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

<sup>362</sup> Correspondence from Victoria Police (Traffic Alcohol Section) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

<sup>363</sup> Correspondence from Victoria Police (Traffic Alcohol Section) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

<sup>364</sup> Section 3 *Road Safety Act 1986*.

Whilst such a definition could encompass most prescription drugs, currently the use of random breath testing solely applies to *prescribed illicit drugs*, which at this stage includes only cannabis and methamphetamine and certain 'party' or designer drugs such as MDMA ('ecstasy').<sup>365</sup>

Despite the current restricted class of drugs to which the legislation applies, VicRoads suggests that the technology can be utilised to make saliva testing for benzodiazepines a possibility:

The manufacturers of the main first roadside drug test have indicated that their devices performance characteristics could be set to only provide a positive result for drivers who have high misuse/abuse levels of the drug. The device would not give positive results for drivers who follow the medical guidelines for prescription use of the drug.<sup>366</sup>

VicRoads intends to seek funding in the next business planning cycle (2007/2008) to assess the suitability of these devices. If the review indicates positive outcomes they will then put forward a proposal to extend the programme.<sup>367</sup>

Victoria Police is more equivocal in their support for random saliva testing to be extended to include certain pharmaceutical drugs. Unlike their support for targeted drug driving impairment referred to in the previous section, they believe that before moving towards an extended random drug testing regime a number of factors need further consideration. These include:

- There is a high level of legitimate benzodiazepine type drug use in the treatment of medical conditions. Consequently, a large number of drivers will be driving when using benzodiazepine type drugs for legitimate medical reasons.
- The relationship between drug dose, drug affect and the drug level present in the body is influenced by the physiological tolerance to the drug in an individual. Many factors play a role in what level of tolerance is present in an individual. Such factor include, the drug dose administered, the frequency of drug administration and the time span over which the drug is administered.
- There is limited research information available in respect of what level of benzodiazepine type drug present in a person produces impairment of psychomotor skills to such an extent as to result in an inability to drive a motor vehicle safely.
- There is limited research information available to indicate what level of benzodiazepine type drug present in a person may be considered a therapeutic level as opposed to a level consistent with misuse and the presence of impairment.
- The currently available technology to test saliva for benzodiazepine type drugs in a roadside situation is relatively limited in terms of accuracy in respect of the level of drug present in a sample.<sup>368</sup>

In short, Victoria Police believe further research and investigation is required into the links between prescription drug use (particularly benzodiazepines) and the driving of motor vehicles and any dangers that may flow from this combination before such a new regime can be introduced.

<sup>365</sup> The initial legislation passed in 2003 established the oral fluid testing procedures on a trial basis only. The legislation was made permanent with the passing of the Road Safety (Drugs) Bill, which commenced on 10 May 2006.

<sup>366</sup> Submission of VicRoads to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

<sup>367</sup> Submission of VicRoads to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

<sup>368</sup> Correspondence from Victoria Police (Traffic Alcohol Section) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.



## Conclusion

Law and legal controls do not consist solely of the written law, regulations, offences or proscriptions. This is particularly true of an area as complex and sensitive as drug regulation where legal matters become entangled with medical and social issues to a large degree. Moreover, prescription and pharmaceutical drug misuse and abuse is particularly complicated by the fact that for the most part one is dealing with licit substances, although sometimes in illicit or illegitimate ways.

## Section Four: Monitoring Systems for Prescription Drugs

### 4.1 Prescription Monitoring Systems in Northern America

In the United States the abuse of prescription drugs including pain killers, stimulants, sedatives and tranquillisers has gone beyond the abuse levels of practically all illicit drugs, with the exception of cannabis. The abuse rate is higher than that of such drugs as MDMA (ecstasy), cocaine, methamphetamine and heroin (International Narcotics Control Board 2007, p.1).

#### Introduction

The Committee's research has revealed that the misuse/abuse of benzodiazepines and other pharmaceutical drugs has been identified for some time as being a serious problem in Canada and the United States. Whilst some rudimentary statistical analysis of the extent of the problem is given in Chapter 2.1 it is worthwhile noting that in the United States according to the 2005 National Survey on Drug Use and Health, the incidence of non-medical users of pain relievers is at 2.2 million Americans aged 12 and older, surpassing the number of new marijuana abusers (2.1 million). Moreover, the 2005 survey found that more than six million Americans reported current (in the past month) non-medical use of prescription drugs, 'more than the number abusing cocaine, heroin, hallucinogens and inhalants combined' (National Institute on Drug Abuse 2007, website).<sup>369</sup>

Similarly, in its Annual Report for 2007 the International Narcotics Control Board (INCB), a United Nations agency, noted with great concern the worldwide increase in the illicit, illegitimate or non-medical use of prescription medications. Whilst the report analyses international trends and is restricted to narcotic drugs, it did single out the United States as having an exceptional increase in the number of people abusing prescription analgesia and suffering severe physical and social consequences as a result (INCB 2007).

As in Australia, most people in the United States and Canada use prescription medicines responsibly and correctly. However, in recent years the number of people using prescription drugs for non-medical purposes, particularly pain relievers, has escalated. As a consequence, these countries have developed a range of regulatory regimes, law enforcement projects and educational, prevention and treatment strategies at both national and state/provincial levels.

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369 See also the figures collated in the most recent INCB Report discussed below.



## Regulation and monitoring of prescription drug abuse and diversion in the United States

### *A brief history of prescription drug monitoring*

In the United States, responsibility for oversight of prescription drug abuse, regulation and diversion of prescription drugs generally is divided between federal, state and local authorities. And therein lies a major problem. This division of roles and responsibilities has resulted in a lack of coordination and uniformity, as indicated in the following quote from the US General Accounting Office's (USGAO) review of OxyContin® abuse:

The [Federal] Foods and Drug Administration [FDA] is responsible for approving new drugs and ensuring that the materials drug companies use to market and promote these drugs are truthful, balanced and accurate. However FDA examines these promotional materials only after they have been used in the market place because the Foods, Drugs and Controlled Substances Act [FD and C Act] generally does not give FDA authority to review these materials before the drug companies use them. Moreover, the FD and C Act provisions governing drug approval and promotional materials make no distinction between controlled substances such as OxyContin® and other Prescription drugs.

The [Federal] Drugs Enforcement Administration [DEA] is responsible for registering handlers of controlled substances, approving production quotas and monitoring distribution of controlled substances to the retail level. It is the states, however, that are responsible for overseeing the practice of medicine and pharmacy where drugs are prescribed and dispensed. Some states have established prescription drug monitoring programs to help them detect and abuse diversion. However, these programs exist in only 15 states<sup>370</sup> and most do not proactively analyse prescription data to identify individuals, physicians or pharmacies that have unusual use, prescribing or dispensing patterns that may suggest potential drug diversion or abuse (USGAO 2003, pp.12–13).

Whilst such a structure is not too dissimilar from that operating in Australia, the problems are exacerbated in the United States because of the number of state and regional divisions. For example, 50 states have jurisdiction over 50 different systems of prescription regulation, as will be discussed below. This and other problems pertaining to addressing prescription drug misuse across the United States have been the subjects of numerous governmental and congressional inquiries and hearings, as indicated in the next section.

### **Congressional hearings and prescription drug abuse**

In the United States a number of federal congressional hearings and inquiries of both the House of Representatives and the Senate have been convened in recent years to address the growing problem of prescription drug abuse in that country. Some of the major ones and the outcomes flowing from these are listed in the following sections.<sup>371</sup>

#### *House Committee on Energy and Commerce, Subcommittee on Health, March 2004*

The Subcommittee on Health held hearings entitled *Prescription Drug Monitoring: Strategies to promote treatment and deter prescription drug abuse* in March 2004. A key element of the hearings was a discussion of the alarming trend in OxyContin® abuse in the rural Appalachian areas of Kentucky and West Virginia. Testimony was given by Congressman Harold Rogers of Kentucky as to the importance of strengthened prescription monitoring systems to combat such abuse. He graphically described to the Committee the effects of OxyContin® trading in his congressional district:

370 However, the number of states that have implemented or are in the process of developing a prescription drug monitoring programme (PDMP) has increased considerably since this USGAO report was written, as discussed later in this chapter.

371 Other congressional hearings held in recent years that have had a peripheral bearing on the issue of prescription drug abuse have included the House Subcommittee on Health's Inquiry into the *Food and Drug Administration and the Safety of the Nation's Drug Supply*. Space constraints preclude a discussion of these hearings in detail. Details can be accessed at <http://energycommerce.house.gov/Subcommittees/health.shtml>

Why do we have such a terrible problem with OxyContin abuse in my district? Simply put, too much of this product is on the market and is finding its way into the hands of the wrong people. There is a veritable glut of OxyContin making its way onto our streets.

Unfortunately also some of the very people sworn to protect life are actually peddling these drugs for their own personal gain. For instance, a doctor practicing in the northern Kentucky region was arrested by federal authorities last September for prescribing drugs without a lawful purpose. On average this doctor was handing out 800 prescriptions a month, which balances out to almost 40 prescriptions each working day.<sup>372</sup>

Congressman Rogers then outlined some of the initiatives and strategies he had sponsored in order to combat prescription drug abuse in his state and nationally:

In order to combat the epidemic of drug abuse in my Congressional District, I have initiated a program called Operation UNITE (Unlawful Narcotic Interdiction Treatment and Education) with \$16 million in appropriations over the last two fiscal years. There are three main components to the program: Law Enforcement, Treatment, and Community Involvement. The success of this program lies in its ability to bring people together for the greater good. Federal, state, and local officials work alongside members of the community to eradicate the scourge of drug abuse from the region.

Drug abuse has stretched the resources of law enforcement to the breaking point in my area. Operation UNITE addresses this problem by creating 3 regional task forces and hiring 32 law enforcement officers to perform undercover operations, which is twice the number of undercover narcotics street agents currently employed by the entire Kentucky State Police. We are also working to create greater coordination among local, state, and federal law enforcement agencies. As a result of these combined efforts, we expect the number of arrests and prosecutions for street-level trafficking to increase dramatically. Resources will also be provided to overburdened prosecutors so they can effectively convict dealers and keep them off of our streets. The creation of a new forensic drug lab will dramatically decrease the wait for narcotics analyses thereby decreasing the time it takes to bring cases to trial.

Getting dealers and corrupt doctors off the street is one thing – real success lies in getting those hooked on drugs back on track. As I mentioned earlier, our treatment centers are overwhelmed. Operation UNITE will address the issue in three stages. In the short term, treatment resources will be coordinated to maximize their potential, making the most of what we already have today. In the intermediate term, drug courts will be created in all 29 UNITE counties. This two-pronged approach will allow our criminal courts to focus on convicting dealers and the drug courts to sentence those of lesser crimes to the treatment they sorely need. Finally, our long term goal is to create new residential treatment centers and after-care programs in order to reduce the waiting period for those who want help kicking the drug habit.

In the past, a lack of coordination between organizations providing drug treatment services existed so that one hand did not always know what the other was doing. Some areas or segments of the population were over-served while others were completely neglected. The important messages being sent out could become muddled or, worse yet, conflicting. Operation UNITE will coordinate these efforts and everyone will be encouraged to become part of the solution. Local citizens will be empowered to join together. The significant resources and abilities of faith based groups and civic organizations will be tapped. Schools will be a focal point so that students can help fight the problem instead of becoming a part of it.<sup>373</sup>

In addition to such state based strategies, Congressman Rogers has also for many years been the key proponent of a national prescription drug monitoring programme (PDMP). The outcome of these hearings was in part an increase in funding and the strengthening of the

372 Accessed at, <http://energycommerce.house.gov/reparchives/108/Hearings/03042004hearing1221/Rogers1868.htm>

373 <http://energycommerce.house.gov/reparchives/108/Hearings/03042004hearing1221/Rogers1868.htm>



national prescription drug programme that bears his name. This is discussed at greater length later in this chapter.

*House Government Reform Committee – Subcommittee on Criminal Justice, Drug Policy and Human Resource, July 2006*

In July 2006 the House Subcommittee on Criminal Justice, Drug Policy and Human Resources (the Subcommittee) convened a series of hearings to address prescription drug abuse in America, entitled *'Prescription Drug Abuse: What is being done to address this new drug epidemic?'* Officials from key government agencies testified on the extent and causes of the problem and on current government efforts to reduce prescription drug abuse. Witnesses included parents of young people who had died from misuse of addictive prescription drugs, medical professionals, scientists, academics and representatives of pharmaceutical companies. Additional witnesses discussed other aspects of the problem as well as possible responses, including a public advertising campaign by the Partnership for a Drug-Free America and means to address the illicit sale of prescription drugs on the Internet.<sup>374</sup>

Of particular importance was the testimony of Mr Joseph Rannazzisi, Administrator of the National Drugs Enforcement Administration (DEA). The DEA is the agency responsible for the regulation and control of substances with abuse potential that are subject to the Controlled Substances Act (CSA (U.S.)), including most prescription drugs.

In addition to being responsible for scheduling controlled substances, the DEA sets production quotas for certain narcotic drugs and establishes import and export controls. Through its Office of Diversion Control (ODC) the DEA also investigates drug diversion at national and inter-state level and is responsible for registering qualified individuals and organizations, including chemists and pharmacists, thus enabling them to handle controlled substances and assist them with their responsibilities under the CSA (U.S.).<sup>375</sup>

In his overview of the problem of prescription drug abuse and diversion in the United States, Mr Rannazzisi stated:

Pharmaceutical investigations and surveys of state and local law enforcement agencies and state medical boards have revealed that the most common methods of controlled substance prescription drug diversion include 'doctor shopping' or other prescription fraud, illegal online pharmacies, theft and burglary (from residences, pharmacies, etc.), stereotypical drug dealing (selling pills to others), receiving from friends or family, and negligent or intentional over-prescribing by physicians or other practitioners. What is not yet adequately understood is the relative proportion of these methods.<sup>376</sup>

Mr Rannazzisi gave an account of the efforts of the DEA to combat prescription drug abuse at a national level. As in Australia, calls for more comprehensive data and surveillance

374 Transcripts of the hearings can be accessed at [www.drugstrategies.org](http://www.drugstrategies.org). A particularly moving testimony was given by Ms Barbara Van Rooyen whose 24-year-old son died after ingesting OxyContin®. Ms Van Rooyen gave evidence that her son, as with many people who have abused prescription drugs, did not feel they were dangerous because they were *legal*:

'He made the tragic mistake of [believing that OxyContin®] was prescription and FDA approved, so therefore safe' ([www.drugstrategies.org/internetdrugs/state08.html](http://www.drugstrategies.org/internetdrugs/state08.html)).

Similar observations were made by Joseph Rannazzisi, Deputy Assistant Administrator of the Drug Enforcement Administration (DEA):

'Controlled pharmaceuticals are readily available for legitimate purposes through one's physician and pharmacy. Distribution channels that are otherwise legal are often manipulated to acquire controlled substance prescription drugs for illegal purposes. Compounding this matter is the perception, particularly among teenagers and young adults, that controlled pharmaceuticals are safe even when used "recreationally." Abusers of controlled pharmaceuticals are using these medicines for non-medical purposes in a manner for which they were never intended. This practice, coupled with the erroneous perception of safety, makes these medicines much more dangerous' (<http://www.usdoj.gov/dea/pubs/cngtest/ct072606.html>).

Ms Van Rooyen believes that education with regard to prescription drug abuse is the most important strategy to address the problems of such abuse. Her comments with regard to this aspect of her testimony are reproduced in Section Six.

375 See generally material in the website of the Office of Diversion Control, at [http://www.deadiversion.usdoj.gov/pubs/brochures/cus\\_services/cs\\_plan.htm](http://www.deadiversion.usdoj.gov/pubs/brochures/cus_services/cs_plan.htm)

376 (<http://www.usdoj.gov/dea/pubs/cngtest/ct072606.html>).



methods; improved education programmes for users, family and friends, and physicians and pharmacists; extended research programmes into the effects of prescription drug abuse and options to treat it; and tighter controls of the pharmaceutical industry were recommended.<sup>377</sup>

The key recommendations of the DEA, however, concerned the need for more stringent regulatory mechanisms and monitoring programmes at a state and national level. This is the subject of the next major section.<sup>378</sup>

## Current approaches to prescription drug monitoring

### *A note on the law*

In many aspects the United States drug scheduling system is similar to the Australian regulatory model discussed in Chapter 4.2.

The CSA (U.S.) 1970 is the legal basis by which the manufacture, importation, possession and distribution of certain drugs are regulated by the United States Federal government through its constitutional powers. The Act also fulfills the obligations of the United States under the United Nations Single Convention on Narcotic Drugs.

The legislation creates five schedules with varying qualifications for a drug to be included in each. The Department of Justice (DOJ) and the Department of Health and Human Services (HHS) (which includes the Food and Drug Administration (FDA)) determine which drugs are added or removed from the various schedules, similar to the role of the Australian National Drugs and Poisons Schedule Committee (NDPSC). Classification decisions are required to be made on the criteria of potential for abuse, accepted medical use in the United States and potential for addiction.

Once a drug has been evaluated by the FDA it is placed in the relevant schedule according to its level of toxicity, purpose of use, potency, danger it may pose to children, potential for abuse, need for the substance and the report or recommendations of the HHS/DOJ. As in Australia, the schedules generally specify who may sell or supply the drug, and who may possess or administer it. Agencies, organisations and individuals authorised to manufacture, prescribe or dispense controlled substances are required to be registered with the national DEA and maintain records, which allows the 'tracking' of these drugs from manufacture to dispensing.<sup>379</sup>

In the United States the lowest numbered schedules contain the drugs with the most propensity to abuse. Thus Schedule 1 drugs are those such as heroin with a high potential for abuse and no currently accepted medical use. Most prescription drugs fall within

377 Two Senate Inquiries into accessing prescription drugs on the Internet have also been held in recent years. The Committee on Governmental Affairs held the *Buyer Beware: The Danger of Purchasing Pharmaceuticals over the Internet* hearings in June 2004, whilst the *Internet Pharmacy and Importation: Exploring Risks and Benefits Inquiry*, convened in January 2005, examined the purchase of pharmaceutical drugs by import from Canada and over the Internet.

In December 2005 the Subcommittee on Oversight and Investigations also held its hearings into *Safety of Imported Pharmaceuticals: Strengthening Efforts to Combat the Sales of Controlled Substances over the Internet*. Both of these inquiries are discussed in the context of Internet prescriptions and purchase in Chapter 5.3.

These hearings, in addition to the Senate Special Committee on Ageing (January 2005), also examined the prohibitive costs of prescription drugs under the American health care system and as a consequence the (illegal) importation and re-importation of pharmaceuticals from Canada and Mexico. Whilst this is clearly an important issue for American consumers and has led to the huge increase in the purchase of illegal pharmaceuticals over the Internet it is beyond the scope of this Inquiry.

378 Other testimony of interest was given by Dr Bertha Madras, Office of National Drug Control Policy (ONDCP), on surveillance data and epidemiological aspects of prescription drug use; Dr Nora Volkow, National Institute of Drug Abuse (NIDA), who spoke to NIDA's recent research efforts into prescription drug abuse and its treatment; and Dr Laxmaiah Manchikanti, American Society for Interventional Pain Physicians, discussing the need not to discount the importance of narcotic pain relief for legitimate conditions requiring analgesia (see also discussion later in this chapter and in the context of pain management and treatment in Section Seven. Space does not permit further discussion of this testimony, however transcripts can be accessed at <http://www.drugstrategies.org/internetdrugs/state11.html#1>

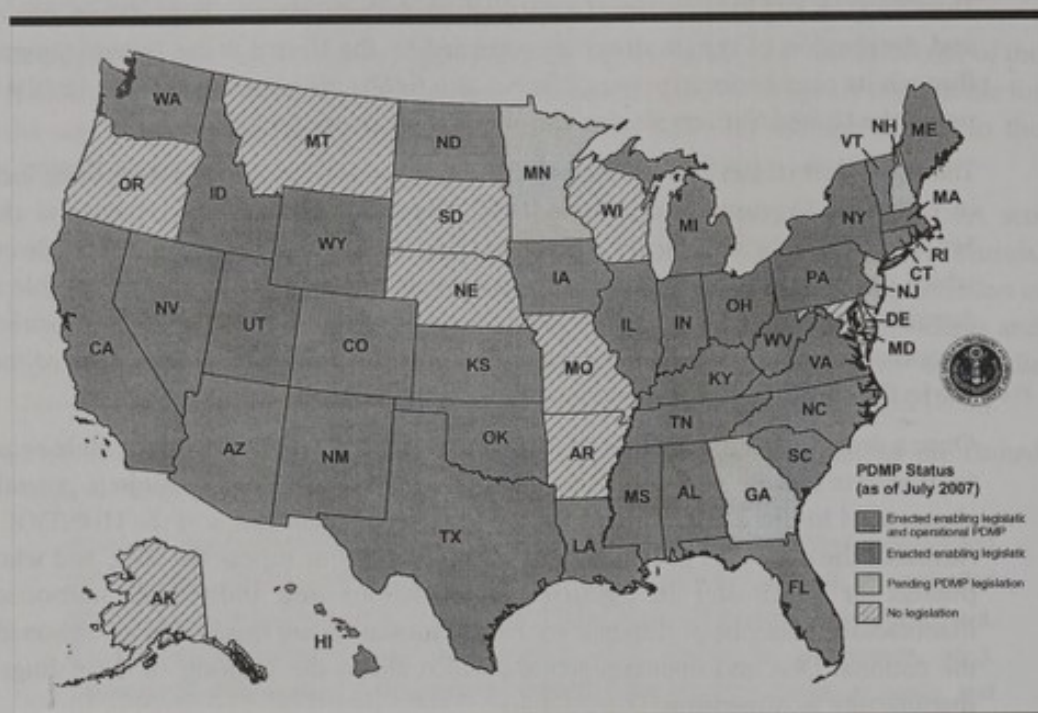
379 However, it is up to the various state jurisdictions as to the form in which such recording takes place. As will be discussed later in this chapter, whilst some states such as Kentucky may have sophisticated electronic recording and monitoring systems other states are still using paper systems of dubious value.



Schedule 2 (narcotic analgesics such as OxyContin® and morphine) and Schedule 3 (steroids, buprenorphine). Benzodiazepines and other major tranquilisers are placed in Schedule 4 with much lower levels of oversight and control. Many states therefore do not include benzodiazepines as scheduled drugs within their state PDMPs.<sup>380</sup>

Prescription monitoring in the United States is for the most part within the jurisdiction of the states. Whilst some states such as California have had some type of PDMP in operation for decades,<sup>381</sup> it has only been in the last five to two years that most states have either introduced PDMPs or sought to improve their current programmes. Some states have yet to introduce them. As of July 2007, 36 of the 50 states had enacted legislation establishing PDMPs, with 25 of those states having operational systems in place. Four states have such legislation pending this year, and 10 states have no PDMPs (National Alliance for Model State Drug Laws 2007).<sup>382</sup>

Figure 4.1a: Prescription drug monitoring status as of July 2007



Source: Office of National Drug Control Policy (ONDCP), Office of State, Local and Tribal Affairs 2007.

### The mechanics of PDMPs

There is a multiplicity of PDMPs across the country, and as such it is impossible to outline definitively the uniform components of a PDMP. Rather, the focus later in this chapter is to discuss in detail aspects of two of the more comprehensive programmes, those of Kentucky and California respectively.

380 Some drugs, however, that are not listed in federal schedules or are placed in a relatively low schedule have been listed in higher schedules under state law. Thus whilst flunitrazepam (rohypnol) has been placed in Schedule 4 federally, some states have put it in Schedule 1 reflecting its perceived danger as a 'date rape' drug. For further discussion of the American scheduling system, see [www.usdoj.gov/dea/pubs/csa.html](http://www.usdoj.gov/dea/pubs/csa.html) and [www4.law.cornell.edu/uscode21/usc\\_sup\\_01\\_21\\_10\\_13.html](http://www4.law.cornell.edu/uscode21/usc_sup_01_21_10_13.html)

381 Indeed a form of prescription drug monitoring can be traced back in California to at least 1940. See United States General Accounting Office (USGAO) 2002 and the discussion later in this chapter.

382 It is certainly true that within the last two years across the United States there has been a flurry of legislative activity in the area of prescription drug regulation, pertaining to but not restricted to PDMPs. Other areas of activity have included legislation and policies with regard to access to, affordability of and licensing of prescription drugs. Clearly the affordability of prescription drugs in the United States is a political 'hot potato'. Many states have legislated schemes allowing their residents to legally purchase or reimport drugs from out of the country, particularly Canada or over the Internet. Some states have allowed for schemes whereby unused prescription drugs can be returned to a central state run depository for re-dispensing to the poor and indigent, and other states have initiated state schemes for subsidised pharmacy assistance to the poor and/or elderly. Yet other states have legislated for restrictions or bans on prescription drug advertising. Whilst much of this legislative activity is creative and interesting it is largely peripheral to the work of this Inquiry, although aspects such as Internet pharmacy and disposal of medications are noted in other chapters where relevant. For an account of the legislative initiatives outlined above and many others, see generally National Conference of State Legislatures 2007.

Nonetheless, Figure 4.1b taken from a brief by the National Conference of State Legislatures usefully outlines some of the major and most common features of these programmes that many states will have incorporated into their systems.

**Figure 4.1b: Components of state drug monitoring programmes**

- Submission of data for Schedules II, III, IV and V drugs
- Doctors, pharmacists and occupational licensing officials have access to the database.
- Access to collected data by federal, state and local law enforcement personnel who are statutorily authorised to access the information by traditional, manual methods.
- Databases are not subject to public or open records laws.
- Individuals using state prescription drug monitoring programmes receive adequate training on the system as well as training on: proper prescribing practices, pharmacology, and referral of addicted and abusing patients.
- Legislation frequently includes penalties for the unauthorised use of the data.
- Out-of-state Internet or mail order pharmacies can be required to submit reports.
- Programmes provide information for research, policy and educational purposes only if personally identifiable information is removed.<sup>383</sup>

Source: Harrison 2006, p.1.

However, the fact that many states may not incorporate all or any of the above components into their systems (for example some states do not have criminal penalties for breach of confidential information whilst others do) gives rise to calls for national uniform approaches to prescription monitoring. The problems associated with uniformity are huge, although a number of projects and programmes are addressing the discrepancies across the American states, as will be discussed.

#### **A problem of uniformity**

As indicated, in the previous section, the lack of uniformity in legislation, programmes and their administration leads to several differences in approaches to the problems associated with prescription drug abuse. These can include:

- ◆ Reconciling privacy and confidentiality issues. States have varying degrees of stringency in their legislation safeguarding privacy and confidentiality issues.<sup>384</sup>
- ◆ Similarly, the extent and quality of programmes educating the public, physicians and policymakers about the extent of prescription drug diversion and the existence of PDMPs is variable.
- ◆ Some states see PDMPs primarily as a disciplinary tool (for either patients or professionals) and use them reactively. Other states utilise them as an educative/therapeutic tool.<sup>385</sup>
- ◆ The programmes are very expensive to administer and run, particularly if used proactively both in terms of start up and ongoing costs. Not all states may match federal funding in this respect.
- ◆ Not all states cover all schedules of drugs under the CSA (U.S.). For example Valium, one of most 'doctor shopped' drugs, is not covered in many states. When members of the American Society of Interventional Pain Physicians (ASIPP) were advocating for national legislation before Congress they stated in this regard:

The need for an electronic monitoring system is evident from the fact that 15 states...have created such systems. Multiple other states are enacting such programs.

<sup>383</sup> For a comprehensive account of the features of the PDMPs and related legislation in the states that currently have them, see National Conference of State Legislatures 2007, National Alliance for Model State Drug Laws 2006, 2007.

<sup>384</sup> See below for a more detailed discussion of privacy issues.

<sup>385</sup> See discussion below.



The state programs vary with respect to the schedules of substances for which reporting is required. Most states, like California, capture data only for Schedule II prescriptions, while a few, like Kentucky, capture data for Schedule II–V prescriptions. The [national data base] that ASIPP is proposing would require reporting Schedule II, III and IV prescriptions. Systems that only target Schedule II drugs fail to track many of the moderately abused drugs.<sup>386</sup>

- ◆ PDMPs across America vary greatly, not only in terms of what drugs are covered, but also programme design, who collects and has access to data, how data is collected and who has responsibility for the programme.
- ◆ The existence of a PDMP in one state appears to increase drug diversion/abuse activities in contiguous non-programme states. For example, OxyContin® use declined dramatically in Kentucky when a PDMP began but increased greatly in contiguous West Virginia that had no monitoring system (United States General Accounting Office (USGAO) 2003). Again ASIPP comment in this regard:

Incidents of drug diversion, however, are on the rise in neighboring states, indicating the problem is proliferating or shifting to states without monitoring programs. This underscores the interstate nature of the problem and the need for a national database.

...Most states, unfortunately, do not have electronic monitoring systems in place. The Government Accounting Office [GAO] explains this as a problem of awareness about the magnitude of the problem. GAO explains that with a highly effective KASPER program in Kentucky, which shares boundaries with seven states, only two of which have prescription monitoring programs, drug diverters have moved their diversion activities to nearby non-monitored states. Consequently, OxyContin diversion problems have worsened in Tennessee, West Virginia, and Virginia – all contiguous non-monitoring states – because of the presence of Kentucky's KASPER program.<sup>387</sup>

Indeed until 2003 five of the seven states bordering Kentucky, which had even at that time a relatively stringent monitoring scheme, did not have prescription monitoring drug programmes and the two that did monitored only Schedule 2 drugs and did not allow pharmacists or doctors to access any data (Legislative Research Commission 2003).

- ◆ Finally, as commentators have indicated 'it is important to differentiate drugs that are produced and distributed legally from those that are produced and distributed illegally' (Simeone & Holland 2006, p.8). Clearly in the latter case PDMPs do not regulate the production and distribution of drugs produced illicitly. This can therefore skew data, particularly that used for epidemiological and research purposes.

To overcome some of these problems two particular federal projects have been endeavouring to use funding grants to encourage states to adopt for the most part uniform models of prescription drug monitoring, allowing for differences that take into account specific state characteristics where appropriate. These are the Harold Rogers Prescription Drug Monitoring Project and the National All Schedules Prescription Electronic Reporting (NASPER).

#### **The Harold Rogers Prescription Drug Monitoring Project**

For the past 15 years Kentucky Congressman Harold (Hal) Rogers has been a driving force behind establishing a national approach to prescription drug abuse and prescription drug monitoring. Largely as a result of his efforts in 2002, the United States Congress appropriated funding to the Department of Justice to support a PDMP. Such monitoring programmes, as has been discussed, help prevent and detect the diversion and abuse of pharmaceutical controlled substances, particularly at the retail level where no other automated information collection system exists. It has been claimed that states that have implemented PDMPs are able to collect and analyse prescription data much more

<sup>386</sup> <http://www.nasper.org/FactSheetNasper.htm>

<sup>387</sup> <http://www.nasper.org/FactSheetNasper.htm>

efficiently than states without such programmes. For the latter, the collection of prescription information requires the manual review of pharmacy files, a time-consuming and invasive process (USGAO 2002).

The increased efficiency of prescription monitoring programs allows the early detection of abuse trends and possible sources of diversion. One indication of the effectiveness of prescription monitoring programs is the prevalence of abuse in states with monitoring programs compared with the prevalence in states without monitoring programs. Studies have found that the five states with the lowest number of OxyContin prescriptions per capita have long-standing prescription monitoring programs and report no significant diversion problems associated with the drug. Conversely, the five states with the highest number of OxyContin prescriptions per capita do not have prescription monitoring programs and have reported severe abuse problems (Bureau of Justice Assistance 2007).

When the Committee met with Ms Rebecca Rose, Policy Advisor at the Federal Bureau of Justice Assistance (BJA) in Washington, she stated that 'the purpose of the Prescription Drug Monitoring Program was to enhance the capacity of regulatory and law enforcement agencies to collect and analyze controlled substance prescription data'.<sup>388</sup>

Ms Rose also observed that:

Harold Rogers, object is really to enhance the capacity of regulatory and law enforcement agencies to collectively analyse controlled substance prescription data. There's really been an evolution. So, a lot – in the beginning – five out of the original 15 programs were really housed in more of a law enforcement capacity, or perhaps in Attorney-General's office. The trend now is really more towards the public health arena such as a health department.<sup>389</sup>

The programme focuses on providing help for states that want to establish a PDMP through competitive grants. However, resources are also available to states with existing programmes.

States are eligible for these grants if they have in place, or have pending, an enabling statute or regulation requiring the submission of prescription data on controlled substances to a central database. States may also apply if they can introduce legislation or regulations for a prescription monitoring program before the annual grant cycle begins. Prescription Drug Monitoring Programs as they exist at state level serve a variety of ends, but all are intended ultimately to reduce the abuse of controlled pharmaceutical substances (Simione & Holland 2006, p.1).

The objectives of the Harold Rogers programme include:

- Building a data collection and analysis system at the state level.
- Enhancing existing programs' ability to analyze and use collected data.
- Facilitating the exchange of collected prescription data among states.
- Assessing the efficiency and effectiveness of the programs funded under this initiative.<sup>390</sup>

In 2005, largely as a result of congressional inquiries such as those discussed above, President Bush signed into law the National All Schedules Prescription Electronic Reporting Act of 2005, which requires the HHS to 'award grants to states to establish or improve programs to electronically monitor dispensing of controlled substances'.<sup>391</sup>

388 Ms Rebecca Rose, Policy Advisor, Bureau of Justice Administration, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Washington DC, 26 July 2007.

389 Ms Rebecca Rose, Policy Advisor, Bureau of Justice Administration, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Washington DC, 26 July 2007.

390 (<http://www.ojp.usdoj.gov/BJA/grant/prescripdugs.html>).

391 (<http://www.ojp.usdoj.gov/BJA/grant/prescripdugs.html>).



This programme has a similar aim to that administered by the BJA. Both BJA and HHS are coordinating efforts and sharing information on the efforts of the states in monitoring prescription activity.

The Harold Rogers programme now coexists and needs to be viewed in conjunction with the particular aims, objectives and mechanisms of NASPER.

### **National All Schedules Prescription Electronic Reporting (NASPER)**

The impetus for NASPER has largely been the efforts of physicians in the ASIPP to have Congress establish a federal prescription drug monitoring database similar to the e-KASPER program in Kentucky.<sup>392</sup> After years of lobbying Congress the ASIPP and other bodies such as the American Society of Anaesthesiologists<sup>393</sup> were successful in having Congress pass and President Bush sign into law the *National All Schedules Prescription Electronic Reporting Act* in 2005. The Act incorporates multiple aspects of state programmes such as the type of drugs a state programme must include in its schedule if the state is in receipt of federal funding.

The Act authorises spending to create a federal grant programme housed at the U.S. HHS Department to help establish or improve state-run PDMPs. States that apply for federal funding or grants to establish a programme will be required to share information from their individual databases, 'a critical component of its success in border areas where patients may live in one state and seek medical care in another'.<sup>394</sup> Such a provision is intended to partly solve the problem discussed earlier whereby a patient in a state with a PDMP seeks to avoid scrutiny by having their prescription filled in a contiguous state that either has no such programme or has less stringent provisions than the state where the patient is resident.

As Congressman Whitfield of Kentucky who introduced the bill into Congress stated, the law will help healthcare professionals and law enforcement detect, prevent and treat prescription drug abuse and provide better surveillance and epidemiological data for physicians and researchers. 'Addicts and dealers no longer will be able to thwart state programs by simply crossing into another state. With prescription drug abuse skyrocketing, a national approach is desperately needed to turn the tide against this devastating addiction'.<sup>395</sup>

Whilst NASPER is clearly a huge leap forwards in establishing a uniform system of monitoring prescription drug use and abuse, it is not a mandatory system. States can still have their own varying systems of control. However, any state that is in receipt of NASPER funding must at the very least share their data with other states to address cross-border issues and include all drugs in Schedules 1 to 4 of the CSA (U.S).

Finally, any discussion of the need to achieve uniformity in developing nationally compatible models of prescription drug monitoring must take into account the work of the National Alliance for Model State Drug Laws (NAMSDL). NAMSDL has been working assiduously to achieve a common approach to prescription drug monitoring over the last decade.

### **The National Alliance for Model State Drug Laws (NAMSDL)**

NAMSDL is a resource for state legislators, attorneys general, health, drug and alcohol professionals, community leaders, and others seeking to enact comprehensive, effective state drug and alcohol laws and policies:

<sup>392</sup> This programme is discussed below.

<sup>393</sup> However, not all medical bodies were in favour of increased intervention at federal level. The bill was opposed *inter alia* by the American Academy of Pain Medicine and the American Association of Surgeons and Physicians.

<sup>394</sup> Quoted in [http://www.nasper.org/nasper\\_becomes\\_law.htm](http://www.nasper.org/nasper_becomes_law.htm). Prior to these new information sharing arrangements a pilot programme had been established by the Department of Justice to enhance information sharing among contiguous states through the use of the Global Justice XML Data Model (GJXDM). This computer programme provided 'a commonly accepted model that enables states to exchange information between contrasting information systems' (Department of Justice awards \$6.2 million to help states fight prescription drug abuse, Department of Justice, Office of Justice Programs 2005, accessed at [www.ojp.usdoj.gov/newsroom/2005/BJA05023.htm](http://www.ojp.usdoj.gov/newsroom/2005/BJA05023.htm)).

<sup>395</sup> Quoted in [http://www.nasper.org/nasper\\_becomes\\_law.htm](http://www.nasper.org/nasper_becomes_law.htm)

It drafts, researches, and analyses model drug and alcohol laws and related state statutes; provides access to a national network of drug and alcohol experts; and facilitates working relationships among state and community leaders and drug and alcohol professionals (National Alliance for Model State Drug Laws 2007, website).

NAMSDL began as the President's Commission on Model State Drug Laws. This Congressionally established Commission was charged with creating a model code of laws to help states effectively address alcohol and other drug abuse:

The Commission made a number of Recommendations for codes in various areas of alcohol and drug policy. However, the Commissioners feared that simply mailing out the Final Report would lead to their model laws collecting dust on shelves. Their solution was to create The National Alliance for Model State Drug Laws (NAMSDL), a non-profit organization, to serve as an ongoing resource on the model laws and related state legislation.

Funded by Congressional appropriations, NAMSDL, in coordination with the Office of National Drug Control Policy, holds annual state model drug law Summits across the country. These two-day events are intense, hands-on workshops designed to educate state individuals about the model laws and policies.

Since its inception, NAMSDL has assisted states with efforts to address the diversion of, abuse of, misuse of, and addiction to prescription drugs. In 2003, the Drug Enforcement Administration and the Bureau of Justice Assistance designated NAMSDL as the technical assistance provider for the Harold Rogers Prescription Drug Monitoring Program (National Alliance for Model State Drug Laws 2007).

The Alliance has also sponsored a Prescription Monitoring Working Group comprised of representatives of prescription drug manufacturers, state licensing boards for doctors and pharmacists, law enforcement officials and state administrators of PDMPs.

The Committee met with NAMSDL staff in Washington in August 2007. Ms Sherry Green, Executive Director, stated that one of the most useful aspects of NAMSDL was its ability to have an overarching and comparative intelligence as to what worked and what did not as far as the rolling out of PDMPs at state level is concerned:

So, what we have found kind of in summary is: that the presence of a prescription drug monitoring program reduces the per capita supply of prescription pain relievers and stimulants, and reduces the probability of abuse for those drugs. We also found that states that are more proactive in their approach...are more effective in reducing that per capita supply also.

A third and interesting thing that they also found is that states with prescription drug monitoring programs do have higher incidences of successful treatment admissions involving prescription drug abuse than states without them.<sup>396</sup>

In the last year several states have either introduced state PDMPs where none hitherto existed or upgraded their existing programmes using model legislation and programmes developed by NAMSDL, particularly with regard to electronic monitoring. For example Maryland and Virginia used NAMSDL's draft model law for establishing PDMPs in drafting legislation in efforts to create their own state systems. Officials in over 20 other states have also utilised NAMSDL's work and knowledge on this issue as they designed their states' proposals to plan and/or implement such monitoring programmes.<sup>397</sup> Additionally, California, Hawaii, West Virginia, Oklahoma, Kentucky, New Mexico and Nevada officials have sought NAMSDL's assistance in enhancing their existing PDMPs, including using

396 Ms Sherry Green, Executive Director, NAMSDL, Meeting with Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Washington, 26 July 2007.

397 Ms Sherry Green, Executive Director, NAMSDL Meeting with Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Washington, 26 July 2007.



funding through the Bureau of Justice Assistance and the Harold Rogers Prescription Drug Monitoring Program.<sup>398</sup>

### *State programmes*

Two of the states with the most comprehensive approaches to addressing prescription drug abuse through monitoring and regulation systems are Kentucky in the east and California on the west coast. California has the oldest prescription drug monitoring system in the country, the original model having been implemented in 1940. In response to a particularly serious problem with prescription narcotics in its rural areas Kentucky has introduced arguably the most sophisticated and advanced of the state monitoring systems.

### **Kentucky**

In the United States the diversion and illicit use of prescription narcotic analgesics has been a huge problem, especially in the Appalachian states such as Kentucky. In particular the abuse of the Oxycodone (trade name OxyContin®) has been prevalent. OxyContin® was prescribed in the early 1990s to Appalachian coal miners with back and other pain and soon after became sought and traded as a drug of abuse. Such was the abuse of the drug in this area that the sobriquet 'Hillbilly Heroin' was coined (USGAO 2002, 2003).

Rural parts of the state in particular have experienced serious problems associated with prescription drug abuse and related crime, to such an extent that some pharmacists in parts of the state were known to carry handguns whilst on duty (see Figure 4.1c) and there are gazetted criminal defence attorneys specialising in prescription drug crimes.<sup>399</sup> The situation prompted MSNBC<sup>400</sup> to call Eastern Kentucky the 'ground zero of prescription painkiller abuse'.<sup>401</sup>

398 For a discussion of the workings of NAMSDDL, see Carnevale Associates 2005.

399 See for example, the following advertisement for James K. Falk of Kentucky, self-styled Prescription Drug Abuse Lawyer:

'James K. Falk – Louisville Prescription Drug Abuse Lawyer

Protecting Your Constitutional Rights!

In recent years, the abuse of prescription drugs such as OxyContin, Hydrocodone, Percocet, and Xanax have made headlines in Kentucky. Law enforcement and prosecutors place just as high a priority enforcing laws against illegal possession and distribution of prescription drugs as they do the laws regarding street drugs. And the consequences for a conviction regarding prescription drugs can be just as serious as for any controlled substance, including prison time, and fines. Moreover, convictions on subsequent offenses carry enhanced penalties. I, attorney James K. Falk, have successfully defended clients charged with illegal possession and trafficking of prescription drugs.

Experienced Kentucky Prescription Drug and Designer Drug Possession Attorney

I have helped many Louisville residents defend themselves against charges of possession and trafficking of the most commonly abused prescription and designer drugs, such as:

OxyContin

Vicodin

Demerol

Ritalin

Dexadrine

Valium

I investigate and analyze the circumstances of every client's case, and employ different strategies depending on the circumstances. Was there probable cause? Was the search lawful? In all drug cases, protecting your constitutional rights is an essential part of your defense.

In some cases, it may be appropriate to work with the prosecution to find an outcome that includes counseling for drug addiction rather than incarceration' (Taken from the website of James K. Falk, at <http://www.falklawyer.com/PrescriptionAbuse.shtml>).

400 MSNBC is a cable news and entertainment network that is accessible by television and the web.

401 Quoted in [www.techlines.ky.gov/2004/dec/drugmonitor.htm](http://www.techlines.ky.gov/2004/dec/drugmonitor.htm)

Figure 4.1c: Photo & caption from *Techlines* article, Commonwealth of Kentucky



**Staff at the Clover Fork Clinic in Perry County work with the new electronic prescription drug monitoring equipment. It's not uncommon for a pharmacist to carry a firearm while on the job.**

Source: Commonwealth of Kentucky 2004, 'Testing prescription drug monitoring in Eastern Kentucky', *Techlines*, December.

As a result of the problems associated with prescription drug abuse, Kentucky has developed one of the most comprehensive of the American PDMPs – the Enhanced Kentucky All Schedule Prescription Electronic Reporting Program (e-Kasper).

Enhanced Kentucky All Schedule Prescription Electronic Reporting Program – e-Kasper

KASPER, a non-electronic monitoring system, began operating in 1999 largely due to the efforts of Congressman Rogers as outlined earlier in this chapter. Prior to that time recording and monitoring of the prescribing and dispensation of controlled substances was rudimentary:

Prior to 1999, Kentucky did not have a centralized prescription monitoring system. Investigations of prescription drug abuse often took several months to complete because investigators had to collect computer printouts from individual pharmacies and providers that a suspected drug abuser might have used. A doctor had no way to determine whether a patient seeking pain medication had recently sought treatment and medication from other practitioners. There was no way to review or track trends in the prescribing or dispensing of prescription medications. There were, however, growing concerns among law enforcement agencies, practitioners, and legislators that prescription drug abuse in Kentucky was growing (Legislative Research Commission 2003, p.5).

The original system tracked all schedule II–V drugs dispensed by licensed Kentucky pharmacists. Unlike many other states this allows for benzodiazepines as well as narcotic analgesics to be listed. It was in part developed to help physicians, pharmacists and law enforcement fight 'doctor shopping' – when patients go from doctor to doctor illegally seeking controlled substances – and the illegal diversion of these substances.

The reports detail Schedule II–V drugs dispensed by pharmacies, dispensing physicians, dispensing veterinarians or other Kentucky licensed dispensers. A private contractor, Atlantic Associates, Inc. (AAI), collects all data and manages the technical aspects of the data collection from the commonwealth's 2,300 reporting dispensers. The primary focus of



KASPER has been to enable physicians and pharmacists to better manage the care of their patients and customers and it is these practitioners who greatly utilize the system. In addition, pharmacists and investigators in the DEPPB review and analyze the data collected. These reviews often identify potential cases of doctor shopping, drug diversion, drug over-utilization, misuse or over-prescribing. Where allowed under the law, suspected patients, prescribers and dispensers are referred to the appropriate practitioners, law enforcement agencies, professional licensing boards or other agencies. Law enforcement and regulatory agencies also request reports to aid in their existing investigations of illegal drug diversion.<sup>402</sup>

Under KASPER, pharmacists had to report all controlled substances within 16 days of the day the drug was given to the patient. The information was kept in a secure database and was confidential, as is the case with other medical records.

In 2002 a pilot pharmaceutical monitoring system in eastern Kentucky was passed by the Kentucky legislature. Congressman Rogers sponsored the project in Perry and Harlan counties. The pilot was designed to test a new electronic method of monitoring prescription drugs. Patients were given unique standard identifier numbers to safeguard confidentiality and privacy.

In October 2003 the system known as e-KASPER was further reviewed and refined by a Prescription Drug Abuse TaskForce established by the State Attorney General.<sup>403</sup>

#### E-KASPER today

As a result of the TaskForce recommendations and subsequent legislative amendment, the system now provides more timely and up-to-date reporting by pharmacists to the system. E-KASPER now requires the collection of data from dispensers on a weekly basis. Other enhancements to the KASPER system include web applications that will allow doctors and prescribers to request reports online and see the results in minutes rather than in four hours, as previously was the case.

This is known as 'real time access' by authorized users, as opposed to 'real time reporting' by pharmacists to the system. New features for the traditional users that fax requests into the KASPER will allow quicker turn around for those requests with reduced staff. Closer to 'real time reporting' to the system has always been an ultimate goal for the KASPER staff, so that the data is more fresh for those who are authorized to receive.<sup>404</sup>

Authorized healthcare providers who previously suspected abuse requested a patient's controlled substance history through KASPER by *faxing or mailing* a form to the state government based health authority seeking the information, with the turnaround no faster than several hours.<sup>405</sup> Now, information is accessed on their computers in about 15 minutes, potentially whilst patients and customers are present in their offices. E-KASPER provides the dates, amounts, pharmacy locations and prescribing physicians for any controlled substances given to a patient. Information required to be submitted to KASPER includes:

- Patient identifier (full name, address including zip code, date of birth, and Social Security or alternative identification number);
- National drug code of the drug dispensed;
- Metric quantity of the drug dispensed;
- Date of dispensing;
- Estimated days of supply dispensed;

402 [www.techlines.ky.gov/2004/dec/drugmonitor.htm](http://www.techlines.ky.gov/2004/dec/drugmonitor.htm)

403 The Attorney General also established a parallel TaskForce to examine the related issue of Internet pharmacies. The work of this Taskforce and its outcomes is discussed in Chapter 5.3.

404 [www.techlines.ky.gov/2004/dec/drugmonitor.htm](http://www.techlines.ky.gov/2004/dec/drugmonitor.htm)

405 See comments of Mr Dave Sallings, Manager, Drug Enforcement and Professional Practices Branch, Kentucky Cabinet for Health and Family Services, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Frankfort, Kentucky, 31 July 2007.

- Drug Enforcement Administration (DEA) registration number of the prescriber;
- Serial number assigned by the dispenser; and
- DEA registration number of the dispenser (Legislative Research Commission 2003, p.6).

Whilst the prescribing data supplied to the authorities at e-KASPER by pharmacists is not received in 'real time', doctors and other prescribers can access that information once it is processed almost instantaneously. Work is also in progress to make the input side of data supply 'real time' in addition to the output in receiving reports. Mr Dave Sallengs, Manager of the Drug Enforcement and Professional Practices Branch, explained this when the Committee met with e-KASPER staff in Kentucky in July 2007:

Over the course of ten years we have been leading the country in monitoring technology and we now have, as of this year, an electronic KASPER system where reports are all generated from online requests. The prescriber has eight days to submit the data of their prescribing activities to our agency, that is submitted to a third party intermediary, it's collected, it's culled and then errors are taken out and then it's transmitted, in I think another eight days. The report has real time access and you can get that report near instantaneously, sometimes within 15 seconds so you can actually be on site and receive it. The physician in the emergency department for example can make that report request on his computer...15-20 seconds later get data that may be eight days old and we're going ultimately to a true real time system of reporting capturing and then re reporting back...<sup>406</sup>

One key aspect of the TaskForce recommendations that is being acted upon by the Kentucky Justice and Health authorities is the use of e-KASPER data in proactive ways. In other words, data generated by the KASPER system will be able to be used by authorised agencies, 'for research, statistical, and educational purposes. To proactively identify trends and potential problem areas, and to produce and disseminate aggregate reports on a quarterly basis' (Legislative Research Commission 2003, p.vii). In particular, it was recommended that key authorities such as the Board of Pharmacy, Bar Association, Medical Board and drug agencies should 'develop and deliver continuing education programs for doctors, pharmacists, attorneys and law enforcement officers regarding the purposes and appropriate use of the KASPER system' (Legislative Research Commission 2003, p.vii).

KASPER is to a large extent focused on law enforcement. Although its investigators are all pharmacists and therefore familiar 'with the workings of doctors offices and pharmacies',<sup>407</sup> Mr Sallengs explained that the reason for the law enforcement focus stemmed primarily from the major problems Kentucky has had with the illicit trading and diversion of drugs such as OxyContin®:

...I read through some statistics recently and...that prescription drug diversion has taken about 100 billion dollars out of the healthcare industry in the USA, that's a significant amount of money obviously but more devastating than that is the impact that it's had on the citizens of the USA. Kentucky is the horse racing capital of the world, the bourbon capital of the world and unfortunately to a certain extent the drug abuse and diversion capital of the world, that's one of the things I reluctantly say but that is the unfortunate reality now, [but] we've made a major stride in reducing some of that diversion and abuse through this KASPER system single handed.

[Because of diversion problems] We reorganized about three years ago into the Drug Enforcement Professional Practices Branch...Originally KASPER was sitting in the Department of Public Health which operates all of our public health facilities throughout the state of 120

<sup>406</sup> Comments of Mr Dave Sallengs, Manager, Drug Enforcement and Professional Practices Branch, Kentucky Cabinet for Health and Family Services, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Frankfort, Kentucky, 31 July 2007.

<sup>407</sup> Comments of Mr Dave Sallengs, Manager, Drug Enforcement and Professional Practices Branch, Kentucky Cabinet for Health and Family Services, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Frankfort, Kentucky, 31 July 2007.



counties in Kentucky, but it made sense [to change] because there's a major law enforcement component to it. Each of the staff investigators...have the ability to make arrests to seize documents, to gather evidence, and that certainly has been very beneficial to have those dual roles together.<sup>408</sup>

State law also allows other law enforcement agencies, Medicaid and other regulatory bodies to seek data from e-KASPER if they are investigating a criminal case. Provision has also been made for multi-state sharing of information as provided for in the NASPER legislation discussed above.<sup>409</sup>

The law enforcement versus health debate, however, is not that simple in Kentucky according to those responsible for KASPER's administration. KASPER, as indicated, originated in the Department of Public Health and according to Mr Sallengs that was probably the only way the programme could be 'sold' to a medical profession suspicious of regulation:

You were asking about whether it was a health initiative or law enforcement focus. We probably wouldn't have KASPER today had we not promoted it as a health initiative because when it went through the legislature as you can imagine there was legislative resistance, there was the Kentucky Medical Association resisted it initially because they saw it as a police action as prohibiting doctors from doing their thing. I guarantee you today the doctors would be up and screaming if you try to take KASPER away from them, they love it.<sup>410</sup>

### California

Although prescription drug abuse, particularly that pertaining to narcotic analgesics such as OxyContin®, has long been considered a problem restricted to the eastern Appalachian states such as Kentucky, there are also problems elsewhere:

[t]he West has considerably greater number of prescription opiate users than any region, with two thirds of that occurring in the Pacific Division, where [in 2004] users of non heroin opiates [ie prescription medications] increased from almost 2 million to almost 2.3 million, and past month use escalated from 696,000 to 922,000 in 2003. Given that California's population accounts for 74% of the total Pacific Division, an extrapolation for Californians 18 years and older would produce a conservative estimate of 1.3 million past year users of prescription opiates and 517,000 past month users...Diversion of prescription drugs is of

408 Comments of Mr Dave Sallengs, Manager, Drug Enforcement and Professional Practices Branch, Kentucky Cabinet for Health and Family Services, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Frankfort, Kentucky, 31 July 2007.

409 Mr Dave Sallengs commented to the Committee that other states have been so impressed with the Kasper technology that they are 'called up regularly by various other states of the USA for advice and assistance and many states have asked us if they could just buy this program off the shelf' (Mr Dave Sallengs, Manager, Drug Enforcement and Professional Practices Branch, Kentucky Cabinet for Health and Family Services, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Frankfort, Kentucky, 31 July 2007).

410 Comments of Mr Dave Sallengs, Manager, Drug Enforcement and Professional Practices Branch, Kentucky Cabinet for Health and Family Services, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Frankfort, Kentucky, 31 July 2007.

Politics has also played its part in determining the focus of KASPER. This was explained to the Committee by Mr Zach Ramsey, Director of the Office of the Inspector General. He observed that Kentucky has had two leading politicians with an interest in prescription drug monitoring – Congressman Hal Rogers who introduced the Prescription Drug Monitoring Funding Project at federal level supports a justice approach and Congressman Ed Whitfield, one of the leading architects of NASPER, is an advocate of public health. This has resulted in some 'mixed messages' in Kentucky politics:

'There are admittedly two sides of the fence you sit on with this system and if you go state by state you'll see that most states put it in their Pharmacy Board or in their public health department and they also have internal conflicts about whether is this a law enforcement tool or is it a medical management tool? Most states come down on one side or the other. We have been forced to be in the middle and to play both sides equally because we have two Kentucky congressmen Hal Rogers on the justice side and then Ed Whitfield...on the medical management side...and there's a lot of uncertainty because of that.

But it is true that maybe there's more law enforcement focus now in Kentucky. It has now changed its philosophy to come from medical management to law enforcement' (Mr Zach Ramsey, Director, Office of the Inspector General, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Frankfort, Kentucky, 31 July 2007).

such concern [in California] that the San Diego Police Department for example assigned officers to deal specifically with the problem. The main source of diverted pharmaceuticals continues to be unscrupulous doctors and pharmacies (Finnerty 2005, p.25).

Given the increasing scale of prescription drug abuse in California, efforts have been made through the state legislature and government agencies to improve the monitoring systems in that state.

#### *Controlled Substances Utilisation Review and Evaluation System (CURES)*

The Controlled Substances Utilisation Review and Evaluation System (CURES) programme administers California's prescription monitoring system, the oldest in the country. However, the programme regulates and monitors the distribution of Schedule 2 and 3 controlled substances only, which includes narcotic analgesics (opiates) but not benzodiazepines (as stated these are Schedule 4 drugs).<sup>411</sup> It provides support to law enforcement agencies, the Medical and Pharmacy Boards of California and individual physicians and healthcare professionals through the identification of individuals engaging in the diversion of legitimately manufactured Schedule 2 and 3 drugs.

California has recently been given a federal government grant through the Harold Rogers Prescription Drug Monitoring Program to upgrade electronic tracking systems. This will allow for the CURES programme to eventually monitor prescribing in real time and address some of the problems currently associated with the system as outlined to the committee by Ms Judi Nurse of the California Board of Pharmacy:

[o]ne of the things that the Bureau of Narcotic Enforcement (BNE) [will be able to do] is to enable the process of automating the physician's and pharmacist's ability to be able to access the data base, in other words they've had that data for many years and we're finally getting to the point where they're going to give the doctor a password and they're going to enter the patient's name, collect the data, print it out. Currently the way they have to do it is the doctor has to fill out a form, he has to fax it in, they have to hand generate a profile on that patient and they have to send it back to him.

Usually they fax it back or mail it and that's obviously not real time, the data's not real time, the turnaround's not real time and of course the people who really go crazy are the emergency room physicians that see these people in the middle of the night, dental clinics, urgent care, places where they've never seen the patient before and of course that's where these people frequent and so it will be a real improvement even if it is 4:00am and even if the data is a week and a half old that an ER doctor can at least check the data without having to wait until 8:00am when the BNE office opens. We still haven't gotten there but we're getting closer through NASPER.<sup>412</sup>

#### **The CURES programme and its antecedents**

In 1940, the DOJ created the California Triplicate Prescription Program (TRIPS) which became the oldest, longest-running multiple copy prescription programme in the nation. Aimed at reducing prescription drug abuse, the programme regulated and monitored the distribution of Schedule II controlled substances through the use of state-issued triplicate prescription forms.

TRIPS issued serially numbered triplicate prescription forms to eligible practitioners upon request. The prescriptions were reviewed and analysed for compliance with state laws and to detect possible illegal diversion of Schedule II substances to illicit markets.

411 However in late 2006 a bill went through the California Congress to provide that CURES shall also monitor and report on the prescribing of Schedule 4 controlled substances. The bill also provided that prescribers who provide a Schedule 2 substance shall provide a report of the transaction to the Department of Justice on a weekly rather than monthly basis as was heretofore the case. See National Alliance for Model State Drug Laws 2006, p.3.

412 Ms Judi Nurse, Supervising Inspector, California Board of Pharmacy, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Sacramento, 2 August 2007.



In 1996, the California Legislature passed a bill requiring that the California Department of Justice establish CURES to automate the collection and analysis of all Schedule II controlled substance prescriptions issued in California.

The Legislature stated that 'the ability to closely monitor the prescribing and dispensing of Schedule II controlled substances is essential to effectively control the abuse and diversion of these controlled substances'. The Schedule II prescription data contained in CURES allows the identification of drug trends or patterns of abuse.

A drug is rated under the California Uniform Controlled Substances Act, Division 10 of the Health & Safety Code as Schedule II, based on the following criteria:

- ◆ The drug or other substance has a high potential for abuse;
- ◆ The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions;
- ◆ Abuse of the drug or other substance may lead to severe psychological or physical dependence.

Morphine, oxycodone, fentanyl, amphetamine, methamphetamine, codeine, hydrocodone, cocaine, and any analogue or derivative of opium are all examples of Schedule II drugs.

In 2003 CURES was extended to Schedule III prescribed controlled substances such as hydrocodone when compounded with codeine. California law also requires that all prescriptions for Schedule II–V controlled substances be written on new tamper-resistant prescription forms obtained from a security vendor approved by the DOJ. The California DOJ describes the operation of CURES as follows:

It is the policy of DOJ to provide medical prescribers, pharmacists, and law enforcement with information maintained in CURES to assist with their authorized duties. The medical prescriber or pharmacist may request a Patient Activity Report (PAR) for a patient under his/her care. A PAR is a printout which contains prescribing history contained in the CURES data system for that patient by medical prescribers in California. Verification by DOJ staff is required to substantiate the validity of the requesting medical prescriber or pharmacist before information on a PAR is released.

It is also the policy of DOJ to provide CURES information to law enforcement agencies and regulatory boards as a tool for investigations. The availability of the prescription data in one system saves valuable time and resources for investigators trying to track down criminals and others abusing controlled substances.<sup>413</sup>

## **Problems, controversies and concerns with PDMPs**

This section examines briefly some of the more contentious issues associated with introducing PDMPs, at both national and state level. Although these issues are germane to all states that have developed monitoring programmes, again the focus where appropriate is on Kentucky and California, particularly as the Committee has had extensive consultation with key representatives responsible for developing or administering the programmes in those states.

### ***Confidentiality and privacy concerns***

A review of PDMPs in 2002 reported that concerns had been expressed by both patients legitimately using prescription drugs and doctors and pharmacists legitimately prescribing and dispensing them as to the confidentiality of the information gathered by monitoring programmes:

All states, regardless of whether there is a state PDMP, have the authority under their laws to conduct investigations of the records of individuals alleged to be involved in prescription drug diversion and abuse, including the records of prescribing physicians and dispensing

<sup>413</sup> For a copy of a pro forma of a Patient Activity Report (PAR), see Appendix 9.

pharmacies. PDMPs, particularly those with electronic databases, raise additional confidentiality concerns, however, because their databases contain complete dispensing records that can more quickly identify individual patients, physicians, and pharmacies and provide an individual report on their prescription drug history. Physicians are concerned that their prescribing decisions and patterns may be questioned and that they could be investigated without sufficient cause. Some physicians contend that patients may suffer because physicians will be reluctant to prescribe appropriate controlled substances to manage a patient's pain or treat their condition. Patients are concerned that their personal information may be used inappropriately by those with authorised access or shared with unauthorised entities. Pharmacists have also expressed concerns (USGAO 2002, p.18).

Some of the key concerns pertaining to confidentiality and privacy with regard to PDMPs are outlined in the testimony of Professor Joy Pritts to federal congressional hearings on prescription drug abuse and monitoring programmes. Professor Pritts is a key advocate of federal uniform privacy standards for PDMPs. Her testimony is worth quoting in full:

The non-medical use of prescription drugs continues to be a widespread and serious problem in this country. As part of the effort to control the illegal diversion of prescription drugs, many states have instituted prescription drug monitoring programs. These programs collect, review, and analyse identifiable prescription data from pharmacies. Although the programs differ in terms of objectives, design and operation, they generally analyse and distribute collected information to medical practitioners, pharmacies, and regulatory and law enforcement agencies.

Many of these programs have been successful at reducing diversion within their states. It is not surprising that expanding the number of state prescription drug monitoring programs and ensuring that they are able to share data across state lines are key elements of the federal strategy to reduce prescription drug abuse nationwide.

While the goals of these programs are admirable, increasing the number of prescription drug monitoring programs that are able to share identifiable information electronically raises serious privacy concerns. Millions of Americans suffer from chronic pain. Without adequate privacy safeguards, patients will not seek treatment and practitioners will be hesitant to adequately prescribe medication. Absent strong privacy protections, [and] there may well be wide-spread public resistance to linking prescription drug monitoring program data.

Federal proposals to encourage the expansion and linkage of state prescription drug monitoring programs should establish minimum, uniform privacy standards for these programs based on well-established fair information practice principles. Federal privacy standards for prescription drug monitoring programs are essential...While states generally have some privacy protections for prescription drug monitoring program data, these protections can vary widely from state to state. For example, some states impose a criminal penalty for unauthorised use or disclosure of prescription drug monitoring program information and others do not. Linking data between states with differing standards can result in decreased privacy protections for citizens of states with stringent privacy laws. Citizens should not lose privacy protections as a result of states' sharing data. As a practical matter, states with high privacy standards may be reluctant to share data with states that have less privacy protections.

Establishing federal minimum privacy standards for prescription drug monitoring programs can help ease these concerns. While states should remain the primary regulators of prescription drug monitoring programs, any federal funds for such programs should be tied to the requirement that state programs meet minimum federal privacy standards. States should remain free to impose higher privacy standards to meet the particular needs of their citizens.

At a minimum such federal standards should:

- Provide individuals with specific notice that certain prescription drug information will be reported to a state prescription drug monitoring program and may be shared with programs of other states



- Provide individuals with a right of access to their information that is maintained in a state prescription drug monitoring program and the right to contest the accuracy of the information
- Limit the information provided under these programs to be minimum amount necessary to accomplish the intended purpose
- Require recipients of information from prescription drug monitoring programs to only use the information for the purpose for which it was disclosed and prohibit them from further disclosing the information
- Establish safeguards for verifying the accuracy of reported information
- Establish security standards for maintaining and transmitting data
- Require requests for inspection from most law enforcement agencies to be reviewed and approved by appropriate officials prior to disclosure
- Require the de-identification of information provided for statistical, research, or educational purposes
- Impose stringent civil and criminal penalties on the improper use and disclosure of prescription drug monitoring program data.<sup>414</sup>

Many states have attempted to address privacy concerns statutorily.

For example, some state laws to regulate controlled substances and to operate a PDMP include health privacy protection provisions. In addition, states with PDMPs generally have statutory and regulatory protections to limit access and use of confidential health care data, as well as statutory penalties for misuse. Under Kentucky's electronic PDMP, for example, the authorised users of its information are statutorily delineated, the knowing misuse of the data can result in a felony conviction, and the PDMP itself is statutorily accountable for ensuring that only authorised users receive its data. Kentucky law also prohibits any person who receives PDMP data from sharing that information with anyone else, unless required by a court, and the Kentucky PDMP advises data recipients of this prohibition. Nevada's state law similarly protects the confidentiality of its PDMP information by requiring a court order for disclosure to non authorised entities (USGAO 2002, pp.18–19).

One state that has recently enacted fairly stringent privacy requirements is New Hampshire. Bill H.B 1346, signed into law by the Governor in June 2006,

enacts a new code section concerning the confidentiality of prescription information. In accordance with this proposed measure, prescription records containing patient-identifiable and prescriber-identifiable data are not to be licensed, transferred, used or sold by any pharmacy benefits manager, insurance company, electronic transmission intermediary or retail/mail-order/Internet pharmacy for any commercial purpose. Use of the confidential information is permitted for purposes of pharmacy reimbursement, formulary compliance, care management, utilization review by a health care provider, the patient's insurance provider or agent of either and health care research. Additionally, the proposed law does not prohibit the collection, use, transfer or sale of patient and prescriber de-identified data by zip code, geographic region or medical specialty for commercial purposes (National Alliance for Model State Drug Laws 2006, p.18).

Moreover, some of the concerns alluded to by Professor Pritts have been addressed in the recent NASPER legislation discussed above. Those states that receive funding under the NASPER programme will have to follow some fairly stringent uniform guidelines:

Under the NASPER, only a practitioner or pharmacist who is currently treating a patient may request information. Each request must be certified by the treating practitioner or pharmacist that the information is necessary for the purpose of providing medical or pharmaceutical treatment or to evaluate the need for such treatment for a bona fide current patient. Thus, the NASPER provides for limited disclosure to the patient's treating physician

<sup>414</sup> Testimony of Professor Joy Pritts, Health Policy Institute, Georgetown University, to the Committee on Health, Education, Labor and Pensions – Hearings into *Prescription Drug Abuse and Diversion: The Role of Prescription Drug Monitoring Programs*, on 23 September 2004.

or pharmacist after the physician or pharmacist has certified that the information is necessary for treatment purposes. With these safeguards, the NASPER is narrowly tailored to serve its purpose. Law enforcement agencies may obtain information, but only when the request is based on a legitimate need and evidence for cause.<sup>415</sup>

All states, regardless of whether there is state prescription drug monitoring program, [will still] have the authority under their laws to conduct investigations of the records of individuals alleged to be involved in prescription drug diversion and abuse, including the records of prescribing physicians and dispensing pharmacies.<sup>416</sup>

In part this has helped address the concerns civil libertarians and others have had with the privacy issues pertaining to PDMPs, although there are still some reasons for concern as Ms Sherry Green, NAMSDL, remarked when the Committee met with her and Bureau of Justice Administration colleagues in July 2007:

I will tell you that PMP programs that we've spoken to are trying to be very careful about that for the obvious reason. If you have somebody who's an addict, the minute they find out who's looking at it, they may not go back to that doctor, they may take off. So, it depends on how the individual state laws are written, because some state patient access laws are very broad and you get to see everything. Some are much more narrow and you would have to act on, basically, information regarding a particular prescriber, that kind of thing. So it actually varies by state.

There are also confidentiality problems associated with identifiers. The programs that we work with for example do often use names, but frankly they find that unreliable because of aliases. They do prefer identification numbers. Now, one of the main issues that has come up however, is initially a lot of programs were using social security numbers. There's a great concern about that now because of all the identity theft. So, we are attempting to find out if there is a unique identifier that a lot of states or most states, at least within a region, could agree on that they would use. Because part of the problem is, if somebody inputs the name just incorrectly – misspelling – or if you get someone with a lot of aliases, you may not actually pull up. So there seems to be a lot of problems with relying too much on the name. We are encouraging states to go more towards employing a unique identifier that would not be a social security number.

Nonetheless, both officials from NAMSDL and the Bureau of Justice Administration have agreed that NASPER in conjunction with the Hal Rogers grant funding system have gone a long way towards addressing problems associated with privacy and confidentiality.<sup>417</sup>

### *Opiophobia and other arguments against and concerns with PDMPs* <sup>418</sup>

PDMPs have not been universally welcomed either in the United States or unreservedly in other countries such as Australia. Opposition to their introduction has come as indicated above by civil libertarians, but they have also been opposed by some sections of the medical community, pharmaceutical companies and allied health services.

In the American context, Forgione, Neuenschwander and Vermeer have canvassed some of the arguments in opposition to the introduction of such monitoring programmes:

415 Similarly the Committee was told that under the Hal Rogers Prescription Drug Monitoring Program, a condition of funding was that any state sharing information agreement had to be limited to: 'one prescription monitoring official asking [for information] from another prescription monitoring official, so that you didn't have an individual police officer or an individual investigator accessing confidential information [without due cause]' (Ms Rebecca Rose, Policy Advisor, Bureau of Justice Administration, Meeting with Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Washington DC, 26 July 2007).

416 [http://www.nasper.org/nasper\\_becomes\\_law.htm](http://www.nasper.org/nasper_becomes_law.htm)

417 Ms Sherry Green, NAMSDL, Meeting with Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Washington DC, 26 July 2007.

418 *Opiophobia* has been defined by the National Institute on Drug Abuse (USA) as: 'A healthcare provider's fear that patients will become addicted to opioids even when using them appropriately; can lead to the under prescribing of opioids for pain management' (NIDA 2006b, p.2). NIDA states that many physicians under-prescribe opioid pain relief because they overestimate the potential of patients to become addicted (see NIDA 2006b).



Issues raised by these groups allege that monitoring programs:

- Alter physician prescribing practices, which *could* adversely affect patient care;
- Encourage diversion transfer to lower schedule drugs;
- Violate patient/practitioner confidentiality
- Carry costs that exceed the effectiveness of the programs (Forgione, Neuenschwander & Vermeer 2001, p.76). (Authors' emphasis)

For example, with regard to the argument about diversion transfer, whilst critics of PDMPs acknowledge that such programmes may result in the prescribing of certain controlled substances, they argue that use and abuse of less controlled but equally dangerous substances may rise as a result. For example, Fishman et al state:

The substitution effect was clearly illustrated by the experience in New York when benzodiazepines were added to the drugs that require a triplicate prescription in 1989. Following this change, benzodiazepine prescriptions decreased, but increases were seen in alternative drugs that were often therapeutically less optimal, held a greater chance of toxicity, and carried equal or greater abuse potential (Fishman et al 2004, p.313; see also Room 2007).

Issues of confidentiality aside, it is the argument that 'artificial' controls over prescribing will prevent or discourage physicians from using valuable tools in the pharmacotherapeutic area that has the most currency in the United States. This is particularly the case when it comes to opioids. One reason this may be the case is the different prescribing histories in the United States as opposed to other developed nations. As Ballantyne argues, lobbying for the opiate treatment of pain is a powerful movement there. This reflects the early American laws that made it illegal for doctors to prescribe opiates in many circumstances, unlike in the United Kingdom (Ballantyne 2007).

Punishment for inappropriate opiate prescribing in the US could (and still does) include loss of medical licence, criminal prosecution, and imprisonment.<sup>419</sup> Therefore the prescription of opiates to relieve pain effectively ceased when these regulations were introduced. Advocacy was needed in the US to restore the use of these invaluable drugs for the treatment of pain (Ballantyne 2007, p.811).

Ballantyne argues further that:

Friction between regulators and medical providers is perhaps inevitable, as they both have noble yet conflicting goals – the one to control diversion, the other to preserve treatment for pain. As drug misuse becomes a greater problem, legislators react by tightening regulations. The American experience teaches that over aggressive regulations that ignore legitimate needs for opiates compromise doctors' ability to treat pain (Ballantyne 2007, p.812).

Fishman et al are perhaps more forthright in their criticisms:

These contradictions can lead to the conclusion that the war on drugs is directly in opposition to the war on pain. This conflict has resulted in a variety of regulations that are intended to prevent drug abuse, but have inadvertently created barriers to the appropriate treatment of pain. This does not conform to the philosophy of national and international policies recognising that efforts to control abuse and diversion of pain medications must not interfere with their availability for legitimate medical purposes...Although physicians are encouraged to prescribe opioids to treat pain when they are the best treatment choice, they

<sup>419</sup> Fishman et al give accounts of cases whereby physicians have been prosecuted for both inappropriate or over-prescribing but also *under-treating* pain because of their fear of disciplinary or regulatory action:

'In recent years, the health care system has become increasingly intolerant of under treated pain. In 2001, a California jury found an internist guilty of elder abuse for under treating the pain of a dying man and was ordered to pay 1.5 million to the patient's surviving family members. A second similar case was recently settled and resulted in the Medical Board of California formally sanctioning the physician involved. Physicians have long been concerned that prescribing for prolonged periods or for large amounts could lead to unwarranted disciplinary actions taken against them, but these landmark cases suggest that the opposite may be just as punishable' (Fishman et al 2007, p.310).

are largely hesitant to prescribe opioids, because they believe that doing so places them at risk for unwarranted regulatory oversight (Fishman et al 2004, pp.309–311).

According to Fishman and other pain specialists both the physician *and* the patient have these fears:

The varieties of restrictions imposed upon controlled substances have created fear in both physicians and patients. PDMPs are believed to have adverse effects on the legitimate prescribing of controlled substances, including the inappropriate substitution of non regulated drugs. Some physicians feel this way because they would rather not be bothered by extra paperwork involved, while others fear that stocking special prescription pads leaves them open to being burglarised. Physicians worry about being labeled as an over prescriber, raising red flags to regulators, or feel that drugs needing a special prescription must be more dangerous and should be avoided at all cost. Patients report that they fear possible loss of confidentiality and stigmatisation by having their names tracked as well as an increased difficulty in obtaining needed medications because many physicians will not prescribe drugs that are monitored by a PDMP. Patients also worry about the increased costs of the extra doctor visits needed to obtain these prescriptions as they are limited to short periods of time (usually 30 days) without the possibility of refills. In addition, problems may arise when one state has a PDMP in place, but nearby states have no such regulations, leading to the persistence of 'doctor shopping' (Fishman et al 2004, p.312).

Such concerns and criticisms are not restricted to North America. Professor Robin Room of Turning Point Alcohol and Drug Centre makes the point that 'Physicians' concerns about their actions being second-guessed by law enforcement agencies have a long history in many countries'. Whilst acknowledging that the problem is most pronounced in America he notes:

In the U.S., at least, it is doctors specializing in pain who feel particularly targeted; commentators on a paper on investigations of physicians by the Drug Enforcement Administration (DEA) calculated that 15% of pain specialists had been subject to investigation in 2003 (Passik & Kirsh, 2006). The American journal for pain specialists, *Pain Medicine*, featured two separate sets of often anguished commentaries on the DEA and pain medicine in its 2006 issues (pp.71–88 and 353–366). In Europe, Open Minds, an international professional group, has launched an attack on 'unnecessarily strict rules and regulations' as a 'burden for doctors [which] can easily become an impediment for patients' in its 'White Paper on opioids and pain: a pan-European challenge' (Open Minds, 2005) (Room 2007, unpublished).

Similar observations have been made in the Australian context. For example the Victorian Youth Substance Abuse Service, commenting on the situation in North America in its submission to this Inquiry, noted with concern the hesitations of some practitioners to use opioids to treat patients with intractable pain:

The effect of US Drug Enforcement Agency (DEA) investigations into Oxycontin abuse on the suffering of chronic pain patients is difficult to quantify, though if the following quotes by doctors represent an accurate picture of medical concerns the indications are for a continuance of under treating intractable pain. 'I will not treat pain patients ever again' (Owen, 2003); and 'Medical schools now advise students not to choose pain management as a career because the field is too fraught with potential legal dangers' (Spencer, 2004).

The context for this is troubling. 100 million Americans suffer from chronic pain (Hall, 1999) and untreated pain cost business \$100 billion in medical costs during 1995 alone (APA, 2003). The total economic impact (JAMA, 2003) is \$61.2 billion per year.

More distressing is the finding (Wolfe, 2000) that 90% of children dying of cancer had 'substantial suffering in the last month' of life. According to the California Medical Board there is a 'systematic under treatment of chronic pain' as a result of '...incomplete integration of current knowledge into medical education and clinical practice, lack of knowledge among



consumers about pain management, exaggerated fears of opioid side effects and addiction and fear of legal consequences' (Hall, 1999).

A significant factor in the under treatment of pain is cited as legal action by the Drug Enforcement Agency against physicians prescribing opioids amid claims of over prescribing (Fleischer, 2003). The US Drug Enforcement Agency (DEA) launched 557 investigations and pursued actions against 441 doctors in a single year including the advocate of high-dosage pain treatment Dr William Hurwitz. After initially being threatened with the death penalty, Dr Hurwitz was sentenced to 25 years imprisonment though the grass roots patient organization, the Pain Relief Network, claim that without Hurwitz many pain patients would have killed themselves. Dr. Benjamin Moore committed suicide in July 2002 rather than testify against his co-workers. Another physician Dr. James Graves is currently serving 63 years.

The DEA action is supported by claims that there were 500 OxyContin related deaths in 2002. Yet the Journal of Analytical Toxicology review found that only 12 of these cases could be confirmed as OxyContin related deaths, the rest being poly drug use mortalities.

In addition to this there are many major harms represented by over the counter medications (OTC) that pain sufferer's turn to when they can't access opioids. Many OTC pain medications can cause serious and life threatening liver and kidney damage.<sup>420</sup>

Professor Jason White, University of Adelaide, stated to the Committee that whilst the monitoring controls on opioids currently in place in the various Australian states were generally appropriate he would not like to see it any harder to prescribe:

...because there is a real danger of doctors becoming afraid to give adequate pain relief to people. That has occurred in parts of the US. You do not want to be draconian with the prescribers, but [at the same time] I am not sure that it is a really wise idea for people to walk around with quite so much medication as they do. Maybe they should go to pharmacists a bit more often and the amount of supply that they have at any one time should be perhaps more closely regulated at a lesser supply; so if, instead of monthly, it is weekly.<sup>421</sup>

Ballantyne, Fishman and other academics quoted in this section opposed to the introduction of stringent controls on (opioid) prescribing are for the most part senior pain medicine specialists and may not necessarily be viewed as impartial in this debate. Nonetheless, they do rightly raise the dilemma that the introduction of regulatory controls may result in 'policy solutions that have been frequently contradictory' (Ballantyne 2007, p.812). The issue as to whether such controls are in the final balance an appropriate direction in which to move is discussed in the evaluation section that follows.

## The effectiveness of PDMPs in the United States

As early as 1993 American commentators have remarked on the value of prescription drug monitoring programs in 'developing effective ways to prevent diversion whilst at the same time minimising their impact on medical practice and patient care' (NIDA 1993, p.1). The

420 Submission of Youth Substance Abuse Service to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2007.

421 Professor Jason White, Director, Drug and Alcohol Services of South Australia, and Head of Department, Pharmacology, University of Adelaide, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Adelaide, 18 May 2007.

Similar comments were made at a forum on prescription drug abuse hosted by the Committee in the provincial Victorian city of Bendigo. For example, Richard Mitchell of Bendigo Community Health Services said to the Committee:

'Could I just say for some balance, though, that we have a number of clients who come in who have actually had long-term pain and who cannot get medications as well, so it is not just all about the market being flooded by all these diverted drugs; there are lots of people who are unable to access because of GPs being scared about, "I don't want to give it to this person that I don't know."' (Mr Richard Mitchell, Clinical Coordinator, Alcohol and Drug Support Services, Bendigo Community Health Services, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Bendigo Community Forum, Bendigo, 30 May 2007).

Other local health professionals including doctors and pharmacists agreed with this comment.

NIDA review *The Impact of Prescription Drug Control Systems on Medical Practice and Patient Care* recognised the tension between the need to promote new (pain relief) medications,<sup>422</sup> protect against their diversion and misuse and 'a need to reassure clinicians that their appropriate use of multiple drugs, of opiates, of parenterally administered drugs, and escalating doses for prolonged periods will not result in their being investigated or sanctions applied' (NIDA 1993, p.3). PDMPs have the ability to relieve this tension, although as has been noted earlier in this chapter some medical practitioners, particularly pain specialists, are concerned that the existence of regulatory controls such as PDMPs may result in doctors being too fearful to prescribe opioids to patients who have a legitimate need for them.<sup>423</sup>

Notwithstanding such criticisms, the overall effect of these monitoring programmes has been viewed as positive in decreasing the prescribing of scheduled substances and arguably their abuse (Fishman et al 2004). However, as several studies have shown, whilst most states have PDMPs that collect information 'about the prescribing, dispensing and use of prescription drugs and distribute it to medical practitioners, pharmacies and state law enforcement and regulatory agencies...the programs differ in terms of objectives, design, and operations' (USGAO 2002, p.3. (Committee emphasis)). These differences need to be taken into account in any evaluation of the effectiveness of such programmes.

In more recent times, since PDMPs have become more sophisticated (and electronic based), the concomitant need for more comprehensive evaluations has become apparent.

A major independent evaluation of PDMPs conducted in 2006 (Simione & Holland 2006) found they affect the probability of prescription drug abuse in two main ways:

Indirectly – operating through the supply of controlled substances. If a PDMP reduces the supply of prescription drugs (perhaps by regulating prescribing behaviour) then this in turn may affect the probability of abuse.

Directly – when supply is held constant, a PDMP may itself reduce the probability of abuse (perhaps by regulating dispensing behaviour) (2006, p.i).

The principal findings of the evaluation Report were that:

- The presence of a PDMP reduces the per capita supply of prescribing pain relievers and stimulants, reducing the probability of abuse for these drugs.
- States that are proactive in their approach to regulation may be more effective in reducing the per capita supply of prescription pain relievers and stimulants than states that are reactive in their approach to regulation. States that are law enforcement-oriented thus may be more effective in curbing abuse.<sup>424</sup>
- A statistical simulation showed that by 2003, the rate of pain reliever abuse would have been 10.1 percent higher and the rate of stimulant abuse would have been 4.1 percent higher in the absence of proactive regulatory control (Simione & Holland 2006, p.v).

422 At the time of writing the NIDA Review the use of narcotic analgesics in pain medicine was still a relatively new phenomenon.

423 Certainly when PDMPs have been introduced they have generally resulted in a decrease in the prescribing of scheduled substances although not necessarily, according to their critics, prescription drug abuse (Fishman et al 2004). The 'substitution effect' may simply result in more dangerous drugs being used (see discussion earlier in this chapter and Fishman et al 2004). After introduction of PDMPs, prescribing of opioids decreased by 50% in Idaho, 50% in New York, 57% in Rhode Island and 64% in Texas (Angarola & Joranson 1992).

424 Recent legislative action in Iowa, in part based on evaluation of other states' PDMPs, has recognised the importance of proactive systems. A bill recently passed by the Iowa Congress authorised the State Board of Pharmacy Examiners to:

'establish and maintain an information program for drug prescribing and dispensing. The program shall collect from pharmacies dispensing information for controlled substances. The information collected shall be used by prescribing practitioners and pharmacies on a need to know basis for purposes of improving patient health care by facilitating early identification of patients who may be at risk for addiction, or who may be using, abusing or diverting drugs for unlawful or otherwise unauthorized purposes at risk to themselves and others, or who may be appropriately using controlled substances lawfully prescribed for them but unknown to the practitioner' (see National Alliance for Model State Drug Laws 2006, p.10).



Such findings generally concur with earlier evaluative reports at both federal and state level.<sup>425</sup>

Certainly it would seem that in terms of results (however defined) the consensus is that states with PDMPs that are reactive in nature are less effective than those where the monitoring programme is 'proactive' in nature; that is, 'identifying and investigating cases and generating "unsolicited reports" where it deems this is warranted' (Simione & Holland 2006, p.3). However, the problem remains, as recognised by all evaluation projects, that proactive type programmes are much more expensive to administer than those which are merely reactive, and consequently most PDMPs are reactive in nature (USGAO 2002, p.13).

At state level, evaluations of the e-KASPER project outlined earlier in this chapter have been particularly favourable (USGAO 2002; Legislative Research Commission 2003). So much so, as indicated above, it has served in part as the basis for the NASPER project discussed earlier. Particularly useful has been the ability of e-KASPER to provide aggregate and trend data for analysis (Legislative Research Commission 2003, p.19).

As early as 2002, however, the USGAO realised the benefits for states such as Kentucky in reducing drug diversion through incorporating sophisticated PDMPs into the regulatory and law enforcement apparatus:

For example, Kentucky's state drug control investigators took an average of 156 days to complete the investigation of an alleged doctor shopper prior to the implementation of the state's PDMP. The average investigation time dropped to 16 days after the program was established. In addition, law enforcement officials in Kentucky and other states view the programs as a deterrent to doctor shopping, because potential diverters are aware that any physician from whom they seek a prescription may first examine their prescription drug utilisation history based on PDMP data (USGAO 2002, p.3).

The evaluative research undertaken thus far also suggests that those states which expand their programmes as tools to educate the public and health professionals such as physicians and pharmacy personnel about the extent of prescription drug diversion and abuse are more effective than those that do not (USGAO 2002, 2003; Simione & Holland 2006):

Programs have provided educational materials to physicians on ways to prevent drug diversion and to educate their patients about the diversion problem. They have evaluated prescribing patterns to identify medical providers that may be over prescribing and inform them that their patterns are unusual. They have also identified patients who may be abusing or diverting prescription drugs and provided this information to practitioners...(USGAO 2002, p.10).

Some PDMPs have also provided physicians with information on addiction treatment options for patients identified as abusers or diverters.<sup>426</sup>

Finally, Kentucky is one of the few states that include *all* scheduled drugs in their PDMP which allows 'them flexibility to respond if drugs on other schedules become targets for diversion'. This accords with the views of agencies such as the DEA, NAMSDDL and the ONDCP 'that comprehensive coverage of all schedules offers the most effective monitoring program' (USGAO 2002, p.12).

PDMPs have been recognised as an excellent tool in preventing and addressing prescription drug abuse, and as such have been gradually adopted with the assistance of bodies such as NAMSDDL by the majority of American states. However, some commentators have expressed one cautionary note: whilst evaluative studies and collated data suggest that these programmes 'have resulted in considerable declines in narcotics prescriptions' Fischer and Rehm suggest that this may have happened in 'ways that may have penalised the wrong

425 See for example, USGAO 2002, 2003; Bureau of Justice Assistance 2007.

426 For example, 'Nevada's PDMP encourages physicians to refer identified doctor shoppers to pain management or drug treatment programs that can help them manage their chronic pain more effectively or treat their addiction' (USGAO 2002, p.10).



targets (i.e. legitimate users) by causing a "chilling effect" among prescribers' (2007, p.500). In other words, physicians may be reluctant, conservative or cautious in prescribing narcotic pain relief or tranquillisers in cases where they are therapeutically warranted because of the extra bureaucratic processes due to the existence of PDMPs. This does not mean that such controls should be relaxed or lessened, however it may mean comprehensive education programmes need to be developed for general practitioners and other health professionals on the best use of opioids in legitimate pain treatment. The need for such education programmes is discussed further in Chapter 6.2 of this Report.<sup>427</sup>

Whatever the beneficial aspects of American PDMPs and despite the efforts at a national level to achieve uniformity of purpose and design, they still vary in effectiveness across the country. Even the best of them, such as in Kentucky, are not as efficient as those found north of the border in Canada, particularly PharmaNet, the system used in the province of British Columbia, and the subject of the final part of this chapter.

## **Prescription drug abuse, diversion and monitoring in British Columbia, Canada**

### *Background*

As with the United States, there has been a substantial increase in the amount of prescription drugs being used for non-medical purposes or otherwise abused or misused in Canada over the past 10 years. This is particularly the case with regard to opiate analgesics such as OxyContin®, although there have also been concerns expressed with regard to excessive and inappropriate benzodiazepine use in Canada (Canadian Centre on Substance Abuse 2005).

As in the United States the increase in such use or at least the amount of drugs in circulation for misuse can be attributed to the changing nature of treating non-cancer pain (Fischer & Rehm 2007). In Canada, as elsewhere, narcotic opioids have been increasingly prescribed for legitimate pain 'but result in being prescribed to the wrong people, for the wrong reasons, or in the wrong quantities (eventually allowing for direct or indirect diversion)' (Fischer & Rehm 2007, p.500).

As indicated in a recent report by a Federal Inquiry into prescription drug use in Canada, one important strategy to prevent the abuse and diversion of prescription drugs including benzodiazepines and opioids is the utilisation of comprehensive PDMPs.<sup>428</sup> The Federal Government noted with approval that the province of British Columbia on the west coast of Canada has had a long history of addressing prescription drug abuse through the building of quality information and monitoring systems. For example, in the late 1980s British Columbia developed a system called the Triplicate Prescription Program to prevent and detect diversion of narcotic drugs; specially produced prescription pads for narcotics were only issued to authorised physicians and printed on paper that was difficult to fraudulently reproduce. Prescriptions were only valid for a few days. As in Australia, prescriptions have to be written in a way that enhances security (that is, written in words and numbers and carrying a unique identifier of the patient and the prescriber). The

427 In the Australian context, see for example the FOCUS programme developed by pharmaceutical company Janssen-Cilag:

'This program will educate GPs to identify what constitutes the appropriate use of opioids as a potential treatment option, outline our commitment to addressing harm and dependence issues among patients and educate GPs to make accurate and confident decisions when diagnosing and prescribing moderate to severe chronic pain' (Submission of Janssen-Cilag to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, August 2007).

This and other similar programmes will be discussed further in the context of education initiatives in Chapter 6.2.

428 In 2004 the Standing Committee on Health of the Canadian House of Commons held an Inquiry into prescription drug use in Canada. Whilst the Inquiry concentrated on three areas largely peripheral to the issues in this chapter (clinical trials, post market surveillance and direct to consumer advertising), it did acknowledge that systems and strategies needed to be found to safeguard the appropriate use of prescription drugs whilst preventing their misuse and diversion. Monitoring systems such as PharmaNet in British Columbia discussed in this section were noted with approval. See House of Commons 2004.



physician and the pharmacist kept a copy of the prescription and, during the initial iteration of the Program, an electronic record was created by the Provincial Government. This system, however, was relatively rudimentary. It improved with the introduction of PharmaNet in the mid 1990s.

### **PharmaNet**

#### **Background**

PharmaNet was developed in 1995 by the Provincial Ministry of Health partly in response to perceived problems associated with adverse drug reactions, prescription drug abuse, diversion and 'doctor shopping', and fraud (Chee & Schneberger 2003).

Historically, pharmacies in British Columbia operated independent of one another, therefore each pharmacy had its own database of patient information. Therefore, as long as a patient filled his prescription at the same pharmacy, the pharmacist was able to check the drug for adverse interactions with other medications and keep track of what medications the patient was on. However, for many reasons, including pharmacy discounts and fraud, patients did not consistently go to the same pharmacy.

A provincial Royal Commission on Health Care completed in 1992 revealed that approximately 10,000 people in British Columbia were hospitalized annually because of adverse drug reactions. The commission recommended that an electronic database networked between every pharmacy in British Columbia could significantly lower these numbers. A system wide network would allow pharmacists access to a patient's drug history, regardless of where he had previous prescriptions filled, and be able to identify and therefore prevent a large number of the adverse drug reactions.

In addition to saving lives, the commission believed that the centralized database would reduce prescription fraud and abuse. Individuals that go to numerous doctors to get the same prescription filled at numerous pharmacies would be identified when the pharmacist checked their records on the database. Pharmacare, the government's prescription drug program that often subsidizes prescriptions estimated a savings of \$10 to \$35 million a year by identifying and preventing drug fraud (Chee & Schneberger 2003).<sup>429</sup>

PharmaNet is an aspect of British Columbia's PharmaCare programme which assists British Columbia residents in paying for eligible prescription drugs and designated medical supplies.<sup>430</sup> PharmaCare's mission is to improve the health status of British Columbians by providing reimbursement to ensure reasonable access to and appropriate use of prescription drugs and related health benefit services for eligible residents of the province. PharmaNet is used both as a tool to monitor diversion and prescribing practices and as an adjunct for data collection with regard to the provincial equivalent of the Pharmaceutical Benefits Scheme – tracking entitlements, concessions and other financial entitlements or liabilities.<sup>431</sup> It is only the former aspect of the system that is the focus of this chapter.

#### **The basics of PharmaNet**

PharmaNet is a secure computer network that links all British Columbia community pharmacies to a central database. The PharmaNet system was described with approval during the inquiry into the murders by the British doctor Harold Shipman in the 1990s.

PharmaNet contains the complete known history of drugs prescribed for every resident of British Columbia and, if a visitor to the province requires medication, a record will be created for him/her. At the time of dispensing any drug (not only narcotic drugs), the pharmacist

429 For a good account of the history of PharmaNet and the reasons for its implementation, see Chee and Schneberger 2003.

430 An account of PharmaCare was given to the Committee by Mr Bob Nakagawa, Assistant Deputy Minister, Pharmaceutical Services Branch, Department of Health, British Columbia, when the Committee visited Vancouver, BC, in July 2007.

431 Comments of Mr Bob Nakagawa, Assistant Deputy Minister, Pharmaceutical Services Branch, Department of Health, British Columbia, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Vancouver BC, 23 July 2007.

enters the details of the prescription into the PharmaNet database. The previous 14 months' prescribing history for the patient is immediately shown on the pharmacist's computer screen, as is any history of, for example, allergy or adverse drug reaction. The pharmacist is under a professional obligation to consider this information and may, if s/he wishes, seek further details of the patient's prescribing history.

An 'alert' can be attached to the name of a particular prescriber or patient. This warns the pharmacist not to dispense any prescriptions which may be subsequently presented issued by the named prescriber or in the name of the named patient.

Every community pharmacy in British Columbia has on-line access to PharmaNet.

Although prescriptions for all drugs, not only narcotics, are entered into PharmaNet, the system makes special provision for the monitoring of narcotics. Each time a prescription for a narcotic drug is entered, an automatic entry is also made in the electronic narcotics log kept by the CPSBC [College of Physicians and Surgeons of British Columbia]. If a physician receives a supply of a narcotic drug for practice use (or office use, as it is called), the supply will be entered into PharmaNet.

The CPSBC has a software program that allows it to analyse PharmaNet data by reference to patients, communities, physicians, groups of physicians or drug types. This flexibility enables the CPSBC to focus on particular prescribing issues. For example, it can keep a watch on individual physicians known to have a history of inappropriate narcotic prescribing. It can isolate high prescribers of a particular drug with a view to identifying outliers [people who prescribe well above the rest of the group] and problem prescribers...The CPSBC can monitor the overall usage (and the usage in a particular area) of specific drugs that are known to have a high value 'on the street'. It can monitor the prescriptions issued to patients known to be addicted to a narcotic. It can identify double scripting patients. It can look out for addicts who might trade one narcotic drug for another (Shipman Report 2005, p.191).

PharmaNet access is also available on request to hospital emergency departments, hospital in-patient pharmacies, non-pharmaceutical providers and dispensing physicians. PharmaNet is also used in the provincial prison and corrections system (Shipman Report 2005). Medical practice access to PharmaNet was piloted during 2000 and is to be extended through reforms to the system in 2007 and 2008, colloquially known as 'PharmaNet 2'. The key aim of PharmaNet 2, as explained to the Committee by representatives of the British Columbia Pharmacy Association and College of Pharmacists BC, is to 'bring more doctors into the system', so that eventually pharmacies, doctors surgeries, emergency rooms and hospitals generally will all be cross-linked into one system.<sup>432</sup>

PharmaNet maintains various types of information, including:

- ◆ patient medication histories
- ◆ drug information
- ◆ drug-to-drug interaction information
- ◆ patient demographic information
- ◆ historical patient claims information
- ◆ PharmaCare adjudication rules.

According to the PharmaCare/PharmaNet Procedures Manual:

PharmaNet assists pharmacists in identifying and warning patients about potentially harmful medication interactions, unintended duplications, and other risks from the misuse of prescription drugs.

When a claim is submitted on PharmaNet, a complete patient medication history is accessed displaying to the pharmacist all the medications dispensed in the previous 14 months, as well as any over-the-counter medications that may have been recorded.

432 Meeting with British Columbia Pharmacy Association and College of Pharmacists BC, Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Vancouver BC, 24 July 2007.



Drug Use Evaluation (DUE) is also performed and will alert the pharmacist to any potential drug therapy or dispensing problems (Ministry of Health British Columbia 2006, p.1.3.1).

All clinical conditions and adverse drug reactions previously recorded on PharmaNet by pharmacists are also displayed. According to the Ministry, the benefits to authorised health professionals who access patient medication histories include:

- Reduced reliance on a patient's memory of the medications dispensed to them by community pharmacies. Access to PharmaNet provides an accurate and complete record of this information when challenges such as language barriers hamper effective communication between a patient and a health professional.
- Real-time, up-to-the-minute information on all drugs dispensed to a patient in the community, including medication prescribed to the patient by a specialist or a prescriber at a walk-in clinic. This information supports effective patient care and also enables quick identification of potential medication-seeking individuals.
- Online, 24x7 availability of patient medication information, reducing the need to call a pharmacy for clarification (Ministry of Health BC 2007, single page pamphlet).

According to the British Columbia Pharmacy Association the benefits of PharmaNet also include:

- Prevention of over use of prescription drugs through unintended duplication or fraud
- Prevention of inappropriate therapies by checking for drug interactions and dosage range
- Promotion of cost effective usage of drugs and other therapeutic alternatives
- Comprehensive drug information and complete patient medication records
- Streamlined adjudication and payment of claims.<sup>433</sup>

Thus PharmaNet has an important therapeutic function in addition to its investigatory and disciplinary roles.

### **PharmaNet in practice**

All prescriptions dispensed in British Columbia community pharmacies must be entered on PharmaNet.

When a patient presents a prescription at a pharmacy, the pharmacist transmits all prescription details electronically on PharmaNet. These details include information pertaining to the patient (ie. patient's personal health number – PHN), the pharmacy (ie. pharmacy code, security qualifiers, etc.) and the prescription (ie. quantity, days' supply, drug cost, dispensing fee, etc.). PharmaNet uses this information to 'adjudicate' the prescription claim. According to the *PharmaCare Policies and Procedures Manual*:

Adjudicating the prescription claim includes:

- Validation of security authorizations for the pharmacy as well as for the patient (if a patient keyword has been assigned)
- Checking patient eligibility for PharmaCare financial assistance; i.e., Does the patient have financial coverage? For which PharmaCare plan is the patient eligible? Does the patient have any restrictions? etc.
- Checking program eligibility for PharmaCare benefits; i.e., Is the drug on benefit? Is it included in the plan for which the patient is eligible? Does the drug have any restrictions? etc.
- Prescription cost distribution; i.e., How much, if any, of the prescription cost is covered by PharmaCare? How much, if any, of the prescription cost will accumulate toward the deductible? How much, if any, of the dispensing fee will be paid by PharmaCare? For what portion of the prescription cost is the patient responsible ('co-payment')? etc. (Ministry of Health BC 2006, p.1.3.2).

<sup>433</sup> Presentation to the Drugs and Crime Prevention Committee on PharmaNet by the British Columbia Pharmacy Association, Vancouver, 24 July 2007.

The pharmacist then receives the following information from PharmaNet on-screen at the time of dispensing:

- confirmation of the prescription costs to be covered by Pharmacare
- confirmation of any patient co-payment to be paid
- any warning messages from the DUE checking including drug interactions and over-medication warnings
- a full profile of all medications previously dispensed to the patient in British Columbia during the previous 14 months. This profile also contains any reported adverse drug reactions or clinical conditions
- PharmaNet also has the ability to provide, at the pharmacist's request, drug information, searches for patient Personal Health numbers (PHN) and searches for practitioner identification numbers (Tatchell 1996, p.49).

When the Committee visited British Columbia in July 2007 it was fortunate to observe PharmaNet. Many of the features of a 'real time' online system were displayed with the appropriate confidentiality safeguards put in place. It was interesting that pharmacy officials from the Pharmacy Association and College of Pharmacists were firmly of the view that whilst the 'first few months of PharmaNet were tough' and that many pharmacists were resistant to being required to implement the system in their pharmacies, 'now we couldn't practice without it'.<sup>434</sup>

PharmaNet is to be further expanded throughout 2007 and 2008 as a result of BC Health's 'e-drug' program. E-drug will allow prescribers to enter prescriptions directly into PharmaNet and conversely pharmacies will be able to retrieve e-prescriptions from PharmaNet for dispensing (see BCPharmaCare 2006).

The e-health and e-drug projects are being undertaken jointly by the Ministry of Health, College of Pharmacists, College of Physicians and Surgeons and the British Columbia Medical Association.

#### **Confidentiality and security issues**

As the system information is automatically recorded in a central database, the responsible central statutory body can review prescribing profiles of all prescribers and identify risky practices. Data relating to individual patients can also be reviewed, for example identifying those individuals who are 'doctor shopping'.

Despite or perhaps because of such comprehensive, even intrusive, coverage and the ability to proactively monitor patient (and professional) records, concerns have been raised about confidentiality and privacy issues, as with systems in the United States.

In the early days of PharmaNet the major criticisms of the system related to privacy issues, described as follows:

The biggest critics of the PharmaNet network were the Information and Privacy Commissioner, the British Columbia Civil Liberties Association, and the British Columbia Freedom of Information and Privacy Association. They felt that the system was an unnecessary invasion of privacy. Their primary concerns were database 'surfing', 'function creep', and the mandatory nature of it. Critics fear that with all of this confidential information available to pharmacists, that some would use it for unethical or illegal reasons. The information could be used to report drug abusers to the authorities or embarrassing or career-harming ailments to their employers. In addition to these basic concerns, there were

434 See comments of Ms Linda Lyttle, Former Registrar, British Columbia College of Pharmacists, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Vancouver, 24 July 2007.

According to Ms Lyttle, pharmacists were aggrieved on two levels. First, they did not think they would be sufficiently reimbursed to install the computer software necessary to become compatible with the system, and second, they feared that privacy implications and threats to the pharmacist-patient relationship could ensue. As discussed later in this section, these concerns have been largely addressed in recent years.



many concerns regarding the security and integrity of the information on the database (Chee & Schneberger 2003, p.5).

In order to address these concerns the introduction of the project was delayed. The government supplied British Columbia pharmacists with extra finance and training to address computer upgrades and to assuage their fears with regard to confidentiality issues:

Several security measures had to be developed in order to deal with the privacy concerns. First, data was to be encrypted before being transmitted over the phone lines. Pharmacists would need to enter a personal password to access the system, and they would need to change their password every 42 days. Second, consumers could put a password on their files so that only the pharmacies that they gave the password to could access their files. Finally, a data trail would be created for every time a file was accessed, which included who accessed it and the time they accessed it. This information could be provided to the consumer upon request. There would be penalties for pharmacists caught doing unethical practices (Chee & Schneberger 2003, p.6).

The database generated by PharmaNet is owned by the British Columbia Government. However, the drug usage information (ie. the patient medication profiles) on the database is managed by the British Columbia College of Pharmacists, which handles inquiries from pharmacists on their own initiative or on behalf of their patients. The British Columbia College of Pharmacists has prime responsibility for the security of the information in PharmaNet. Only that College and the College of Physicians and Surgeons of British Columbia have unfettered access. It has a duty to safeguard patient confidentiality. Information provided for research or Government purposes is anonymised before release<sup>435</sup> (Shipman Report 2005).

The drug database has become accessible to more groups in recent years. These groups include general practitioners,<sup>436</sup> nurses, medical clerks, specialists and medical staff in British Columbia hospitals and prisons.

Given the relatively wide coverage of PharmaNet, concerns have been expressed as to the security of the data and the privacy protection afforded by the system. There are significant safeguards, however, built into the system, the most important of which is that a patient or recipient of medicines can choose to 'opt out' of the system. These privacy concerns were recognised from a very early stage of the system's evolution:

Any patient with concerns about confidentiality can attach a keyword or password (up to eight letters, numbers, or a combination of the two) to their file to further limit access. Once a keyword has been assigned to a patient file, pharmacists can only access that patient's

<sup>435</sup> Privacy issues, however, could prove a barrier for the implementation of such a system in Australia. For example a representative of the Pharmacy Guild of Australia gave evidence to the Committee relating his misgivings that a comprehensive monitoring system may not be achievable in Australia:

'About 10 years ago now, I was asked to appear as a witness for the Pharmaceutical Society in relation to a death being investigated by the coroner. It turned out that it was the death of a person I had known, because we had dispensed for him from my pharmacy in Collingwood. I think there were seven supposedly expert witnesses: someone from pharmacy, someone from medical practice, someone from the coroner's office, someone from forensic science and so on, and an academic from Melbourne University. She was the last to appear. It was unanimous amongst the first six of us that we could have avoided this with a tracking system – if Michael had not received his medication from 20 pharmacies in five days and if he did not have these massive amounts of drugs that he used to eventually kill himself. I remember the opening line of the academic lawyer who got up at the end. She said, "Well, I'm here to tell you it will never happen, because privacy will never allow this to happen." Here were all these people saying that we could have avoided a death, and probably many deaths, and a lot of malaise in the community – all we need is this little intranet to operate – and the lawyers were saying that it will never happen because there are privacy provisions that we will never overcome.

In British Columbia, with the stroke of a pen, they overcame the problems, but we have never been able to do that. I think most of us would say we could have a huge effect on the abuse of drugs. We could certainly be better in the appropriate provision of drugs through the HIC for bona fide users of all other drugs as well. The privacy provisions, it seems to me, are the great blocker' (Mr Irvine Newton, Pharmaceutical Society of Australia, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 19 June 2006).

<sup>436</sup> Doctors' offices have been eligible to access PharmaNet since February 2005.

records if the keyword is revealed by the patient. The patient can change the keyword at any time.<sup>437</sup>

Other features of the new arrangements intended to safeguard patient privacy include the following:

- medication information on PharmaNet is controlled by the College of Pharmacists of British Columbia
- improper use of this information by pharmacists could result in the loss of their registration to practice pharmacy in British Columbia
- patients may obtain a copy of their medication record, including a record of all those who have accessed their file, by asking any pharmacist at a PharmaNet linked pharmacy to have their medication records printed out at the College of Pharmacists and mailed to them (Tatchell 1996, p.49).

In addition to the key word supplied to the patient, a pharmacist or doctor must use their own unique identifier:

He or she and all members of his/her staff must sign a confidentiality undertaking before a user number will be issued. An electronic log is created every time the PharmaNet database is accessed so that browsing of the system can easily be detected (Shipman Report 2005, p.192).

Finally an added safeguard that protects against abuse of the system is the requirement of the College of Pharmacy that every pharmacy receives an annual PharmaNet audit. The audit asks pharmacists to supply comprehensive information pertaining to their dispensation practices and the reasons they need to access PharmaNet. The purpose of such an audit, which is supported by the BC Privacy Commissioner, is 'to help the College assure the public that pharmacists look at PharmaNet records only for appropriate reasons'.<sup>438</sup> According to a representative of the BC Pharmacy Association these audits are valuable in determining who may have inadvertently or inappropriately accessed a patient's records.<sup>439</sup>

The privacy and confidentiality concerns associated with PharmaNet were comprehensively discussed when the Committee met with various representatives from British Columbia pharmacy organisations and the British Columbia Ministry of Health.

A representative of the Board of Pharmacy told the Committee that notwithstanding the initial concerns pertaining to privacy, a number of provisions that were put in place have assuaged these concerns. Of particular importance were the following factors:

- The developers of PharmaNet had [and still have], an excellent relationship with the BC Pharmacy Commissioner
- Stringent conditions pertaining to access were put in place such as the use of the Patient Health Number [PHN]
- The Board of Pharmacy and College of Pharmacists established a PharmaNet Users Group to train and inform pharmacists and other stakeholders on the privacy issues pertaining to the system

<sup>437</sup> When the Shipman Inquiry examined the confidentiality aspects of PharmaNet it commented that somewhat surprisingly only about one per cent of patients in BC take this option (Shipman Report 2005).

<sup>438</sup> 'PharmaNet Audits Reassure Public', accessed 7 June 2007 at <http://www.bcpharmacists.org/pharmanet/resources/community.php>.

<sup>439</sup> For example, the Committee was told of the case whereby a patient having asked to access her own record was aware that a third party had inappropriately or at least inadvertently sighted her confidential history. The College of Pharmacists was then able to deal with this breach through the audit process. (Comments of Ms Linda Lyttle, Former Registrar, British Columbia College of Pharmacists to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Vancouver, 24 July 2007).



- Technical aspects of the system designed to safeguard confidentiality were best practice and are constantly being refined and improved.<sup>440</sup>
- All staff working in a pharmacy, hospital department or medical surgery who may come in contact with the system must sign individual confidentiality agreements
- Significant fines of up to \$15,000 [CAD] can be imposed on people found to have abused the system.<sup>441</sup>

In particular, Linda Lyttle, former Director of the British Columbia College of Pharmacy, stressed to the Committee how crucial training of pharmacists and their staff is in addressing privacy and confidentiality issues:

We worked hard to make sure the pharmacists were aware of the privacy issues and that you didn't leave the screen on and your staff signed confidentiality agreements. That is, someone came in requesting information they didn't give it out. We made sure the pharmacists were really aware of the privacy concerns of the information...[and as a result] there has not been a privacy breach in six or eight years. I know about one case that was being investigated, but it never came up to anything.<sup>442</sup>

The views of the PharmaNet representatives with whom the Committee met accord with a study done by Chee and Schneberger in 2003. The authors examined the confidentiality issues facing the BC government at the time PharmaNet was introduced and in subsequent years. It found that over the years since its introduction fears with regard to the abuse of private and confidential information of both the public and health professionals have largely proven to be ungrounded (Chee & Schneberger 2003; Shipman Report 2005).

### Evaluating PharmaNet

The system appears impressive, and various commentators suggest that it is world's best practice. One review by an Australian medical commentator who had observed PharmaNet noted the myriad benefits of PharmaNet for British Columbia as follows:

The claimed benefits of PharmaNet flow to pharmacy, the government and the community.

It is claimed that PharmaNet benefits community pharmacists by:

- enabling immediate claims 'adjudication' by Pharmacare
- enabling immediate processing of the prescription claim and electronic payment within 7 to 10 days of dispensing
- providing complete patient profile information for all patients regardless of where previous prescriptions have been dispensed in the Province
- providing comprehensive drug utilisation checking of any prescription about to be dispensed
- removing the need for pharmacists to administer British Columbia's safety net scheme – this information is now collected centrally and the pharmacist knows at the time of dispensing if the patient or family has achieved the safety net threshold.

440 For example, as part of PharmaNet 2 consideration is being given to implementing not only a system of PHN or password access but also biometric forms of identification. In addition, Canadian law will prevent the information stored in PharmaNet to be transferred or transmitted out of the country. According to Ken Foreman, Former Deputy CEO of the British Columbia Pharmacy Association, this is not an insignificant consideration given that some pharmacies that are part of multinational chains have been known to send data 'off shore', particularly to pharmacies in the United States (Mr Ken Foreman, Former Deputy CEO of the British Columbia Pharmacy Association, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Vancouver 24 July 2007).

441 See comments of Mr Ken Foreman, Former Deputy CEO of the British Columbia Pharmacy Association, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Vancouver 24 July 2007.

442 Ms Linda Lyttle, Former Registrar, British Columbia College of Pharmacists, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Vancouver, 24 July 2007.

PharmaNet benefits the Provincial Government by:

- decreasing administrative costs to run the Pharmacare program eg 100 processing staff reduced to a 25 person Help Desk
- reducing fraud by patients and pharmacists
- reducing drug-drug interactions and drug related hospitalisation
- reducing over-consumption of prescription medications
- reducing multi-pharmacy and multi-doctor shopping by patients
- enabling future changes to be made to Pharmacare benefits and plans with less disruption to the industry.

PharmaNet benefits the community by:

- protecting citizens from dangerous drug interactions and overuse of prescription medications
- providing current drug information to allow more informed use of prescription medications
- providing electronic claims coverage at point of sale, thus eliminating the time consuming wait for Pharmacare coverage reimbursement
- protecting patient confidentiality (Tatchell 1996, p.50).

Dr Tatchell also remarks on how a further indirect though highly significant benefit of PharmaNet is:

the statistical data base it generates. For example, the PharmaNet database keeps a track of the number of occasions on which a drug interaction is flagged in a patient's medication profile *at the time of dispensing* (Tatchell 1996, p.50) (Author emphasis).

Medical staff and pharmacists value PharmaNet and the system has supported the implementation of a range of quality research into prescribed medicines. A news release from the British Columbia government stated:

In 2005, PharmaNet captured 41 million prescriptions at community pharmacies across the province, and generated millions of warning messages about potential medication management issues. PharmaNet detects possible drug-to-drug interactions, ingredient duplication in therapies, fill-too soon and fill-too late warnings (Ministry of Health, British Columbia, Canada, website, 17 May 2006).

However, PharmaNet was not always so warmly received, particularly in the early years of its implementation. In addition to the privacy concerns that have already been discussed, pharmacists also had misgivings about the costs they would have to meet to run the mandatory program. As stated earlier, when PharmaNet was first introduced the British Columbia Pharmacy Association negotiated a compensation package whereby each pharmacy received a one-off payment of between \$3,000 and \$3,800 from the Ministry of Health. The Ministry also met the costs of the telecommunication and connectivity links needed between each pharmacy and the central system and the ongoing costs of the central system (Tatchell 1996, p.49). The one-off payment was intended to cover the costs of initial software applications, upgraded hardware, data file conversion and training for the new system. For some pharmacists such an amount was seen as inadequate:

Pharmacists recognised the need and the benefits of the PharmaNet network; they also had concerns about the systems. Their main concern was over the added time it would take to fill a prescription...They were also concerned about the [cost of] training, software and hardware necessary to implement the system (Chee & Schneberger 2003, p.5).

When the Committee met with Mr Ken Foreman, former Deputy Chief Executive Officer of the British Columbia Pharmacy Association and one of the original people responsible for implementing PharmaNet, he acknowledged that the initial financial compensation probably 'fell short of the mark':



There was a degree of reimbursement that was offered, some \$3500 / \$3800 which was really quite minimum considering the cost. And one of the challenges became measuring the reimbursement model for the ongoing costs.<sup>443</sup>

One adjustment the Ministry of Health did make to alleviate pharmacists' concerns was to implement a compensation system for those occasions when pharmacists, on the basis of data collected from the PharmaNet network, are not able to fill a prescription.<sup>444</sup> Pharmacists were thus 'given an incentive not to fill those prescriptions' (Chee & Schneberger 2003, p.5). As Ms Linda Lyttle, former Director of the College of Pharmacy told the Committee:

One of the positives for pharmacies is that while it hasn't been as utilized as it could have been the Ministry has brought in a reimbursement called the Refusal to Fill service fee. So through PharmaNet if you determine that a prescription is inappropriate to fill and if the government would have paid anything towards the filling of that prescription, you can claim up to \$17.20 for not filling that prescription. That is still in use today.<sup>445</sup>

Pharmacists concerns were also mollified by the changes to the payment system introduced by PharmaNet and PharmaCare. The advantages of this system were explained to the Committee by Mr Bob Nakagawa:

PharmaNet supports dispensing and drug monitoring and claims processing. So we do the claims processing for everybody. It provides for a better cash flow for pharmacies because they get cheques on a weekly basis instead of having to save up a bunch of stuff and mail it in with all the claims.

We're paying them based on the electronic interaction rather than waiting for claims to be submitted...Much faster turn around, you'll hear some concerns about the program but that's a bonus, very fast cash turn around.<sup>446</sup>

Ministry of Health officials in conjunction with the various pharmacy and medical professional associations are currently negotiating a new costing agreement for 'PharmaNet 2'. It is envisaged that the new agreement and model will be more consistent and fairer in terms of both starting up and ongoing operating costs:

One of the challenges that we are facing right now going in with PharmaNet 2 is what are those first time costs going to be for stores to upgrade to the new system. As we go through the next 12 to 18 months with Pharmanet 2 we will see more consistency and fairness just because of the experiences we have gained over the previous years.<sup>447</sup>

Despite such initial and on occasion ongoing concerns, PharmaNet has been viewed as a 'success story' according to a number of the representatives with whom the Committee met in British Columbia including Ministry officials, pharmacists and pharmacy organisation representatives. For example, in the context of 'doctor shopping' or 'double doctoring', as it is termed in Canada, Mr Ken McCartney of the British Columbia Pharmacy Association stated:

I think that double doctoring has certainly been reduced...I think that there is a major opportunity that has been gained there, where you can see that the person has been going to more than one doctor, where in the past you just stumble on that by blind luck if that...And I think that pharmacists are grateful for having the information, because they

443 Mr Ken Foreman, Former Deputy CEO of the British Columbia Pharmacy Association, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Vancouver, 24 July 2007.

444 For example, the PharmaNet data may reveal a person is a 'doctor shopper' not to be supplied with a prescription.

445 Ms Linda Lyttle, Former Registrar, British Columbia College of Pharmacists, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Vancouver, 24 July 2007.

446 Mr Bob Nakagawa, Assistant Deputy Minister, Pharmaceutical Services Branch, Department of Health, British Columbia, comments to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Vancouver, BC, 23 July 2007.

447 Mr Ken McCartney, Deputy CEO and Director of Professional Services, BC Pharmacy Association, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Vancouver, 24 July 2007.

want to be able to use the information for the benefit of the patient.<sup>448</sup>

The College of Pharmacy believes one of the reasons PharmaNet works so well is that it has been a mandatory system from the outset. In other words, a pharmacist cannot dispense medications in British Columbia unless he or she 'hooks into PharmaNet'.<sup>449</sup> Mr Ken McCartney pointed out that although a system similar to PharmaNet has been introduced in the neighbouring province of Alberta its implementation has been voluntary and as a result the 'uptake [by pharmacists] is pretty poor'.<sup>450</sup>

Without a mandatory system the best features of the system such as guaranteeing patient safety and addressing drug diversion and 'multiple doctoring' are nowhere near as effective...The integrity falls over unless it is mandatory. As much as we didn't like it to begin with, boy did we do the right thing by making it mandatory right from square one.<sup>451</sup>

However, no systematic review or evaluation of its effectiveness in reducing pharmaceutical use, whilst at the same time upholding quality care for those who have 'genuine need', has taken place in recent years.<sup>452</sup> This lack of formal evaluation is certainly seen as a weakness of the system, at least in its initial phase. When the Committee met with Mr Gerritt Van Der Leer, Director of the Mental Health and Addictions Branch of the British Columbia Ministry of Health, he was critical that no evidence based evaluations had been conducted of PharmaNet:

We have not been able to measure it. I think it's criminal not to be able to say yea or nay [as to its effectiveness]. I mean we have not developed the right indicators to really see what the impact is. Nonetheless, it definitely has received a very positive reception in BC and I would say it has made a positive impact because it is more difficult for people to shop around.<sup>453</sup>

## Conclusion

Prescription drug monitoring systems generally, and models such as PharmaNet, e-Kasper and CURES specifically, have shown they can be effective strategies in reducing prescription drug abuse, diversion and fraud whilst also addressing non-intentional medical misadventures such as adverse reactions to prescription medicines. Although concerns have been expressed with regard to the privacy and confidentiality aspects of these systems, for the most part the projects discussed in this chapter have been refined to such an extent that these concerns are now negligible. Overall, the Committee was very impressed with the operation and effectiveness of the overseas prescription monitoring models discussed in this chapter.

448 Mr Ken McCartney, Deputy CEO and Director of Professional Services, BC Pharmacy Association, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Vancouver, 24 July 2007.

449 Mr Bob Nakagawa, Assistant Deputy Minister, Pharmaceutical Services Branch, Department of Health, British Columbia, comments to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Vancouver BC, 23 July 2007.

450 Mr Ken McCartney, Deputy CEO and Director of Professional Services, BC Pharmacy Association, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Vancouver, 24 July 2007.

451 Mr Ken McCartney, Deputy CEO and Director of Professional Services, BC Pharmacy Association, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Vancouver, 24 July 2007.

452 Although in the first few years of its operation some BC pharmacists were not in favour of its introduction. Some pharmacists feared 'government interference', others had problems adapting the computer software required, and others were concerned about privacy issues. An overview of the computer-generated problems, some tightening of the privacy rules and some generous financial assistance to BC pharmacists in the intervening years lessened these criticisms substantially. See Tatchell 1996, Wrobel 2003 and Shipman Report 2005 for a discussion of some of these implementation problems.

A report of an Australian trial of a system based on PharmaNet indicated mixed results in the early stages of PharmaNet's development (Wrobel 2003). In particular, a significant proportion of medical practices withdrew before or during the trial and there was a low response rate from those who continued. It is also understood that the later iterations of this initial model are still facing significant practical challenges (Wrobel 2003). However, there appears to be widespread and consistent support for investment in such an approach by a number of individuals and organisations that contributed to this Inquiry.

453 Mr Gerrit Van Der Leer, Director, Mental Health and Addictions Branch, BC Ministry of Health, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Vancouver, 23 July 2007.





## 4.2 Prescription Drug Monitoring in Australia – National Initiatives

### Introduction

The primary Commonwealth government mechanism for addressing prescription drug fraud and misuse in Australia is Medicare Australia. It does so through the Pharmaceutical Benefits Scheme (PBS) and programmes such as the Quality Use of Medicines Program and the Prescription Shopping Program, as well as through consultation with state and territory governments, healthcare professionals, pharmacists, and other interested parties.<sup>454</sup> Whilst this system is reasonably effective in monitoring prescription drugs, limitations of the current communication and database technology may be restricting efficiency.

### Medicare Australia

Medicare Australia (until recently called the Health Insurance Commission) has a central role regarding access to drugs considered in this Inquiry. Located within the Australian Government Department of Health and Ageing (DoHA), Medicare Australia is responsible for, among other things, Quality Use of Medicines, the Professional Services Review Scheme<sup>455</sup> and the PBS. The Department of Veterans Affairs (DVA) has similar responsibilities related to the services provided to veterans.

Medicare Australia relies on advice and input from a variety of interested parties such as state and territory governments, health professionals and consumers. For example, the Australian Pharmaceutical Advisory Council (APAC) is a consultative group that includes nurses, pharmacists, medical staff, government personnel and representatives of the pharmaceutical industry.

The Council identifies and considers issues and needs in health care with particular reference to pharmaceuticals. In this role, the Council can comment on, review or endorse guidelines (DoHA 2006a, p.1).

Medicare Australia functions in the context of the National Medicines Policy (DoHA 2000), which directly influences a number of procedures including the Quality Use of Medicines programme discussed in Chapter 5.1 and the PBS.

### The Pharmaceutical Benefits Scheme

The Pharmaceutical Benefits Branch and the Pharmaceutical Access and Quality Branch of the Australian Government DoHA jointly manage policy relating to the PBS. For approximately six decades the PBS has been a central component of the Australian Government's management of prescribed medicines, governing access to and affordability of medicines. At a cost of \$6 billion per year, the PBS is applied to approximately 80 per

454 Other relevant Commonwealth bodies such as the Therapeutic Goods Administration, the Australian Pharmaceutical Advisory Council, Quality Use of Medicines Program and the Professional Services Review Scheme are discussed in Chapter 3.1 (Law and Regulation) and Chapter 5.1 (Prescribing Practices).

455 The Quality Use of Medicines Program and Professional Services Review Scheme are discussed further in Chapter 5.1.



cent of all medicines prescribed in Australia, covering some 170 million prescriptions in the financial year 2004–2005 (DoHA 2006a).

The PBS is used to facilitate access to identified medication by removing potential cost barriers – that is, by subsidising costs to patients according to set schedules for specific drugs. Thus, consistent with the National Medicines Policy, the PBS aims to ensure improved health outcomes in relation to access to medicines, in the context of economic/efficiency concerns such as avoiding cost shifting, ensuring value for money effectiveness and affordability in selected medicines. The policy also focuses on judicious use of medicines.<sup>456</sup>

### *The Schedule of pharmaceutical benefits for approved pharmacists and medical practitioners*

This Schedule, which is regularly updated, identifies the relevant drugs, controls, processes, and requirements for medical staff and pharmacists who prescribe and provide controlled drugs. That is, the Schedule lists the medicines available under the PBS and specifies how they can be used. Medicines may still be available outside this Schedule, but they will not be subsidised under the PBS.

As discussed in Chapter 3.1, only products registered on the Australian Register of Therapeutic Goods (ARTG) are considered for listing on the PBS. The ARTG is a database of medicines/therapeutic drugs (and devices) that have been approved for use in Australia through the Therapeutic Goods Administration (TGA). The TGA:

Carries out a range of assessment and monitoring activities to ensure that all therapeutic goods available in Australia are of an acceptable standard. At the same time, the TGA aims to ensure that the Australian community has access, within a reasonable time, to therapeutic advances (DoHA 2006b, p.1).

After review by the Pharmaceutical Benefits Advisory Committee (PBAC), an independent expert body with a membership that includes medical practitioners, other health staff and a consumer representative, a medicine may be placed on the PBS list. The PBAC will recommend the maximum quantity and number of repeat prescriptions. There are three broad categories of PBS drugs, each category related to the degree of restriction or required authority that may relate to any prescription, dosage, quantity, duration of treatment and/or repeat prescriptions. The practitioner (for example, a GP) has to apply for the authority to prescribe outside these guidelines. The categories are:

- ◆ **Unrestricted benefits** – there are no restrictions on therapeutic use through the PBS;
- ◆ **Restricted benefits** – a drug can be prescribed through the PBS when the practitioner is satisfied that the clinical condition matches the approved therapeutic uses of the medicine; and
- ◆ **Authority-required benefits** – a drug can be prescribed through the PBS when the practitioner is satisfied that the clinical condition matches the approved therapeutic restrictions and prior approval is provided by Medicare Australia (or DVA for the treatment of veterans). For some drugs there are ‘continuation criteria’ for continued treatment. Concerns about abuse potential (as well as other factors such as cost) have informed decisions to designate a medicine as ‘Authority required’. As a general rule only medical practitioners (not dentists or other health professionals) can write ‘authority-required prescriptions’.<sup>457</sup> An authority PBS prescription will not be valid until it has been approved by Medicare Australia. Until then pharmacists cannot supply the item as a PBS benefit (DoHA 2006c).

<sup>456</sup> For a good general account of the history, development and current features of the PBS, see Duckett 2004.

<sup>457</sup> Authorities-to-prescribe under the Commonwealth PBS are not to be confused with the permits that must be obtained to prescribe or dispense drugs of dependence under the state *Drugs, Poisons and Controlled Substances Act 1981*. See Chapter 3.2 for further discussion.

With regard to 'drugs of dependence and addiction' the Schedule states that:

Prescribers must heed State/Territory laws when prescribing drugs listed as narcotic, specified or restricted and must notify, or receive approval from the appropriate health authority (DoHA 2006c, p.35).

The Schedule also describes the application of the following guidelines:

- the maximum quantity authorised is generally for one month's therapy (e.g. one week's therapy with three repeats);
- where supply for a longer period is warranted, quantities are usually for up to three months' therapy;
- telephone approvals are limited to one month's therapy (DoHA 2006c, p.37).

The following list, using specific medicines as examples, illustrates conditions and requirements that must be complied with before authorities-to-prescribe are granted. It is important to note that these are attenuated summaries and do not include the full information provided in the Schedule:

**Temazepam:** The maximum quantities and/or repeat prescriptions for temazepam are not granted except as detailed. For example, an Authority may be given when temazepam is to be used for malignant neoplasia (late stage) where patients are receiving long-term nursing care on account of age, infirmity or other condition in a residential facility (for example, hospital; nursing home) and are demonstrated to have recent (last 6 months) dependence on benzodiazepines and have not responded to gradual withdrawal. The Authority specifies the maximum dose and quantity (for example, 25 x 10mg tablets).

Authority may also be granted for the treatment of insomnia in palliative care. Authority may be for the initial supply (up to 4 months) for patients where insomnia is a problem and continued supply may be authorised where consultation with a palliative care specialist or service has occurred.

**Alprazolam:** May be authorised when panic disorder has been diagnosed and where other treatments have failed or are inappropriate.

**Bromazepam:** May be authorised for patients with terminal disease or patients with refractory or anxiety states. However, the drug is for short-term use and palliative care, and should not be used as a 'first line of treatment' – other benzodiazepines should have been tried and found to be ineffective or otherwise inappropriate. Increased quantities and/or repeats may be granted to patients with terminal disease and other patients who are dependent and for whom gradual withdrawal has not been effective.

**Oxycodone:** There is a high risk of dependence. Authority for increased maximum quantities only granted for severe disabling pain associated with malignant neoplasia or chronic disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is for less than 12 months.

**Morphine sulphate:** There is a high risk of dependence. Authority for increased maximum quantities only granted for severe disabling pain associated with malignant neoplasia or chronic disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is for less than 12 months. Authority required for use in chronic and severe disabling pain due to cancer (200mg controlled release tablet or sachet of controlled release granules) (DoHA 2006c).

These examples give an indication of the way in which the PBS processes can be used to control access to particular medicines, given doses, quantities and duration of treatment.



This obviously has relevance for reducing the risks from medicines that may be misused, including those under consideration by this Inquiry.

### Medicare Australia and the 'doctor shopping' or 'prescription shopping' program

As discussed in Chapter 2.4 a key element of pharmaceutical diversion has been described as 'doctor shopping' or 'prescription/pharmaceutical shopping'.<sup>458</sup> Such behaviours may occur to support an individual's own misuse. 'Doctor shopping' may also be used to accumulate drugs that are then sold onto the black market.

Various 'prescription shopping' programmes have been implemented to respond to this problem, and the latest one has been referred to as the 'Prescription Shopping Program', initiated by Medicare Australia.<sup>459</sup>

The Prescription Shopping Program is one of a number of initiatives administered by Medicare Australia to facilitate the proper and sustainable use of the Pharmaceutical Benefits Scheme (PBS)...

The authority to administer the Prescription Shopping Program has been conferred upon Medicare Australia by Section 30 of the Medicare Australia (Functions of the Chief Executive Officer) Direction 2005.<sup>460</sup>

The programme aims to identify patients who, within a three-month period, have:

- (a) PBS items prescribed to them by 6 or more different prescribers (excluding specialists and consulting physicians); or
- (b) Obtained a total of 25 or more target PBS items; or
- (c) Obtained a total of 50 or more target PBS items

The target PBS medicines include analgesics, antiepileptics, anti-Parkinson medicine, psycholeptics, psychoanaleptics (including antidepressants), and all other nervous system medicine.<sup>461</sup>

Any such programme can raise concerns about privacy and confidentiality. However, this programme addresses these issues, for example, by ensuring that information is only provided by email if appropriate encryption software is installed.<sup>462</sup> Further:

Information will only be disclosed about patients identified under the Program's criteria. Strict privacy guidelines are in place and patient details are limited to PBS items supplied to a patient in the 3 month period for which they were identified.<sup>463</sup>

The Commonwealth Privacy Commissioner has also developed exhaustive guidelines for the operation of the Prescription Shopping Program and the Prescription Shopping Information Service. In particular the Program must comply with the 10 National Privacy Principles contained in the *Privacy Act 1988*.<sup>464</sup>

<sup>458</sup> See Chapter 2.4 for further discussion of the practice of 'doctor shopping'.

<sup>459</sup> For a discussion of the history and development of earlier doctor shopping systems operating at federal level in Australia, see Australian Medical Association 1997; Wrobel 2003.

<sup>460</sup> Submission of Mr Colin Bridge, A/g General Manager, Program Review Division, Medicare Australia, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

<sup>461</sup> Submission of Mr Colin Bridge, A/g General Manager, Program Review Division, Medicare Australia, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

<sup>462</sup> See Medicare Australia Document *Public Key Infrastructure Security (PKI) Security*

<sup>463</sup> Submission of Mr Colin Bridge, A/g General Manager, Program Review Division, Medicare Australia, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

<sup>464</sup> Information Sheet on the Prescription Shopping Program and Prescription Shopping Information Service and privacy considerations – *The Prescription Shopping Information Service and the Privacy Act* (April 2007). Further discussion as to the privacy and confidentiality considerations pertaining to a new prescription drug monitoring system for Victoria is found in Chapter 4.4

The Program was established at the beginning of 2005, and by June 2006 there were 11,705 medical practitioners registered with the service. Registration with the service results in access to information.<sup>465</sup> That is, these doctors can seek patient information via telephone if:

they suspect (them) to be obtaining PBS Medicine in excess of medical need, in relation to:

- (a) whether or not a patient has been identified under the Program's criteria, and
- (b) the details of PBS items supplied to a patient in the 3 month period for which they were identified.<sup>466</sup>

Complementing inquiries by medical practitioners, Medicare Australia may contact a practitioner through a Medicare Australia Compliance Pharmacist to alert them that a patient may be obtaining PBS medicines 'in excess of medical need'

Once a patient is identified for intervention under the Program, a Patient Summary Report<sup>467</sup> including information on the number of PBS items prescribed to that patient over a 3 month period is made available to prescribers of the identified patient. This information is made available to assist when prescribing to these patients.

Under the Prescription Shopping program an average of 23,000 patients are identified each quarter and 4% are intervened with by a Medicare Australia Compliance Pharmacist.<sup>468</sup>

By June 2006, on average the service was responding to over 250 inquiries per week.<sup>469</sup>

### *Limitations of the Prescription Shopping Program*

Whilst the Medicare Prescription Shopping Program is clearly performing a service in addressing prescription drug fraud and 'doctor shopping', it has not been without its critics. As Room remarks in his review of international prescription monitoring regimes, the modern trend is for electronic reporting of prescribing and dispensing records to state registries and increasingly in 'real time' (Room 2007). Yet the Medicare Program still very much relies upon contact through telephone and faxing and the system is definitely not 'real time' nor, according to some observers, is the most relevant information always available to those practitioners who are seeking it.<sup>470</sup> For example, Peter Halstead, Registrar of the South Australian Pharmacy Board, told the Committee that he had:

...some frustrations with the system, because Medicare has legislation that is very narrow in its use, so we have been unable to gain access to information that we could have used over the years on a number of fronts. We know the information exists, because to be honest Medicare personnel tell us that it does, and I think genuinely they would like to be able to provide that to us but they are hamstrung by the legislation. I also...think some people [in the past]...have raised that issue in a number of forums. The new CEO of Medicare, I think in 2005, held some Australia wide forums where he wanted feedback on what practitioners

465 See *Prescription Shopping Information Service Doctors Registration Form* (Medicare Australia).

466 Submission of Mr Colin Bridge, A/g General Manager, Program Review Division, Medicare Australia, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

467 For a copy of a pro forma *Patient Summary Report*, see Appendix 10.

468 Submission of Mr Colin Bridge, A/g General Manager, Program Review Division, Medicare Australia, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

469 See Key Statistics – Prescription Shopping Program attached as Appendix 11. For copies of other key documents pertaining to the PSP, see the Appendices.

470 For a discussion of the possibilities inherent in computerising systems for the monitoring of prescription drug prescribing and dispensing, see the report by Chris Lynton-Moll (2006) for the Collaborative Centre for e-Health, University of Ballarat.

Chris Lynton-Moll met with the Committee in Ballarat in May 2007. He stated that he thought there was much more scope technically available for more efficient electronic transfer of data with regard to the monitoring of prescription drug prescribing and dispensing. In his view there was no real technical reason why all pharmacies and GP practice systems could not be hooked up to an online system. It was his hope that Commonwealth bodies such as HealthConnect and the National e-Health Transition Authority (NETA) would push for some improvements in both the Medicare and state systems and the interface between them. (See Evidence of Mr Chris Lynton-Moll, Director, Collaborative Centre for e-Health, University of Ballarat, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Ballarat, 29 May 2007).



felt were the Medicare issues. We were invited to that forum and one of the points we expressed was that, if the information is gathered and it can help both the community and Medicare and ultimately the wider professions, why wouldn't that be accessible?<sup>471</sup>

Mr Halstead's Victorian counterpart, Mr Steve Marty also expressed similar criticisms to the Committee. He was particularly concerned that Medicare:

does not pass [prescribing and dispensing] information on in a timely manner. They do not pass it on effectively to the state drugs and poisons unit so that it can do something about [misuse or overprescribing] – whether it is at the prescriber level or the patient level.<sup>472</sup>

Such criticisms are not restricted to the pharmacy profession. Medical professionals have also on occasion found fault with the current operations of the Medicare Prescription Shopping Program. For example, representatives of the Victorian Australian Medical Association (AMA (Vic)) were quite forthright in their criticisms when they gave evidence to the Committee at public hearings in June 2007. Dr Mark Yates, Past President of AMA (Vic), told the Committee:

I think the Commonwealth has a responsibility to ensure that there is adequate feedback of data to prescribers. While we run a \$7 billion program that runs off Microsoft DOS (disk operating system) we will never ever be able to bring together enough information with adequate speed and accuracy to address this issue so that we as prescribers can understand what is happening around us and how it is potentially being abused.

The second thing is that if we do not have a data system that even tells us what is going on, it cannot possibly know whether it is a doctor or a non-doctor prescribing or advising use of a medication. This is a huge problem that is about to strike the whole database systems that we have, particularly as the prescribing opens up for podiatrists...If Medicare Australia could actually provide us – I mean the real-time data that you are looking for should be existing already within the data systems that Medicare Australia holds, but it is a disaster.

[And] it is not an issue of privacy; it is that the system does not work. We are just trying to roll out the streamlined authority process for doctors. The only way we can get any sense of audit is if someone from the department physically picks up the hard copy prescriptions and actually finds out who has done the prescribing. It is an absolutely archaic system that would require less than 1 per cent, probably less than 0.5 per cent, of the entire Medicare Australia PBS budget to completely and radically change the whole system.<sup>473</sup>

Similarly, whilst acknowledging that the Prescription Shopping Program could be helpful in addressing 'doctor shopping', Dr Harry Hemley, Vice-president of AMA (Vic), suggested to the Committee that evaluations of existing programmes were also needed:

There are a range of programs that try to help doctors and pharmacists to deal with prescription shoppers, and the AMA would like to see more comprehensive evaluation of these to determine what works and what does not work. One of the major problems has been the Commonwealth's doctor shopping program. If you ring them up at lunchtime they are closed between about 12.00 p.m. and 2.00 p.m. You just get a dead phone, so there is no point ringing them.<sup>474</sup>

Although representatives of the pharmaceutical industry were generally supportive of Commonwealth attempts to address 'doctor shopping' through the Prescription Shopping

471 Mr Peter Halstead, Registrar, Pharmacy Board of South Australia, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Adelaide, 18 May 2007.

472 Mr Steve Marty, Registrar, Pharmacy Board of Victoria, Evidence to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007.

473 Dr Mark Yates, Past president, AMA (Vic), Evidence to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Melbourne, Public Hearings, 26 June 2007.

474 Dr Harry Hemley, Vice-president, AMA (Vic), Evidence to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Melbourne, Public Hearings, 26 June 2007.

Program, they also expressed reservations about the operation of the current system. For example, a submission from Mundipharma – a pharmaceutical supplier of opioids – observed:

Whilst this initiative is an excellent contribution to *begin* to address the issue of doctor shopping for prescriptions, it is understood that the current system suffers from a number of limitations, conveyed to us as follows:

- It doesn't collect information about drugs for which there is no PBS benefit entitlement. That is, it only collects information about drugs subject to entitlement for a benefit under the Pharmaceutical Benefits Scheme. It does not include information about private prescriptions for drugs not on the PBS, or prescriptions prescribed for people not entitled to benefits when the drug costs less than the patient contribution [currently \$30.70] for a general patient, that is, for concessional patients.
- It is retrospective, often by several weeks after the event of supply.
- An inquiry by a potential prescriber is only initiated, if at all, if the prescriber has grounds to suspect that there is a problem with a particular patient.
- It relies on a potential prescriber of psychoactive drugs being committed enough to take the time and make the effort to contact the service. It requires a time-consuming effort which may deter many busy medical practitioners who rely on their own volition to make an inquiry to the service (our pamphlet, currently in development, on how to use this service may overcome some of these time-consuming obstacles).
- There is no provision for information about prescription shoppers to be communicated to State or Territory agencies working to address problems of prescription drug-seeking behaviour.

Mundipharma is not aware of the extent that doctors utilise this service to identify doctor shoppers but believes that, whilst the system is not ideal and in the absence of a better system, it should be fully utilised by all doctors, including those in Victoria, and supported by medical peak bodies. However, the doctor shopping "hot line" will not be fully utilised unless General Practitioners are educated in the recognisable behaviours of doctor shoppers.<sup>475</sup>

## Conclusion

The Prescription Shopping Program, whilst a laudable initiative, clearly has some weaknesses. In particular it is relatively slow in providing practitioners with the information they may need to address 'doctor shopping' among their patients. Moreover, unlike some state systems it does little to address inappropriate, inadvertent or negligent prescribing practices among health professionals. Finally, there has been no comprehensive or evidence based evaluation of the service it provides.

The next chapter in this Section examines monitoring regimes at state level, most notably those in Victoria, South Australia and Tasmania, to ascertain whether any features of these systems could usefully inform a more comprehensive and up-to-date monitoring system for the benefit of patients, prescribers and dispensers alike.

<sup>475</sup> Submission of Mundipharma to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and other Pharmaceutical Drugs in Victoria, June 2007.

Further discussion on the need to 'educate' doctors with regard to drug seeking behaviour is found in Chapter 6.2.



The Commission has received a large number of submissions from a wide range of stakeholders, including health professionals, patients, carers, and the public. These submissions have provided valuable insights into the complexities of benzodiazepine misuse and the challenges faced by the healthcare system in managing this issue. The Commission has carefully considered all submissions and has sought to ensure that its findings and recommendations are based on a comprehensive understanding of the problem.

The Commission's findings are based on a thorough review of the evidence, including clinical data, research, and the experiences of those affected. It has identified a number of key areas for improvement, including the need for better education and training for health professionals, the importance of patient education and support, and the need for a coordinated approach across all levels of the healthcare system. The Commission's recommendations are designed to address these issues and to ensure that the healthcare system is better equipped to manage benzodiazepine misuse.

The Commission has also identified a number of areas for further research, including the need for more data on the prevalence and impact of benzodiazepine misuse, the need for more research into the effectiveness of different interventions, and the need for more research into the experiences of patients and carers. The Commission believes that this research is essential for ensuring that its recommendations are based on the best available evidence.

The Commission's findings and recommendations are set out in detail in the body of this report. It believes that these findings and recommendations will provide a clear and practical guide for the healthcare system in managing benzodiazepine misuse. The Commission is confident that these findings and recommendations will lead to a more effective and coordinated approach to managing this issue, and to a better outcome for patients and the healthcare system.

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## 4.3 Systems of Prescription Drug Review at State Level

### Introduction

Whilst the Australian states do not have prescription drug monitoring systems that specifically review prescription drug fraud, 'doctor shopping' and over-prescribing in the way such programmes operate in North America, to a limited degree the processes of review through the permit system can act as a de facto system of monitoring prescription drug misuse.<sup>476</sup> Given that this system is limited, however, it may be that a dedicated prescription drug monitoring programme with a centralised database is required at state level. Currently the most comprehensive state systems for monitoring prescription drugs appear to be those operating in Tasmania and South Australia, although in Queensland *Project Shop* a system monitoring a specific aspect of illicit drug production has the potential to be adapted to include a wider range of prescription drugs.

### Current regulatory and monitoring systems in Victoria

The way in which a health professional such as a prescribing doctor operates in accordance with his or her licence to practice in Victoria is subject to a number of factors which include but are not restricted to his or her obligations under the *Drugs, Poisons and Controlled Substances Act 1981* (DPCSA) (hereinafter the Act), and also the regulations and any practice directions issued by the Drugs and Poisons Unit (DPU) of the Department of Human Services (DHS) Victoria.<sup>477</sup> Equally important are any codes of practice, professional standards or guidelines issued by peak bodies or professional colleges such as the Medical Practitioners or Pharmacy Boards. The practice issues that arise from these obligations are discussed in more detail in Chapter 5.1.

#### *Obligations and responsibilities under the Act – Reviewing prescribing and dispensation practices*

Health professionals, particularly medical practitioners and specialist nurse practitioners, have a number of responsibilities under the Act to ensure prescription drugs are only prescribed, administered or dispensed to those people whose medical conditions warrant it.

<sup>476</sup> All states have monitoring or review systems administered through state health departments or equivalent. Most of these systems are restricted to monitoring Schedule 8 controlled substances, particularly opioids, although as discussed later in this chapter Tasmania also monitors the prescribing and dispensing of the benzodiazepine alprazolam. The legislative framework for each state monitoring system is found in the following Acts:

ACT – *Drugs of Dependence Act 1989*

NSW – *Poisons and Therapeutic Goods Act 1966*

NT – *Poisons and Dangerous Drugs Act (n.d.)*

QLD – *Health (Drugs and Poisons) Regulations 1996*

SA – *Controlled Substances Act 1984*

TAS – *Alcohol and Drug Dependency Act 1968*

VIC – *Drugs, Poisons and Controlled Substances Act 1981*

WA – *Poisons Act 1964*.

<sup>477</sup> Such guidelines or directives are issued regularly and are available online at [www.health.vic.gov.au/dpu](http://www.health.vic.gov.au/dpu). The DPU is at pains to remind practitioners that as regulations and directives are amended regularly such guidelines must be thought of as 'dynamic'. See, for example, *Guide to the Drugs, Poisons and Controlled Substances Regulations 2006a*, DHS Victoria, Melbourne.



The types of obligations that are incurred by practitioners generally relate to both their general ability to prescribe, dispense or administer medicines by virtue of their status as qualified and registered medical professionals or because of the permits or licences they have been given to prescribe or administer particular drugs, such as drugs of dependence, under the Act.<sup>478</sup> For example, provisions that may curtail the otherwise 'free hand' doctors and nurses have in conducting their professional responsibilities may include:

- ◆ Restrictions on to whom certain drugs may be prescribed<sup>479</sup>
- ◆ Restrictions on the period for which certain drugs may be prescribed<sup>480</sup>
- ◆ Special notification procedures with regard to people considered drug dependent<sup>481</sup>
- ◆ Conditions pertaining to the quantity (including repeats) or type of drug permitted to be administered or prescribed<sup>482</sup>
- ◆ Conditions pertaining to the reasons a patient may seek certain drugs.<sup>483</sup>

It is an offence for registered medical practitioners to administer, supply or prescribe Schedule 8 and 9 drugs and for nursing practitioners to administer Schedule 8 drugs without the authorised permits, although some exceptions are made for patients with malignant cancers for whom the prescription of opioid analgesics (Schedule 8 drugs) is appropriate.<sup>484</sup> It is also an offence for such practitioners to prescribe these drugs in excess

478 See Section 34 DPCSA.

479 For example, under Section 34 permits may be issued for practitioners to prescribe Schedule 8 and 9 drugs to drug-dependent persons or non drug-dependent persons (for example to relieve the pain of terminally ill patients). Different conditions will apply in both cases. Whilst most benzodiazepines do not fall within the permit category, a submission from the Transport Accident Commission (TAC) Medical Panel recommends that consideration should be given to make the prescription for long-term use of benzodiazepines subject to licensing or permit controls (Submission of TAC to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006).

480 For example, special permits may be needed to prescribe or administer a Schedule 8 or 9 drug to a non drug-dependent person for a continuous period greater than eight weeks.

481 Under Section 33 of the DPCSA, registered medical and nurse practitioners must give notice to the Secretary of the DHS of any of their patients whom they consider to be 'drug dependent'. They must also give notice to the Secretary of their intention to prescribe, supply or administer Schedule 8 and 9 drugs (in the case of a medical practitioner) and Schedule 8 drugs (in the case of a nurse practitioner) for a period longer than eight weeks.

It has been argued that such notification requirements may act as a barrier to treatment for drug-dependent clients. For a discussion as to why this may be the case, see Chapter 7.2.

482 As indicated in Chapter 3.1, Commonwealth laws and policies also circumscribe such prescribing practices or conditions. For example, medical practitioners must contact Medicare Australia for authorities to prescribe Schedule 8 drugs when the prescription quantity and/or number of repeats are in excess of the PBS maximum. This is *in addition* to any permit required by the state DPU. According to some commentators, 'obtaining authorisation is not well received by doctors and is seen as bureaucratic and not evidence based' (Liaw et al in Duckett 2004, p.56).

483 For example, a practitioner may only prescribe or administer drugs of dependence to a drug-dependent patient to assist with the clinical treatment of his or her condition rather than solely to support that drug dependence.

484 Whilst this is the general obligation under state law, it cannot be divorced from the additional and supplementary requirements that bind a doctor under relevant professional guidelines. A good example is with the prescription of drugs of dependence. Assuming a doctor has the required permit to prescribe a Schedule 8 drug, he or she must also follow Medical Practitioners Board of Victoria guidelines that state:

'Whenever possible, doctors must attempt to authenticate the histories and documents presented by contacting the doctor, clinic or hospital cited by the patient.

A doctor must not administer or prescribe a drug of dependence to or for any person unless:

- that drug is for the medical treatment of a person under his or her care; and
- he or she has taken all reasonable steps to ascertain the identity of that person; and
- he or she has taken all reasonable steps to ensure a therapeutic need exists for that drug.

When a doctor does not have access to the patient's history, to comply with these requirements he/she would need to:

- be satisfied that the need is genuine by history and physical examination;
- be satisfied that there are no signs suggestive of drug dependence such as pupillary size or injection marks; and
- attempt to independently verify details of the history given by the patient for his or her need for drugs of dependence directly with the purported previous prescribers' (Medical Practitioners Board of Victoria, Circular: Drugs, Poisons and Controlled Substances Act 1981, accessed 6 June 2006 at [www.medicalboardvic.org.au/content.php?sec=44](http://www.medicalboardvic.org.au/content.php?sec=44)).

This directive also has a comprehensive discussion of the other exceptional circumstances in which permits may not be required in clinical practice. Many of these cases concern the administration of Schedule 8 drugs to children (with Attention Deficit Disorders), the prescriber is an accredited specialist, and/or the prescription/administration takes place in hospital-based settings. Nonetheless, although permits may not be required, even in such cases the DPU will still need to be notified of the treatment regime.



of any quantities specified in the permits or for a period longer than the permit specifies.<sup>485</sup>

The Act and the regulations give some leeway to practitioners in observing these obligations. For example, there may be emergency circumstances or exigencies of clinical practice that prevent a practitioner from renewing or applying for a permit to administer drugs of dependence. In such situations it may be possible to give the required notice as soon as practicable after the prescription or administration of the drug.<sup>486</sup>

Nonetheless, contraventions of the Act are viewed seriously. Apart from any penalties issued under the Act or regulations, medical professionals are also subject to disciplinary proceedings from the various state professional boards.

Pharmacists also have specified obligations under the Act in addition to any professional codes of practice or guidelines they must observe. In particular, under Section 36 a pharmacist who 'is called upon to dispense for any person greater quantities of or more frequently than appears to be reasonably necessary' any drug of dependence or drugs from Schedules 4, 8 or 9 is required to notify the Secretary of the DHS of that fact.<sup>487</sup>

The above account is not exclusive of the offence provisions that are applicable under the Act. They are the main ones, however, that relate to those who prescribe or administer the drugs rather than those who seek to abuse them. Other more general criminal law offences such as theft or trafficking are dealt with in Chapter 3.2.<sup>488</sup>

### ***An overhaul of the system: The Drugs, Poisons and Controlled Substances (DPCS) Regulations 2006***

Whilst the 1981 Act provides the broad framework for medicines, drugs and poisons control in the state, it is the DPCS regulations that govern the day-to-day practice issues that

485 See Section 35 DPCSA. It is of great concern that a submission to this Inquiry by the Victorian TAC states that 51 per cent of doctors prescribing for TAC clients prescribed Schedule 8 drugs without the relevant permits (Submission of TAC to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006).

486 For examples of how these emergency services may work in practice, see Transcript of Evidence given by Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 13 July 2006.

487 Of course the legal obligations imposed upon medical practitioners, nurses and pharmacists can and are compromised by the vicissitudes of practice. This may be because of ignorance, wilful neglect, the constraints of medical practice (for example, short consultation periods that do not allow a doctor to explore options other than pharmaceutical prescription), or even criminal behaviour. Some coronial cases, for example, relate incidences of doctors who did not apply for or receive permits to prescribe scheduled drugs, prescription anomalies or other failures to follow regulations or appropriate procedures. For example, see State Coroner Victoria, Case No: 1720/99 (1 March 2001) where methadone was allegedly prescribed and dispensed for the deceased, already taking benzodiazepines, without the appropriate permit.

At the extreme end of such cases is the criminal behaviour of professionals who abuse the system with malevolent intent. The most notorious case in recent years being the murderous acts of Dr Harold Shipman in England. See [www.the-shipman-inquiry.org.uk](http://www.the-shipman-inquiry.org.uk)

Following the regulations appropriately also assumes a culture in which health professionals are encouraged and supported to follow the system. For example, the obligation of pharmacists to report suspicious or inappropriate requests for dispensation under Section 36 DPCSA assumes that the pharmacist will feel confident to question the prescribing patterns of their professional colleagues in medicine. This may not always be the case.

For a discussion of the relationship between pharmacists and prescribers and the possible problems that may arise when pharmacists believe there has been inappropriate or excessive prescribing of medicines, see Transcripts of Evidence given by the Pharmaceutical Society of Australia (Victoria) (Mr John Iltott and Mr Irvine Newton) and the Pharmacy Guild of Australia (Victoria) (Mr Dipak Sanghvi and Mr Maurice Sheehan) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 19 June 2006.

488 It is axiomatic that health professionals who abuse or misuse drugs of dependence and certain other scheduled drugs without due cause or authorisation may be subject to criminal penalties and/or action for professional misconduct. A submission to this Inquiry by the Nurses Board of Victoria (NBV) states that in 2004–2005 a total of 23 complaints were made to the NBV with regard to the abuse of medications by nurses, including the misappropriation of medications from the workplace:

'However, these complaints must be considered within the context of a lack of a legislative framework that requires mandatory reporting. The Board is aware that not all incidents are reported to the Board, including some situations where the employer chooses to manage the incident within the employment relationship' (Submission of the Nurses Board of Victoria to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006). For a more general discussion of the issue of health professionals who abuse drugs and medicines, including benzodiazepines, see Chapter 2.3. The issue of criminal charges and penalties for drug possession and trafficking is considered in Chapter 3.2.



arise with regard to *inter alia* the prescription, dispensation and administration of scheduled drugs and medicines. These regulations have been recently amended, partly in recognition of the complexity of the issues associated with the prescription and dispensation of these medicines.<sup>489</sup>

The new regulations cover a wide variety of matters pertaining to the prescription, dispensation and administration of prescription and other drugs and poisons.<sup>490</sup> They include:

- ◆ New criteria for computer generated prescriptions<sup>491</sup>
- ◆ An extended range of persons who may be able to possess or administer scheduled drugs and medicines in certain circumstances<sup>492</sup>
- ◆ Stricter rules on ascertaining the identity of patients seeking drugs of dependence<sup>493</sup>
- ◆ Stricter rules on the notification of fraudulent obtaining of drugs of dependence<sup>494</sup>
- ◆ More stringent requirements for the storage and record keeping of Schedule 4 and 8 drugs.

Of particular relevance in the context of this Inquiry are the tighter controls imposed on the dispensation of Schedule 4 and 8 drugs (including benzodiazepines) by pharmacists. Pharmacists in most circumstances must only supply such drugs on the presentation of an original prescription<sup>495</sup> from an authorised person such as a medical practitioner (or where relevant, nurse practitioner, dentist, optometrist etc).<sup>496</sup> However, in certain defined emergency circumstances a pharmacist may supply a Schedule 4 drug (which would include most benzodiazepines) without a prescription where the pharmacist is satisfied that there is an immediate therapeutic need for the drug.<sup>497</sup> It should also be noted that a pharmacist must not supply a Schedule 8 drug to a patient on the prescription of a medical practitioner unless that practitioner is registered in Victoria.<sup>498</sup>

The above account of the 2006 changes to the law governing drugs and poisons administration and monitoring in Victoria is a relatively rudimentary framework that outlines the most salient points applicable to this Inquiry. The devil, however, is in the detail. The regulations need to be read carefully and in conjunction with the various

489 The Department of Human Services has recently produced a Discussion Paper examining the Victorian permit and regulation system for controlled substances. See discussion in Chapter 3.1.

490 Unless otherwise specified the regulations discussed in this section primarily apply to Schedule 4 and Schedule 8 drugs only.

491 See Section 26 DPCS Regulations 2006.

492 For example, in defined circumstances ambulance officers may be able to administer certain Schedule 4 and 8 drugs or a municipal council officer employed in environmental health may administer Schedule 4 vaccinations as part of an authorised immunisation programme. See Table in Division One, Section 5 DPCS Regulations 2006 for a full listing of all authorised persons or class of persons.

Podiatrists have also recently been given prescribing authority in certain circumstances. (See Drugs Poisons and Controlled Substances (Health Professions Amendment) Regulations 2007). This is a development that some medical bodies are critical of. In particular, see the Submission of the Australian Medical Association (Victorian Chapter) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007, and the discussion in Chapter 5.1.

493 For example, unless the patient is in effect well known to the healthcare professional (including doctors, nurses, pharmacists and dentists), the healthcare professional must not prescribe, sell or supply a drug of dependence to that person unless 'all reasonable steps' have been taken to ascertain the identity of the person and all reasonable steps have been established to ensure a therapeutic need exists for the drug. See DPCS Regulations 2006, Division 2.

494 Healthcare professionals who suspect that a person has obtained drugs of dependence or prescriptions for them by fraud or false pretences are required to notify both the Victoria Police and the Secretary of the DHS (DPCS Regulations 2006, Regulation 14).

495 Under Regulation 16 there are defined circumstances when a pharmacist may supply a Schedule 4 or 8 drug on a copy of the original prescription.

496 See Regulations 15–17 DPCS Regulations 2006 for further details of the obligations and requirements with regard to pharmacists in these circumstances.

497 See Regulation 15(2) DPCS Regulations 2006.

498 See Regulation 17 DPCS Regulations 2006.

practice directions of the DPU.<sup>499</sup> In addition to the advisory statements issued by the professional colleges and peak bodies, Chapter 5.1 will also examine the problems associated with the prescribing and dispensation of these drugs in light of the regulatory framework discussed here.

### Localised 'monitoring' practices

It is important to note that in addition to state (and national) systems for authorising and reviewing controlled substances, it would seem there are a number of local projects that also aim to reduce the amount of inappropriate drug seeking happening in Victorian communities, particularly with regard to opioid drugs. For example, when the Committee held a forum on prescription drug misuse in Ballarat it was informed of a system whereby local recipients of pharmacotherapy treatments such as methadone or buprenorphine would be subject to identification checks through screening of the iris of the eyes.<sup>500</sup>

Generally in small towns or provincial cities it is easier for local healthcare professionals to informally implement their own crosschecking or linked computer monitoring systems. This is certainly the case where pharmacies form part of a chain or group practice in the one area, as was noted by Ballarat pharmacist Colin Dorn when he gave evidence to the Committee in May 2007.<sup>501</sup>

Clinicians at Warrnambool in south-western Victoria also spoke to localised agreements initiated by drug and alcohol workers whereby prescribers would put notes on their prescriptions 'To be dispensed only at X pharmacy' as a way of preventing 'doctor shopping'. Also in the south west of the state a local Aboriginal cooperative (Gunditjmarra Aboriginal Cooperative) has implemented their own monitoring system called Communicare for the prescribing of drugs by local physicians. This database red flags instances of a client's prescription and medical history, including inappropriate drug seeking, and can be used to better case manage that client's treatment.<sup>502</sup>

Whilst such localised practices are important initiatives and can no doubt serve their communities well, the Committee has not received sufficient information as to their development or implementation to comment further. It is also arguable that for a monitoring system to be optimal in preventing prescription drug misuse, fraud and diversion it needs to be comprehensively developed, and implemented at least at state level.

## Prescription drug monitoring in South Australia

The monitoring of drugs of dependence and other prescription drugs in South Australia is generally covered by the *Controlled Substances Act 1984* (SA) (CSA) and the *Controlled Substances Act (Poisons) Regulations 1996* (SA) (CSAPR). As in Victoria, this legislation is only one part of a regulatory regime for monitoring the prescribing and dispensation of controlled substances. Healthcare professionals in South Australia also must be aware of and adhere to a number of Health Department Codes of Practice and Clinical and Professional Guidelines.<sup>503</sup>

499 Particularly circulars such as *Key Prescribing Requirements for Medical Practitioners Practice* (DHS Victoria 2006b); *Obtaining Information about Drug Seeking Patients* (DHS Victoria 2006c); *Managing Drugs in General Practice* (DHS Victoria 2006g); and *Interventions by Pharmacists* (DHS Victoria 2006h). All available at <http://www.health.vic.gov.au/dpu/>

500 See comments of Mr Ray Beecham, Team leader, Alcohol and Drug Centre, Ballarat Community Health Centre, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Ballarat, 29 May 2007.

501 Mr Colin Dorn, Pharmacist, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Ballarat, 29 May 2007.

502 For further details of the above processes, see comments of Ms Annette Ludeman, Gunditjmarra Aboriginal Cooperative Ltd, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Warrnambool, 29 May 2007.

503 For details of these, see the website of Drug and Alcohol Services South Australia (DASSA) at [www.dassa.sa.gov.au](http://www.dassa.sa.gov.au) (Policy and Legal Obligations).



Unless otherwise indicated, the following discussion applies primarily to 'drugs of dependence' or controlled drugs that are for the most part Schedule 8 medicines and would include all opioids.

The Drugs of Dependence Unit (DDU) of the Drug and Alcohol Services of South Australia (DASSA) is the body responsible for monitoring the prescribing, sales and dispensing of controlled prescription drugs in South Australia. In the case of a drug of dependence, Regulation 27 of the CSAPR requires a pharmacist to forward to the Unit after dispensing:

- ◆ each prescription dispensed for the last time, or
- ◆ if this cannot be done the duplicate (eg. original to be forwarded to Medicare Australia for payment), or
- ◆ a copy of the prescription(eg. repeat dispensings owing).

Thus the DDU is forwarded the prescription or a copy of each prescription dispensed each month. When the Committee met with Mr Geoff Anderson, Chief Pharmacist of the South Australian DDU, he explained the system thus:

One of the main differences between South Australia and Victoria is that we actually monitor the dispensings and the sales of drugs of dependence to individual patients, and supplies to medical practitioners...The information was required to be sent in, on paper, quarterly, and from about 1985 it was supplied on a monthly basis. We changed to an electronic system seven or eight years ago, purely because the number of prescriptions has increased dramatically. In 1984, when it first started, we were having something like 3 and one half thousand scripts per month and now it has gone up to about 28 and one half thousand.<sup>504</sup>

Mr Anderson elaborated on the monitoring system in a written submission to the Committee in July 2007.

Prescription dispensing records must be forwarded to the Unit by the pharmacist in charge of the pharmacy by the 7<sup>th</sup> day of the following month. The pharmacist must also notify the Unit if no drugs of dependence had been dispensed. The Unit follows up pharmacies that do not send in a return and the 'nil return' identifies those that do not need to be followed up. A similar requirement exists for forwarding sales of Drugs of Dependence, eg filling bag orders of medical practitioners (PBS monthly bag order and private orders) and this identifies prescribers who may purchase for example large quantities of injectable opioids and this usually indicates self administration.

The Unit receives about 29,000 prescriptions per month. This has grown from about 3,500 in 1984.

Pharmacists are requested to also provide an electronic dispensing record of their dispensings of drugs of dependence. The major dispensing software companies have developed a S8 export file to permit this to occur and the jurisdictions that monitor prescriptions have agreed to the content of this export file. The file is sent to the Unit either through the Government's internet business site (Bizgate) which is a secure site or by posting a floppy disc with the hard copies. The internet transmission is the preferred method due to less time required for reloading and floppy disc failures. About 80% of pharmacies provide electronic returns.

The electronic dispensing data is loaded into an in-house computer program. SA's program has been adapted from the Tasmanian program. This permits prescriptions to be monitored against patients, prescribers, pharmacies and drugs for monitoring. A problem with this is that an administration officer is occupied almost full time going through prescriptions and correcting prescription data that is not accepted by the program due to an inaccurate match, usually the result of inaccurate pharmacist entries.

The electronic data allows ready interrogation of the data. If any action or investigation is required, the actual prescriptions or copies are located and action based on those, as the

<sup>504</sup> Mr Geoff Anderson, Manager and Chief Pharmacist, DDU/DASSA, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Adelaide, 18 May 2007.

electronic data is not totally reliable with some potential 1000 pharmacists entering data at time of dispensing with various skills and accuracy levels.<sup>505</sup>

The electronic data held by the DDU allows the system to generate monitoring letters to the following prescribers and dispensers:

- Prescribers who hold an authority and prescribe an unauthorised drug
- Prescribers who hold an authority and prescribe a quantity in excess of that authorised
- Prescribers who prescribe for a patient and a prescriber at another practice holds an authority
- Prescribers who have prescribed for a patient who has received a drug of dependence for more than the statutory two month period after which an authority is required.
- Prescribers who prescribe for themselves
- Prescribers and pharmacists who prescribe or dispense to a known drug seeker
- Pharmacists who dispense for an interstate prescriber (these are not valid for drugs of dependence)
- Pharmacists who dispense from an expired prescription (drugs of dependence prescriptions valid for 6 months)
- Pharmacists who fail to send in a return by the required date.<sup>506</sup>

The computer programme also monitors patients and is used to generate authorities and provide a record of authorities issued and events, including records of any telephone discussions, computer generated letters etc. Authorities are required where treatment exceeds two months or for treating drug dependence. There are a few exceptions such as terminal patients (life expectancy not more than 12 months) and elderly patients (over 70 years of age) provided the short-acting drugs pethidine, or hydromorphone are not involved. South Australia has about 16,000 patients under authorised treatment.

At time of consideration of issuing an authority, the dispensings listing the prescribing date, dispensing date, prescriber, pharmacy, drug and quantity is instantly available to show drug history.

The computer generates letters to prescribers when a progress treatment report or a specialist or pain clinic report are due, as well as a request for a renewal application when current authority is about to lapse.

#### ***Publication of material regarding drug seekers or 'doctor shoppers'***

Under the South Australian system, Section 58 of the Act permits delegated officers to release normally confidential information to specific persons involved in drug distribution such as prescribers (medical practitioners and dentists), pharmacists, hospitals etc in certain circumstances. Mr Anderson explained this function as follows:

The information is gathered from a number of sources – authority applications and issues, prescription monitoring (limited to 58 drugs), medical practitioners and pharmacists reporting suspected drug seeking. We also have a number of cases such as psychiatrists reporting persons seeking all sorts of medications to misuse or to attempt suicide, and at times persons having trouble controlling their drug seeking request a medical practitioner [to] arrange for their details to be circulated so they are refused additional supplies from other sources when they relapse. We also received requests from concerned relatives or friends to curtail a person's drug seeking and this can be included if some medical confirmation can be obtained.

Information is published in three ways.

505 Submission of Mr Geoff Anderson, Manager and Chief Pharmacist, DDU/DASSA, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2007.

506 Submission of Mr Geoff Anderson, Manager and Chief Pharmacist, DDU/DASSA, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2007.



- Prescribers and pharmacists are encouraged to telephone the Unit if they suspect drug seeking or are unsure of the history of a patient.
- If prescription monitoring identified a prescription for a drug seeker, letters are sent to the prescriber and the dispenser.
- Patients who are persistent, are extensive or potentially serious consequences [sic] (eg overdoses, suicide attempts) are included in a circular that is forwarded to hospitals with accident and emergency services, after hours locum services, the AMA for distribution to their members, some colleges of GPs for their members, and pharmacy organisations to issue to their members. Persons receiving a hard copy are asked to destroy them after twelve months for privacy reasons. If patients remain active they are included in following publications. The current copy and the last 12 months editions are available on a secure web site that is accessible 24 hours per day. Access to the web site is by application for a PIN [Patient Identifier Number]...

The Privileged Circular<sup>507</sup> contains names & aliases used, dates of birth used, addresses used, usual claims for requesting drugs, drugs abused and recommended action. Recommended action includes referral to their nominated prescriber if they have one or for assessment for drug dependence treatment. Warnings may also be included for persons suspected of stealing prescription forms or letterheads or [who] may be aggressive or violent to health professionals.<sup>508</sup>

Mr Keith Evans, Chief Executive Officer of DASSA explained the advantages of such a process to the Committee when it met with DASSA representatives in Adelaide:

By having this system available, we are able to send the circular...around to medical practitioners, for instance, and say, 'These are the people out there that we are aware of who are doctor-shopping. These are people who have come to our attention for a variety of reasons'...When you have a major critical issue [with drug seeking] – and there is one currently in this state – as long as we get a name from the police, we are able to identify whether that person is known to us by that name or a range of other names...We were able to say, 'Tell us the suburb', and then we know who is on our program, that lives in that suburb – But if the police were to come to us and say, 'Is this person known to you?' we would be able to do that. Now, you can only do that if you monitor truly; if you do something with the authorisation once you have handed it out.

The other significant issue is that people are prepared to prescribe, under duress often from patients, significantly above the authorised level. So we will say, 'You can have authority to prescribe 200 milligrams of morphine a day', and you find somebody is getting a thousand milligrams of morphine. The only way you can know that is if you have a system of monitoring it, unless the person dies, and then there is a coronial inquiry and the whole question then comes up: 'Why on earth are you handing these things out and don't have a system?'<sup>509</sup>

### **'Monitoring' doctors**

The last point is related to the issue of using the South Australian monitoring system not only to monitor 'doctor shoppers' but also those who prescribe for them. The computerised

507 A copy of the Privileged Circular with identification features omitted is attached as Appendix 12. As the Circular itself states, the list is not a complete list of persons believed to be consuming prescription drugs in excess of therapeutic need: 'It is a list of persons identified as being extensive or persistent in their behaviour or at high risk of harm'. See Drugs of Dependence Unit, *Controlled Substances Act 1984, Privileged Circular*, update December 2006.

508 Submission of Mr Geoff Anderson, Manager and Chief Pharmacist, DDU/DASSA, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2007.

509 Mr Keith Evans, Chief Executive Officer, DASSA, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Adelaide, 18 May 2007.

data on hand to a large degree allows the investigation of doctors' prescription practices, at least with regard to Schedule 8 drugs. Mr Anderson explains the process as follows:

If we had [relevant] information, we would write to the prescribers saying, 'We have noticed you've prescribed for this patient', and we ask them to provide information relating to their treatment of that patient. From that we form an opinion whether the person is a drug seeker or they have a pain problem that is not properly treated or whatever. Then, if we form the opinion they are a drug seeker, we circulate letters that come out of our wonderful system. We automatically each month generate letters to prescribers and dispensers for those patients, telling them that the person is known to us to be a drug-dependent person and they should be referred to a drug treatment clinic and not prescribed any drugs of dependence. We also do the same thing with authorities, provision of authority to a further prescriber. If we see someone else has prescribed, we write to that second prescriber telling them not to prescribe for that patient but refer them back to the authorised prescriber, who we name. We are trying to increase communication so different prescribers know and get a better picture of what is going on with the patient.<sup>510</sup>

The system can thus be used to inform the unaware practitioner, advise the inadvertently over-prescribing doctor or even bring disciplinary action against 'rogue' prescribers. With regard to the last group, Mr Anderson states that if the system has identified the fact that a prescriber has continually over-prescribed to a known drug seeker despite having received warning letters or other notifications there are a number of ways in which he or she can be managed:

If it is the same doctor and we have already sent one of those letters to them, we interview them. It could be seen as prescribing to treat drug dependence when we have already told them that they are drug-dependent. Under section 57 of our act we can actually remove the privileges that they are given under the legislation to possess and prescribe these drugs, if the minister forms an opinion that they are prescribed in an irresponsible manner. We can actually take away their ability to handle the drugs in the future.<sup>511</sup>

Whilst such a system is used relatively rarely according to Mr Anderson, it also has to be remembered that most of the South Australian monitoring provisions apply to controlled substances or Schedule 8 drugs. The majority of prescriptions written by doctors would not be reviewed to the same extent.

### *Applicability of the system to other states?*

In South Australia a number of safeguards are built into the system to protect privacy, for example information is usually only released if there is the prospect of serious harm or injury occurring to a person, or if the police need the information for investigative purposes. Although, even in such cases a warrant usually has to be served on DASSA.<sup>512</sup> Nonetheless, theoretically privacy considerations can be overridden as the enabling legislation allows the system to operate in the way that it does.

The South Australian system is certainly comprehensive. But it does have its drawbacks, even according to its supporters and those who administer it. One issue is that of cost. Representatives of DASSA told the Committee that in terms of both set-up and ongoing costs, the monitoring system could be very expensive to run, particularly in a large state like Victoria or New South Wales. For example, in South Australia with a relatively small

510 Mr Geoff Anderson, Manager and Chief Pharmacist, DDU/DASSA, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Adelaide, 18 May 2007.

511 Mr Geoff Anderson, Manager and Chief Pharmacist, DDU/DASSA, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Adelaide, 18 May 2007.

512 Sometimes joint investigations will be held by South Australia Police (SAPOL) and DDU/DASSA officers, in which case warrants would not be required. There is also a protocol in place between SAPOL and the DDU as to the circumstances in which monitoring information can be used for investigative purposes. (Information provided by Mr Geoff Anderson, Chief Pharmacist, DDU, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Adelaide, 18 May 2007).



population base the monitoring system is administered by between 10 and 12 people, usually with graduate or postgraduate degrees in pharmacology or health science. As Mr Anderson stated in his submission to this Inquiry:

I advise that some of the [monitoring] functions require significant resources due to the large numbers of prescriptions and patients involved. As the numbers of patients in treatment is continually increasing, it is a constant challenge to manage resources and workloads. The size of the population serviced will influence what can be done and the way it can be done.<sup>513</sup>

Another issue is that the South Australian system only covers a relatively small number of drugs, those viewed as the most problematic in terms of dependence, addiction or harms caused such as opioids. The system, for example, does not monitor the benzodiazepines and again this comes back mainly to questions of money:

Benzodiazepines and codeine containing preparations are recognised as drugs sought after and misused in the community and there is some demand to be able to monitor and provide more information regarding these activities. To expand to cover these drugs would require significant resources due to the large quantities prescribed.<sup>514</sup>

As DASSA's Chief Executive Officer stated to the Committee, whilst the system has proved itself in terms of its monitoring and surveillance functions and thus arguably saved costs in terms of reducing drug seeking and 'doctor shopping' in South Australia, the expense is by no means negligible. This is particularly so given South Australian (and indeed Victorian) practitioners and bureaucrats also have to comply with Medicare regulations and protocols. Mr Evans remarked to the Committee:

If we were starting from scratch again, I doubt whether there would be such a comprehensive monitoring role, because the expense is not insignificant.<sup>515</sup>

## Prescription drug monitoring in Tasmania

Drug monitoring of Schedule 8 drugs in Tasmania, including all opioids, is covered by the *Alcohol and Drug Dependency Act 1968*.

Tasmanian pharmacies are required to report to the Health Department (Pharmaceutical Services Branch) the movements of all Schedule 8 substances they dispense or supply. Currently, the requirement is that reports for one month be submitted at the beginning of the following month in accordance with Regulation 96 of the Poisons Regulations 2002. They are submitted in disc format using the automated reporting facility in their dispensing system. As discussed in Chapter 2.2, from 1 September 2007 all strengths of the Schedule 4 benzodiazepine alprazolam were added to the monitoring system for the purposes of Regulation 96.

### *The Drugs and Poisons Information System (DAPIS)*

The Drugs and Poisons Information System (DAPIS) is currently managed and operated by the Pharmaceutical Services Branch (PSB) of the Department of Health and Human Services (DHHS). The application is primarily used to monitor the usage of Schedule 8 medications across Tasmania. Dispensing data, sent in by pharmacies, is used to crosscheck prescribed medication against an authority which may be in place in accordance with the State legislation, and to monitor for opioid misuse in the interests of public health and clinical

<sup>513</sup> Submission of Mr Geoff Anderson, Manager and Chief Pharmacist, DDU/DASSA, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2007.

<sup>514</sup> Submission of Mr Geoff Anderson, Manager and Chief Pharmacist, DDU/DASSA, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2007.

<sup>515</sup> Mr Keith Evans, Chief Executive Officer, DASSA, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Adelaide, 18 May 2007.

support. The system was explained at length in a submission to the Committee from representatives of the PSB:

Each of the 142 pharmacies in Tasmania currently sends prescription data to PSB on a monthly basis via floppy disk. This information is imported into the DAPIS database by PSB staff where software algorithms are used to match the data with the prescriber issuing the prescription, the patient receiving the medication and the dispensing pharmacy.

Reports are generated from this data in order to identify (a) prescribers who have not obtained the required authority, (b) prescribers prescribing to a patient where another prescriber (practice) holds the authority, and (c) prescribers exceeding the authorised dose and/or drug. Even though prescribers are required by law to apply for an authority on their own initiative (as previously described), the reality is that most prescribers require reminders to be sent.

DAPIS is also used to authorise and monitor the prescribing of psychostimulant medication in Tasmania under the Tasmanian Psychostimulant Prescribing Guidelines.<sup>516</sup>

All applications by prescribers to prescribe controlled substances are reviewed initially by the PSB and then if necessary by specialist panels. The approval process is described as follows:

- Authorisations to prescribe as clinically necessary are routinely issued to doctors in relation to patients in nursing homes, those with either terminal conditions, or who are over 70 years of age.
- Patients who are under the care of an oncologist/palliative care specialist are not referred to an advisory panel but are given an authorisation for 12 months.<sup>517</sup>
- Uncomplicated authorities with specialist reports for long acting opioids at low doses are approved by PSB pharmacists.

An assessment of the other applications is made by Pharmaceutical Services Branch pharmacists and cases are referred to either:

- ii) Consultant Medical Officer (CMO) – Normally this involves the review of cases with the CMO. These cases are usually stable and reasonably routine.
- iii) Section 22 Expert Advisory Panel: – This panel comprises a pain specialist, an Alcohol and Drug Specialist and a GP nominated by the RACGP [Royal Australian College of General Practitioners].<sup>518</sup>

This process was elaborated on when the Committee spoke with Tasmanian Deputy Chief Pharmacist, Ms Mary Sharpe in June 2007:

Under our current poisons regulations we require pharmacies to report at the end of each month all narcotic drugs supplied in Tasmania. We also require doctors to get an authorisation from us if they wish to prescribe a narcotic for a patient for longer than two months. By using our monitoring system we can pick up where doctors do not have an authorisation. Doctors are not always efficient at getting the authorisations. We have to run a process of reminding them to get that authorisation. When that application comes in that can go through a series of different processes of approving. It is basically a three-tiered process where simple ones are approved in-house, minimal complex ones are approved with the use of a consulting medical officer, and then the more complex ones we take them to a

<sup>516</sup> Submission of Mr John Galloway, Chief Pharmacist and Ms Mary Sharpe, Deputy Chief Pharmacist, Pharmaceutical Services Branch (PSB), Department of Health and Human Services (DHHS) Tasmania, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

<sup>517</sup> An authorisation under S22 of the *Alcohol and Drug Dependency Act 1968* (ADDA) is not issued to a doctor to prescribe an opioid to a patient whose need is solely for addiction or dependence unless pharmacotherapy providers seek the authorisation as part of a pharmacotherapy programme. Opioid dependent patients need to be enrolled for treatment in the Tasmanian Opioid Pharmacotherapy Program, which is overseen by the Alcohol and Drug Services.

<sup>518</sup> Submission of Mr John Galloway, Chief Pharmacist and Ms Mary Sharpe, Deputy Chief Pharmacist, PSB/DHHS Tasmania, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.



panel of advisers, an expert panel of advisers, a pain physician, an alcohol and drug specialist and a GP who has been nominated by the Royal Australian College of General Practitioners. Some of those complex authorisations we issue to doctors with doping supervision to pick up conditions. Again, even with all that, we can still have a problem with doctors complying and getting the authorities in on time. Sometimes even then, they need to be massaged a fair bit to ensure that they are doing the right thing. It does give us an ability to monitor patients, even though it might be four to five weeks after the supply. There is an ability to monitor patients and hopefully keep a small control on the whole process. It does not allow for immediate real-time intervention as the information is received some time after the event.<sup>519</sup>

Whilst the Tasmanian monitoring system is not real-time, it is arguably a faster system, certainly compared to the national system. The Tasmanian Health Department currently has a submission before the Commonwealth's Health Connect program for funding to develop a secure real-time reporting system. The other major difference between monitoring systems in the larger states such as Victoria and New South Wales is that the latter states, according to the PSB, 'do not have a system that reports Schedule 8 substances at the point of dispensing and supply'.<sup>520</sup>

#### *What can be learnt from the Tasmanian system?*

Proponents of the Tasmanian system for monitoring the prescribing and dispensing of Schedule 8 and some Schedule 4 drugs, such as alprazolam, acknowledge it is not perfect. For example, in some cases data may not be matched to patients and prescribers until up to six weeks have elapsed from the time of dispensing. Nonetheless, there are definite positives in the Tasmanian system. For example, according to the PSB, the advantages of the Tasmanian system include:

- It gives the Department ability to assist prescribers in making better informed clinical decisions in relation to Schedule 8 prescribing.
- It provides information of the status of a patient that can assist the prescriber when confronted with a patient whose history cannot be fully evaluated. This interaction and decision making assistance relies on the contact being made by the prescriber with the Department. Future developments may allow for on-line prescriber verification of the authority status of a patient.
- ...it can be readily adapted to respond to emerging issues. An example of this is the [rescheduling] alprazolam changes.<sup>521</sup>

Any review of monitoring and permit systems that may take place in Victoria would do well to take into account current practice in Tasmania and South Australia. Another model that may contribute to improving monitoring systems in Victoria is that of Project Stop.

### **Project STOP**

Project STOP is a computer-based tool initially developed by the Queensland Branch of The Pharmacy Guild of Australia in consultation with the Queensland Police and the Queensland Department of Health. It uses a database to track pseudoephedrine sales in real-time. It records the details of people purchasing pseudoephedrine-based medicines, who have given their consent to this, and alerts police when a person has attempted to purchase such products from a number of different pharmacies in a given period of time. Currently it is limited in its application to pseudoephedrine, which is not a prescription

<sup>519</sup> Ms Mary Sharpe, Deputy Chief Pharmacist, PSB/DHHS, Tasmania, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 18 June 2007.

<sup>520</sup> Submission of Mr John Galloway, Chief Pharmacist and Ms Mary Sharpe, Deputy Chief Pharmacist, PSB/DHHS, Tasmania, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

<sup>521</sup> Submission of Mr John Galloway, Chief Pharmacist and Ms Mary Sharpe, Deputy Chief Pharmacist, PSB/DHHS, Tasmania, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

only medicine. This is a drug, however, that in recent times has become more closely monitored as a result of being used as a precursor for the manufacture of illicit amphetamines.

Project STOP commenced in November 2005 and was implemented in a state-wide pilot of Queensland pharmacies. It currently has an uptake of 85 per cent of Queensland pharmacies. A funding agreement with the Attorney General's Department has been reached for a national roll out of the system, with all States and Territories committing to the project. The national roll out of Project STOP commenced in April 2007.

The Pharmacy Guild of Australia has outlined some of the benefits of Project STOP:

Project STOP provides pharmacists with a decision support system to assist in making judgements regarding supply of products containing pseudoephedrine. It helps pharmacists make informed decisions and avoid value judgements based on purely superficial qualities, like physical appearance. At the same time, it allows pharmacies to record sales of pseudoephedrine products.

In addition to this, Project STOP also allows police and other authorities to track the movements of potential pseudoephedrine runners. Data from all participating pharmacies is collected centrally and this can then be monitored by law enforcement agencies and health regulators to look for inappropriate patterns of use. The collected data is graphically depicted using a Global Positioning System (GPS), which demonstrates where these activities are taking place. This system of tracking sales of pseudoephedrine in real-time is the first of its kind in the world.<sup>522</sup>

Despite the apparent benefits of Project STOP it has not to date been formally evaluated.<sup>523</sup> Nonetheless, it is the online real-time capabilities of Project STOP that make it a potentially attractive tool for adaptation to a wider array of prescription drugs. In many ways it is a similar operating system to PharmaNet in Canada, discussed in Chapter 4.1. However, Project STOP relies on the patient 'opting in', that is, giving his or her consent to being monitored by the system. In practice this means that if a potential consumer is not willing to have his or her identification details tracked and stored on the system that person may be refused service.<sup>524</sup>

The Committee was fortunate to be given a demonstration of Project STOP by one its designers, Mr Shaun Singleton of the Innovation and Development section of the Pharmacy Guild of Australia (Queensland) Branch.<sup>525</sup> The Committee asked Mr Singleton if there were any reasons why the technology of Project STOP could not be adapted and formulated for a wider range of prescription drugs. Mr Singleton indicated that there was no technical impediments to including drugs such as opioids and benzodiazepines in a model such as Project STOP, although it was possible issues pertaining to privacy, confidentiality and the relationship between prescriber, dispenser and patient would come under more scrutiny.<sup>526</sup>

522 <https://www.epotheary.com.au/eguuld/projectstop.aspx>

523 Personal communication from Mr Sean Singleton, Pharmacy Guild of Australia (Queensland), to the Drugs and Crime Prevention Committee Secretariat, 11 September 2007.

524 Although not on the basis that the person has refused to give an identifier to the dispensing pharmacist. According to the Pharmaceutical Guild of Australia the refusal would have to be based ostensibly on the fact that the provision of pseudoephedrine in these circumstances was not based on therapeutic need. (See evidence of Ms Jenny Bergin, Pharmacy Guild of Australia to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Canberra, 16 May 2007).

525 Mr Singleton has also developed a number of other web-based tools for the Pharmacy Guild of Australia. The most notable being [www.epotheary.com.au](http://www.epotheary.com.au) – a tool which, for the first time anywhere in the world, connects every pharmacy in a nation together via the Internet and delivers support services to them. In addition to this he has been overseeing the development of a single national database for the Pharmacy Guild of Australia, the backbone for which will be [www.epotheary.com.au](http://www.epotheary.com.au)

526 Comments made to the Drugs and Crime Prevention Committee during a demonstration of Project STOP for the Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Melbourne, 4 June 2007.



This was also the view of many other interested parties with whom the Committee consulted.<sup>527</sup>

## Conclusion

There are clearly a variety of approaches to address prescription drug abuse, fraud and diversion at international, national and state levels. These programmes however vary in their degrees of detail and technical sophistication. It is not simply a matter of extrapolating a model from another jurisdiction to the system that is already in existence in Victoria. Issues such as privacy and confidentiality considerations, ownership of monitoring data, the relationship between Commonwealth and state jurisdictions and the balance between establishing a system that is health oriented in focus compared to one that has law enforcement as its primary aim are only some of the matters that will need to be given serious consideration.

<sup>527</sup> See, for example, Evidence given to the Drugs and Crime Prevention Committee by Ms Khin Way and Ms Jenny Bergin, Pharmacy Guild of Australia (Canberra, 16 May 2007); Ms Kerry Deans and Dr Kay Sorimachi, Pharmaceutical Society of Australia (Canberra, 17 May 2007); and Mr Steve Marty, Pharmacy Board of Victoria (19 June 2006 and 26 June 2007).

## 4.4 An Electronic Real-Time Monitoring System for Victoria?

### Introduction

There are arguments for and against introducing an online/real-time centralised prescription drug monitoring system in Victoria. Whilst such a system may address problems associated with prescription drug diversion, doctor shopping and over-prescribing, issues such as confidentiality and cost must also be considered. Fortunately monitoring systems of this nature operating in other countries such as the United States and Canada can provide experiential data on this complex issue.

### **A new prescription drug monitoring system for Victoria: Issues for consideration**

As can be seen from the discussion in previous chapters, various models of prescription drug monitoring programmes (PDMPs) have been developed, particularly in North America. Whilst it is not the task of this Committee to develop or recommend a 'blueprint' for any new prescription drug monitoring system that may be introduced in this state, it does believe there are some important considerations that need to be taken into account in assessing the most suitable model that could be implemented. These are as follows:

- ◆ The relationship between the Commonwealth and Victoria with regard to any new monitoring system
- ◆ Confidentiality and privacy issues
- ◆ Who should be able to access the system?
- ◆ Who should have ownership of the data?
- ◆ What should be included in the system?
- ◆ Health versus law enforcement: What is the underlying purpose of the system?
- ◆ Provisions for education, training and evaluation with regard to the system.

Each of these issues will be dealt with in turn.

#### ***Commonwealth-State relations***

If Victoria was to have a centralised real-time database to monitor prescription drug use, clearly one issue that will need to be addressed is how such a system would interact with and relate to Commonwealth data systems run through Medicare Australia, such as the Prescription Shopping Program described in Chapter 4.2. Although to some extent parallel systems of drug monitoring already exist, for example the authorisation permit system under the Pharmaceutical Benefits Scheme (PBS) and the system of drug permits issued under the state *Drugs, Poisons and Controlled Substances Act 1981*, the legal and constitutional implications of a new centralised monitoring system for Victoria would need to be considered. For example, how would such a system be implemented and work in practice in border regions of the states such as Albury-Wodonga?



Whilst the Commonwealth would of course still be monitoring prescription drug use through its subsidy of the PBS, it begs the question as to whether two services established to 'interrogate' data on prescribing practices and 'doctor shopping' would be required. It may be that any Victorian system should be able to link into the electronic health infrastructure systems of the Commonwealth.

### *The privacy balancing act*

Clearly, in developing any system that seeks access to individuals' private records, particularly information as potentially sensitive as health data, safeguarding privacy and confidentiality will be a major consideration.

As drug and alcohol clinician Dr Alex Wodak explained to the Committee:

[E]lectronic surveillance. This is something that is still being discussed in the community and amongst the medical profession. Privacy is a significant issue, and how we can improve surveillance without too much impact on privacy I think is still something that needs a lot more discussion, and it is a highly specialised area. I do not know what the College of Physicians' policy would be on that, but I think most doctors would want to see the benefit but would not want to see privacy being threatened. Medical records are very sensitive, and we could all imagine how our community would feel if we thought that our own medical records would be available to the public. It is not in anybody's interest to threaten that privacy.<sup>528</sup>

On the other hand, some witnesses appearing before the Committee who have been at the forefront in calling for a centralised prescription monitoring database have indicated that whilst privacy is important it is not the only consideration that needs to be taken into account. For example, in relation to concerns that some people could view such a PDMP as a denial of privacy, State Coroner for Victoria Mr Graeme Johnstone responded:

The term I have used often is 'confidentiality kills', and...we have to balance the privacy/confidentiality issue very carefully. If we do not balance it carefully it ends up in needless deaths occurring. We see that in relation to the drug issue, that if you go too strictly down the privacy path, then you do have a risk that other people will be injured on the roads or the individual will be injured, where that individual might be able to be helped with a different management technique.<sup>529</sup>

In Victoria, depending on the context, privacy rights and information access are governed by the federal *Privacy Act 1988* and the state *Information Privacy Act 2000*, and in the specific context of health information the state *Health Records Act 2001* which applies to both the private and public sectors. In addition, the legislation needs to be read in conjunction with the 10 Victoria Health Privacy Principles. Clearly any new system would have to comply with the provisions, where applicable, of each of these Acts and principles unless enabling legislation specifically exempted the legislation from applying.<sup>530</sup>

Undoubtedly privacy and confidentiality issues are foremost in the minds of many people, even those who support the introduction of a PDMP. This is one of the reasons the Committee met with Ms Beth Wilson, the Health Services Commissioner and her staff to

528 Dr Alex Wodak, Director, Alcohol and Drug Service, St Vincent's Hospital, Darlinghurst, and Fellow of Chapter of Addiction Medicine, Royal Australasian College of Physicians, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 25 June 2007.

529 See Evidence of Mr Graeme Johnstone, State Coroner for Victoria, given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 20 August 2007.

530 Another factor that would need to be taken into consideration is what impact the possible introduction of a proposed federal *Access Card* would have on privacy protection in Victoria. Many questions remain unanswered as to how such a system might work, including who would have access to any information register containing personal information, including health information. At the time of writing such questions remain to a large extent unanswered. For a discussion of the possible pitfalls and privacy implications of introducing such a card, see the submission of Privacy Victoria to the Commonwealth Consumer and Privacy Taskforce Discussion Paper No 3, 2007, accessed at [www.privacy.gov.au](http://www.privacy.gov.au)

discuss the privacy aspects of introducing a system similar to PharmaNet in Victoria.<sup>531</sup> Ms Wilson believes that with the relevant legal and ethical safeguards put in place there is nothing to stop a PDMP being introduced in Victoria. Indeed Ms Wilson gave support for such a system being implemented in this state although with the expected caveats:

We do support the establishment of a real-time database such as that anticipated. We do have concerns that if it was only in Victoria we would certainly be running into border problems, particularly in places like Albury-Wodonga. Also, this is a national problem; there is no doubt about that. Having said that, most people who are taking prescription medication are not misusing it, and we do not want whatever solutions we come up with for the minority to be overly intrusive on people who are simply on medication because they need it for pain and other conditions, particularly people with cancer, for example.<sup>532</sup>

The Committee notes Ms Wilson's exhortation to give due consideration to the privacy implications of introducing a PDMP in Victoria. Perhaps one of the best safeguards for ensuring privacy rights is to suggest that, as in British Columbia, a person be given the opportunity to restrict access to their information. That is, the consent of the patient is required before access to the patient's prescription history can be authorised generally. The extent to which a patient could opt out would be a matter for ongoing consultation during the development phase of the system. For example, there could be different degrees of access to patient data. Depending on who had 'ownership' of the database, access could be restricted to prescribing doctors only or health bureaucrats responsible for interrogating such data. It is also suggested that in developing the system a set of minimum privacy standards similar to those proposed in the United States and discussed in Chapter 4.1 be considered.

Finally, it is the considered view of this Committee that each patient who is the subject of the system have a unique Patient Identifier Number or PIN similar to that used in British Columbia, as described in Chapter 4.1. Whilst it is true that under Medicare each patient does have a unique identifying number, currently this cannot be used for any purpose other than PBS/Medicare administration. As Mr John Galloway observed in the context of the Tasmanian monitoring system:

If this number could be used for all health related activities it would significantly assist jurisdictions to identify patients and eliminate even further potential 'double dipping'. Currently, there is no unique patient identifier used in Tasmania and this makes it very difficult to implement efficient automated reporting of problematic behaviour. The current system relies on manual matching dates of birth and addresses which can prove problematic at times (e.g. T Smith, Tom Smith, Thomas Smith, Tommy Smyth etc.).<sup>533</sup>

Similar comments were made by Mr Steve Marty, Registrar of the Pharmacy Board of Victoria:

The biggest problem is the lack of a unique patient identifier, as it is called. We have issued substantially more Medicare cards in Australia than there are Australians, so that is a bit of a problem when it is a primary identifier. I do not want to quantify it, but that is an issue. You can certainly have people who have the same number, or you get children of parents in a defacto relationship who get a card in dad's name and a card in mum's name, so it is hard

531 The Committee is appreciative of Ms Wilson and her staff for briefing the Committee on the privacy implications of introducing a prescription drug monitoring programme (PDMP) in Victoria.

532 Ms Beth Wilson, Health Services Commissioner Victoria, Evidence to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 9 July 2007.

533 Submission of Mr John Galloway, Chief Pharmacist and Ms Mary Sharpe, Deputy Chief Pharmacist, Pharmaceutical Services Branch, Department of Health and Human Services Tasmania, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.



when you bring them up on a system to know which number they are using today. It often depends on who is going to pay. So there is a need for a unique patient identifier.<sup>534</sup>

The Committee considers that, as in Canada, any patient with concerns about confidentiality should be able to attach a keyword or password to their file to further limit access. Once a keyword has been assigned to a patient file, pharmacists or other health professionals can only access that patient's records if the patient reveals the keyword. As in Canada, the patient should be able to change the keyword at any time. Patients should also be able to obtain a copy of their medication record, including a record of all those who have accessed their file.

#### *What information should be included in the system?*

It is not possible to be prescriptive with regard to the minutiae of what should be included in any system adopted, certainly not as far as the technical considerations are concerned. The major imperative of any new system in this Committee's view, however, is that as far as possible it allows the recording and retrieval of relevant prescription data in real-time, that is at the time of medical consultation and/or dispensing.

Whilst the provision of real-time data will undoubtedly assist in recognition of problems at an earlier stage, its introduction will not necessarily be without its problems, as a submission from the Tasmanian Pharmaceutical Services Branch indicates:

The provision of real-time data will generate new and higher responsibilities in relation to requirements for corrective action. The risk of not intervening when it could be said that the system would have given information to enable action to be taken to prevent an incident is something that needs to be considered, and new procedures put in place to identify these incidents/risks. The more information collected means the higher the level of responsible action required. Consequently, the purpose, objectives, principles and procedures of real-time reporting will need to be examined and considered very carefully.<sup>535</sup>

Nonetheless, drawing from PharmaNet and some of the PDMPs already established in the United States, it is possible to suggest some common sets of data elements that should be considered in any proposed system. These include:

- ◆ Dispenser or Prescriber Identification Number
- ◆ Prescription Number
- ◆ Date prescription issued
- ◆ Whether the prescription is original or a repeat
- ◆ Quantity of prescription dispensed
- ◆ Number of days supply of prescription drug dispensed
- ◆ Prescription pad or serial number if applicable
- ◆ Patient Identification Number
- ◆ Patient last and first names
- ◆ Patient address
- ◆ Patient postal code
- ◆ Patient date of birth
- ◆ Whether the patient is already listed as having an authority to be prescribed controlled substances
- ◆ Source of payment for prescription.

<sup>534</sup> Mr Steve Marty, Registrar, Pharmacy Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007.

<sup>535</sup> Submission of Mr John Galloway, Chief Pharmacist and Ms Mary Sharpe, Deputy Chief Pharmacist, Pharmaceutical Services Branch, Department of Health and Human Services Tasmania, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

The last point is particularly pertinent as it raises the issue as to whether the system should include private prescriptions and how this could be done.

Finally, one matter that will need considered attention is to which class of scheduled drugs any new PDMP should apply. As was discussed in Chapter 4.1 the evaluative literature in North America suggests the most effective systems are those that incorporate all or most scheduled drugs. Increasingly the American state systems are following this trend, with California one of the most recent to include benzodiazepines and other Schedule 4 drugs in its remit.<sup>536</sup>

As the discussion in Chapter 4.3 has indicated however, in Australia most state permit systems for controlled substances are limited to monitoring Schedule 8 or opioid drugs, although Tasmania as noted has extended their review system to include the Schedule 4 benzodiazepine alprazolam.

#### *Who should be able to access the system?*

One of the weaknesses of systems such as the federal Prescription Shopping Program is that currently pharmacists, an extremely significant group in addressing issues such as 'doctor shopping' and prescription drug fraud, do not have access to the Medicare database. One of the beneficial aspects of PharmaNet in British Columbia is that whilst it was initiated as a system for pharmacists only, increasingly the number of healthcare professionals who can access the system has been widened and now can include medical practitioners and, where appropriate, their staff. It is the view of the Committee that no real inroads can be made into reducing 'doctor shopping', prescription drug fraud or over-prescribing unless accredited medical practitioners and pharmacists, at the very least, can access the relevant database. Whether access should be extended to other health professionals such as nurses or dentists is in the view of the Committee a matter that should be considered further, during the development stage, in the light of experience in British Columbia and the United States.

It is also the view of the Committee that, as in Canada, appropriately accredited officials of the medical and pharmacy boards and the state health department should be able to access the database records for investigatory, statistical and research purposes. Such a facility would be particularly useful in identifying prescription drug misuse trends and potential problem areas or 'hot spots'. In the latter case it would not be necessary for such officials to have access to information that would identify a particular patient.

The Committee also believes that whoever ultimately has responsibility for developing a PDMP for Victoria must give considered thought to who has control or 'ownership' of the database, records and operating systems. In British Columbia this is the responsibility of the College of Pharmacy whereas in many American states control rests in the hands of state government agencies. Mr Steve Marty, Registrar of the Victorian Pharmacy Board, suggested that the responsibility for 'owning' the system should be shared among a number of key players:

I would set up an organisation that was multidisciplinary, with some statutory authority to deal with breaches, and make sure that the system was maintained. You cannot give it to a third-party funding organisation. I think it has to go to a body with some teeth that can take disciplinary sanctions against people for breaches of the system, failure to maintain, and if necessary they can also refer them to the appropriate registration authority...When a national registration system comes into COAG, there will still be bodies, even if they are state-based committees, that will be able to deal with the relevant health practitioner and their registration status for breaches of legislation.<sup>537</sup>

<sup>536</sup> See discussion in Chapter 4.1.

<sup>537</sup> Mr Steve Marty, Registrar, Pharmacy Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007.



### *Health or law enforcement?*

The various systems of prescription drug monitoring the Committee has examined, particularly in North America, seem to have their ethos or rationale in either a health or law enforcement model. Often such a bifurcation reflects the department or auspicing authority in which the programme is located. For example, the health focus of PharmaNet is partly explained by the control of the programme being in the hands of the British Columbia College of Pharmacy. Conversely, the fact CURES (Controlled Substances Utilisation Review and Evaluation System) is for the most part administered by the California Department of Justice agencies explains the priority that criminal investigation is given in that state. Of course in reality the situation is not so clear-cut. Both types of programme usually have provision for both therapeutic and investigative/punitive functions and roles.

Almost without exception the witnesses who gave evidence to the Inquiry about the efficacy of introducing a PDMP to Victoria indicated that the primary aim of such a system must ultimately be the patient's welfare and the safeguarding of public health. For example, Dr John Whitlam, Director of Medical Affairs for Mundipharma, said to the Committee that:

What we can sometimes overlook is that at the end of the manufacturer producing a product, a doctor writing a prescription, there is a patient there at the end. What we need to be mindful of is that if someone is going to all the trouble of prescription shopping they have a problem, and if they have a problem and even though we cannot pick it up immediately, if [a prescription drug monitoring programme] can pick it up and they can be directed to get some support and help, then in my view that is valuable. You may not immediately pick up a way of preventing diversion but at least you are helping some poor soul that has a problem with prescription medicines.<sup>538</sup>

The State Coroner Mr Graeme Johnstone made similar remarks when he met with the Committee in August 2007:

I think [prescription monitoring] is a health and harm minimisation issue because if you are treating it as a harm minimisation issue then you are going to be treating it as a harm minimisation issue not only for the individual who is taking the drugs but for the rest of the community. The more you encourage people to seek treatment, come into the process and not be penalised for it but helped through the process and supported through the process, the less harm will occur to outside people, to the individual, the man in the street. If you then push it down the law enforcement road then you are going to get this reluctance to seek treatment, reluctance to be involved. All it is going to do is hide it, I would have thought.<sup>539</sup>

The Victorian Alcohol and Drugs Association (VAADA) also recommended to the Committee that any system introduced to monitor prescription drugs in Victoria must take the following principles into account:

- All monitoring programs should focus on collecting information about prescribing practices, rather than on building dossiers on patients
- Monitoring programs should avoid making dispensers generally suspicious of patients seeking treatment by the use of benzodiazepines and other commonly misused pharmaceutical drugs
- All monitoring programs should avoid stigmatising patients whose treatment may include the use of benzodiazepines and other commonly misused pharmaceutical drugs

<sup>538</sup> Dr John Whitlam, Director of Medical Affairs, Mundipharma, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Pharmaceutical Company Forum, Parliament House, Melbourne, 16 July 2007.

<sup>539</sup> Mr Graeme Johnstone, State Coroner for Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Melbourne, Public Hearings, 20 August 2007.

- Monitoring the pressures on prescribers, including but not limited to standover tactics from 'doctor shopping' patients
- Monitoring the impact that promotions by pharmaceutical companies have on how prescribers prescribe drugs
- Patients must be informed that, by filling a prescription for monitored pharmaceutical drugs, they will enter a monitoring program
- Any prescription monitoring program must be subject to regular review
- Medical professionals prescribing monitored pharmaceuticals must have free access to relevant information from the monitoring program's database
- Over-prescribers identified by the monitoring program must be required to undertake training in proper prescription of commonly misused pharmaceutical drugs. If over-prescribing continues, these dispensers should be subject to a graduated scale of sanctions
- 'Doctor shopping' patients identified by the monitoring program must be provided with counselling or other support to help them change their behaviour. If doctor shopping continues, these patients should be subject to a graduated scale of sanctions.<sup>540</sup>

This Committee agrees that the main object of any new prescription monitoring system should be primarily therapeutic. If prescription monitoring data is used to identify doctor shoppers there should be, where applicable, some feature built into the system to provide that person with a range of treatment options. Only if it appears that the system is clearly being used for criminal or diversion purposes should other law enforcement options be considered. It is also essential that the system be established in such a way as to not disrupt or interfere with the therapeutic relationship between doctor or client, particularly in the case of legitimate pain patients. As was discussed in the American context in Chapter 4.1, doctors should feel that PDMPs are tools to assist them with their prescribing practices not cudgels to punish them with. The least wanted outcome of introducing such a programme for Victoria is that doctors may under-prescribe pain relieving medications for those patients who are truly in need of it. A key element of any PDMP should be providing healthcare professionals with information on addiction treatment options for patients identified as abusers or diverters. Another aspect of a health-oriented focus is that it in effect allows prescribers and dispensers to present a valid reason as to why they may not write or fill a prescription. In other words if the programme 'red flags' a patient by bringing to the doctor's attention that they have been receiving medication in excess of therapeutic need, they can legitimately inform the patient that the system will not allow them to prescribe any more drugs. This in turn would ideally give the prescriber an opportunity to consider other treatment options with the patient.

Finally, the evaluative research undertaken on PDMPs in America suggests that those states which use their programmes as tools to educate the public and health professionals such as doctors and pharmacy personnel about the extent of prescription drug diversion and abuse are more effective than those that do not (United States General Accounting Office (USGAO) 2002, 2003; Simione & Holland 2006).

Certainly a key aspect of the introduction of PharmaNet and its ongoing development in British Columbia has been the importance of training pharmacists in its applications and usage. This has particularly been the case in the technical aspects of the programmes, safeguarding patient privacy, and the importance of using PharmaNet for therapeutic purposes.<sup>541</sup>

540 Submission of Victorian Alcohol and Drugs Association to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

541 This was stressed to the Committee when it met with representatives of the British Columbia Pharmacy Association and the British Columbia College of Pharmacists in Vancouver, 24 July 2007.



The Committee agrees that any PDMP introduced into Victoria should have an inbuilt education and training component, allowing healthcare professionals to be confident in using and accessing the programme and to deal appropriately with any patients who may be identified as 'doctor shoppers'.

### **Evaluation**

One of the weaknesses of PharmaNet in Canada and most state PDMPs in the United States is that there have been no formal evaluations of their effectiveness. It is essential in the Committee's view that a properly designed evaluation of any such programme introduced into Victoria be a condition of its funding and establishment. Objective results from such an evaluation will greatly assist policymakers to justify the expenditure of these programmes, particularly if, as is hoped, their introduction leads to a reduction in 'doctor shopping' and prescription diversion.

## **Endorsements for a prescription drug monitoring system for Victoria**

As the discussion in this chapter suggests, there are clearly strong arguments in the literature and the experience of other jurisdictions to support the introduction of a PDMP for Victoria.

The Committee also sought the views of experts in the community as to the benefit or appropriateness of introducing a PDMP in this state. These opinions were usually expressed in meetings with the Committee, public hearings, Committee sponsored forums or interstate visits. The views were overwhelmingly in favour of introducing a PDMP, particularly one similar to the health-oriented focus of PharmaNet. In addition to this testimony, many people made unsolicited written submissions to the Committee endorsing or expressing support for a centralised monitoring system.

This section gives a selection of the views endorsing PDMPs. Whilst some submissions expressed reservations as to the way in which this type of programme might be introduced and the need for safeguards protecting privacy and confidentiality, no evidence was given in opposition per se to the implementation of such a project.

The State Coroner, Mr Graeme Johnstone has long been an advocate of a centralised real time prescription monitoring system:

What troubles me is that I have been making recommendations on doctor shopping for basically as long as I have been a coroner and what appears not to have happened is we are not at the moment using our technology – and I can understand there are reasons of privacy and confidentiality and other difficulties in relation to that – but the technology is certainly there to be able to identify where someone is either doctor or pharmacy shopping. There are some situations where that technology is used but it could be far more broadly used...Once a prescription is written out you should be able to use our technology on line and say, 'So-and-so has been to another doctor in this practice or another doctor in another practice yesterday or this morning.' [It should be as simple as] if I use my credit card in any bank it literally can tell what has happened a few minutes before.<sup>542</sup>

Mr Johnstone made the above comments when he gave evidence to the Committee in August 2007. He provided the Committee with numerous coronial investigation reports where people were found to have died through the ingestion of prescription drugs, often in combination with alcohol or illicit substances.<sup>543</sup>

<sup>542</sup> Mr Graeme Johnstone, State Coroner for Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 20 August 2007.

<sup>543</sup> See for example, *References to Doctor Shopping within Australian Coronial Findings*, Paper prepared for the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, by Mr Graeme Johnstone, State Coroner for Victoria, August 2007.

Indeed, Mr Johnstone has been expressing the need for a centralised database for prescription drug monitoring for many years. In 2000, for example, he made the following recommendation:

The Federal Health Department (with State and Territory Health Departments and representatives of the medical and pharmacy professions) develop, and implement as a matter of urgency, a computer aided system to begin to manage the problem of 'doctor' and 'pharmacy' shopping. The system would need to be readily available to all prescribing medical practitioners and/or dispensing pharmacies. It would also need to operate in real time.<sup>544</sup>

When the Committee met with Mr Johnstone he not only reiterated his support for such a system but also expressed his frustration that seven years after this recommendation and several others from both himself and other coroners nothing had been done to implement such a system.

Support for a PDMP was generally forthcoming from medical and health organisations that gave evidence to the Committee. For example, the Australian Medical Association (AMA (Vic)) and the various pharmacy organisations, which would all have members directly affected by the introduction of such a system, for the most part approved. Representatives of the AMA (Vic) stated that a system such as PharmaNet:

[w]ould be very useful. I think there are going to be some civil liberty issues but [if they could be resolved]...The thing is that the pharmacists are as little in contact with each other as the doctors are and there is no mechanism for information to flow except by the telephone call...Honestly, a system like that would be very valuable, certainly from the point of view of limiting the doctor shoppers, but not only that, being able to identify people who had a problem and being able to offer some sort of service to them.<sup>545</sup>

The AMA also expressed the view that such a system could also feasibly give doctors a let-out in a situation where they are confronted with potentially violent patients. In other words, a doctor could refuse to give an inappropriate prescription on the basis that the 'system' will not allow him or her to do so.

Similar views in support of a centralised system were expressed by a representative of the Medical Practitioners Board of Victoria (MPBV), the body responsible for registering and disciplining doctors in Victoria. When asked his views on the introduction of a centralised database, Dr Con Constantinou, Health Manager of the MPBV, stated:

From my perspective in the work I have done for the board I think it is the best idea possible. I do not think it is fair to expect an individual doctor to be the auditing point for what medications a person is receiving. There are too many ways of breaking around that. Patients are notoriously devious if they are seeking drugs, and some of them are excellent actors, therefore I do not think that is appropriate. As to how the profession feels about it, I can only say that the medical members of the board, whenever we have discussed it, are in favour of it...I cannot think of anything that would compare with such a system...I think it is a convenient way, and then either the doctor or the pharmacist can tap into that live electronic information and see just what the prescribing history is.<sup>546</sup>

When asked how privacy considerations may impact upon the introduction of such a system Dr Constantinou replied:

I know there have been attempts to create it over the last several years on the commonwealth basis. I do not know whether it is the privacy considerations that have meant

<sup>544</sup> Case Number: 19990281 Date of finding: 13th April 2000. Coroner: Graeme Johnstone.

<sup>545</sup> Dr Harry Hemley, Vice-President, Australian Medical Association (AMA) (Victoria), Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007.

<sup>546</sup> Dr Con Constantinou, Health Manager, Medical Practitioners Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 9 July 2007.



it has not proceeded, but sometimes you have to balance the priorities. Privacy is important, but the health and safety and life of patients is equally important at least.<sup>547</sup>

Professor Olaf Drummer of the Victorian Institute of Forensic Medicine also gave his support to introducing a PDMP in Victoria:

It would be nice – not just for benzos but for other drugs, too – if in the future we could have a system where a doctor, usually a GP, could withhold the prescription they have written without any prolonged process to delay the visit, to get an idea of whether that person is in some risk category.

Members of the pharmacy profession from whom the Committee took evidence were equally supportive of introducing a PharmaNet type database. The Committee received evidence by way of submission and/or testimony at public hearings from the three major pharmacy organisations in Victoria – Pharmacy Board, Pharmacy Guild and Pharmaceutical Association. A submission from the Pharmacy Board of Victoria was emphatic in its recommendation for a centralised online real-time database:

No centralised medication history is available outside of hospitals or within a clinic setting, ie. there are no linked databases of medication history. Abusers of prescription drugs usually do not give truthful histories and it is virtually impossible for the prescriber to know the true (medication) history of a patient without an independent real-time record...

The current permits system under the Drugs, Poisons and Controlled Substances Regulations has the potential to assist with coordination of treatment – but most applications relate to people who do not abuse. Therefore, the majority of red-tape (for medical practitioners and government) is an unnecessary burden. An online real-time system would make it easier to identify appropriate treatment at the time of initial consultation and make it less likely that people will commence, or if they have already begun to be successful, at drug-seeking.<sup>548</sup>

The Registrar of the Pharmacy Board, Mr Steve Marty, testified to the weaknesses of the current Commonwealth Prescription Shopping Service and the need for an improved centralised database when he gave evidence to the Committee in June 2007. Mr Marty believed in particular that such a system could be used not only to address 'doctor shopping' but also to reduce the number of medical misadventure casualties in Victoria each year:

We manage to have about 1500 Australians a year die from medication misadventure across the whole of the health professions, but any prescribers – and that is these days medical practitioners, dentists, podiatrists from 1 July are endorsed, optometrists, nurse practitioners – can all prescribe and yet they are doing so in the dark because people who are going to seek things become very adept at having convincing stories. Now either the medical practitioner has got to call them a liar or put them under some suspicion because they are very convincing. I did an inquest last December where the woman who was previously a nurse obtained, off the top of my memory, 177 prescription items over 12 months from 24 different doctors supplied from 17 different pharmacies, and none of them would have been aware of the other supplies because the only database is at the commonwealth level, and it may be six weeks behind, and then they will not provide the information to the state authorities allegedly under privacy issues...I had to threaten an application of the coroner's certificate, which the coroner told me he could easily supply, to get the information. That is crazy; they are working in the dark. [Medicare Australia's system]...is looking at saving the commonwealth money. I am more concerned about saving lives and reducing hospital admission adverse effects.<sup>549</sup>

547 Dr Con Constantinou, Health Manager, Medical Practitioners Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 9 July 2007.

548 Submission of Pharmacy Board of Victoria to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

549 Mr Steve Marty, Registrar, Pharmacy Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007.

The Chief Pharmacist of Tasmania, Mr John Galloway, has also testified approvingly to the benefits of PharmaNet and its application to Australian circumstances. In a submission to this Inquiry he stated that the perceived benefits of the system are that:

- It provides an effective clinical management of patients in that a patient's complete medication history is available to the dispensing pharmacists.
- Information of the level of subsidy available to the patient is also readily available.
- There is an ability to monitor patients who may be going to a number of prescribers or receiving their medication too frequently.<sup>550</sup>

However, Mr Galloway also warned the Committee that:

- Patients can opt out of the system or have sections of their history hidden.
- Patients seeking to obtain excessive amounts of medication may tend to opt out of a system.
- The problem with illicit use of Schedule 8's and benzodiazepines at least in Tasmania (and possibly elsewhere) is the illicit use of legally prescribed medications where the prescribing is based on a clinical decision by the medical practitioner. This occurs after the prescription is supplied and the validation by the PharmaNet type of system.<sup>551</sup>

It is not only the pharmacy organisations and regulatory bodies that approve the introduction of a PDMP. Support has also come from individual pharmacists with whom the Committee has met. For example, Ms Toni Riley, a pharmacist with a number of pharmacies in Bendigo, stated to the Committee that such a system should be able to link medical and prescription histories together for the betterment of the patient. This reflects the ethos underlying PharmaNet that whilst addressing prescription drug diversion and fraud is clearly an important object of such a programme it is by no means the only reason this system should be introduced. Experience in British Columbia has shown that one of the key values of prescription monitoring systems is the health benefits that can result for the general community, particularly through preventing and reducing medical misadventure.<sup>552</sup>

Ms Riley also stated that currently patients are able to spin misinformation to medical practitioners and pharmacists in order to access prescription drugs:

Representatives of pharmaceutical companies with whom the Committee met have also been supportive of a system such as PharmaNet or even an adaptation of Project STOP.

It is understood that in British Columbia, Canada, online real-time medication history is available to prescribers and pharmacists at the time of prescribing or dispensing through a system called Pharmanet. Implementation of a similar system in Australia would enable a complete medication history to be captured for patients suspected of doctor shopping, and enable an informed decision to be made about appropriateness and safety of prescribing these drugs. Mundipharma would support a thorough evaluation of the Canadian Pharmanet system, with a view to its potential application and implementation in Australia.

We would also draw the Committee's attention to the 2nd April 2007 announcement by The Pharmacy Guild of Australia's president concerning the national roll-out of Project STOP. Project STOP is a '...nationally linked online database that records sales of pseudoephedrine products through pharmacies and allows tracking, identification and blocking of pseudoephedrine "runners"'. It is reported that both the Pharmacy Guild's Project STOP and PSA's pseudoephedrine diversion training project were sponsored by the Federal Attorney General's Department.

550 Submission of Mr John Galloway, Chief Pharmacist and Ms Mary Sharpe, Deputy Chief Pharmacist, Pharmaceutical Services Branch, Department of Health and Human Services Tasmania, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

551 Submission of Mr John Galloway, Chief Pharmacist and Ms Mary Sharpe, Deputy Chief Pharmacist, Pharmaceutical Services Branch, Department of Health and Human Services Tasmania, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

552 For example through listing allergies, contra indications and medical histories of individual patients.



Pharmacists are in a unique position to generate real time information about patients procuring large quantities of opioids either for their own use or for on-selling to the illicit market. Most importantly, such a system at the point of dispensing would also capture information on private as well as PBS prescriptions. Private prescriptions may be an important source of diverted and abused opioid but at this time, this is unknown. We are not aware that at this time, private prescription for Controlled Drugs are monitored. Should it be determined that extension of Project STOP to opioid analgesics is feasible and practical, the primary outcomes we would hope to achieve are to:

- Promote the Quality Use of Medicines, in this case opioids, throughout Australia
- Potentially, identify patients with dependency problem so that they can be encouraged to seek appropriate help
- Potentially identify instances of procurement of opioids solely for personal misuse or diversion to illicit market (criminal activity) for referral to the appropriate agency.<sup>553</sup>

Finally, it is pertinent to close this section with the observations of one couple whose son tragically has been physically and psychologically damaged as a result of prescription drug abuse.<sup>554</sup>

When the Committee met with Mr and Mrs Brown in a central Victorian provincial town they expressed both their despair and frustration as to how 'the system' so easily enabled their son to access time and time again a deadly cocktail of prescription drugs without any scrutiny or checks being put on his 'doctor shopping' practices.<sup>555</sup> They told the Committee they were in favour of any regulatory process that would prevent similar deaths, casualties or harms occurring in the future:

Perhaps the government could introduce a system whereby doctors and chemists could be alerted to an emerging pattern of overuse or addiction. If, for example, a patient on benzos or analgesic opiates were to be issued with a prescription card, like our credit cards, which needed to be scanned through a database on presentation of a script, then and only then would doctors and chemists be alerted to the pattern of drug abuse and perhaps knowing what stage the patient was at with regard to the practice of doctor-shopping and it could be somewhat controlled.<sup>556</sup>

553 Submission of Mundipharma to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

554 In addition to the testimonies quoted in this section, support for a centralised system similar to the health-oriented focus of PharmaNet has also been expressed to the Committee by the following people:

Professor Jason White, Head of the Department of Pharmacology, University of Adelaide, 16 May 2007.

Dr Mike Moynihan, President, Rural Doctors Society of Victoria, 18 June 2007.

Mr John Galloway, Chief Pharmacist, Pharmaceutical Services Branch, Department of Health, Tasmania, 18 June 2007.

Mr Geoff Soma, Director, Western Region Alcohol and Drug Centre, Warrnambool, 29 May 2007.

Dr David Richards, Addiction Medicine Physician, Western Region Alcohol and Drug Centre, Warrnambool, 29 May 2007.

Dr Benny Monheit, Drug and Alcohol Clinician, Alfred Hospital, Submission to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

These people and others, whilst generally supporting the need for a PDMP or centralised monitoring system, all to various degrees warned of the need to take into account privacy and civil liberties issues and not to use the system in punitive ways; in other words as discussed throughout the chapter the emphasis should be on protecting public health.

555 The names of the witnesses and the location have been changed to protect their privacy.

556 Mr and Mrs Brown, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Victoria 30 May 2007. The names of the witnesses have been changed to protect their privacy.

## Conclusion

The Committee is strongly of the view that an electronic real time presumption recording service should be introduced in Victoria. Whilst the cost as indicated in Chapter 4.3 may be considerable in a state with the population base of Victoria, it is hoped that a well designed programme would ultimately save money in terms of the costs associated with healthcare, treatment and crime prevention. There are some caveats that the Committee would place on the introduction of a PDMP in this state:

First, the ethos of the system should, as discussed throughout this chapter, be primarily one that puts the health of the patient first and foremost. It is the view of the Committee that any new system must primarily have public health as its focus, as in British Columbia, rather than being a law enforcement tool.

Second, partly in an attempt to reduce costs the system should be able to link into the electronic health infrastructure systems of the Commonwealth 'with the potential for common monitoring across jurisdictions with access to interstate data'.<sup>557</sup> Possibilities of co-funding from the Commonwealth should be looked into.

Third, a full review of privacy provisions as they may apply to the establishment of such a system should be undertaken.

557 Submission of Mr John Galloway, Chief Pharmacist and Ms Mary Sharpe, Deputy Chief Pharmacist, Pharmaceutical Services Branch, Department of Health and Human Services Tasmania, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.





## Section Five: Prescribing Practices for Benzodizepines and Opioid Narcotics

### 5.1 Examining Prescribing Practices – Standards, Concerns and Review

#### Introduction

Prescription regimes are the major control structure through which controlled psychoactive substances are made available for consumption in the modern world. The prescription is a written or otherwise recorded instruction from a licensed physician or other authorised health worker, which is filled by a licensed pharmacist or equivalent. The instruction specifies the composition (nowadays mostly in terms of a named substance, compound or trademarked name) of the substance to be provided to a named recipient, the dose size and number of doses to be provided, and the number of times (if any) that the prescription can be refilled. The prescription should have a medical purpose, that is, the prescription should be provided for the purpose of alleviating or curing illness or physical or mental discomfort, or to prevent their occurrence. Whilst prescriptions can be provided under other circumstances, [in most cases]...the physician's script is mandatory, that is...the pharmacist is not allowed to dispense the substance and the customer/patient is not supposed to obtain it unless a physician has prescribed it.

This basic triangle of the physician, the pharmacist and the customer/patient presumes a number of other prior actions, and may be surrounded with a variety of further complications, varying often with the particular substance to be prescribed. The pharmacist or the physician or both may be required to establish the customer's identity, and to keep a record of the transaction, and to transmit this record immediately or periodically to a central authority. There may be a requirement that the customer be known to one or both, or that the customer's identity be established. There may be a requirement that the prescription be written on a special form, for instance a triplicate form from a sequentially numbered pad of forms. There may be a prohibition on refills. There may be requirements on the labelling of the container for the prescribed substance. Generally, in any prescription system these further complications are at their most developed for the internationally controlled substances (Room 2007, p.1).

It is evident that the professional practices of those given authority to prescribe drugs and medicines, such as medical practitioners and dentists, are key factors that can have influence on prescription drug misuse. The role of pharmacists is also crucial in this regard.



Regulatory, government and professional organisations and agencies also play an important part in supervising or overseeing the prescribing and dispensation of medicines and drugs. For example, the Department of Human Services (DHS) provides direction and advice to professional boards and individual practitioners on the requirements of good prescribing practice. The police are also involved in detecting and responding to prescription forgery or monitoring the way in which the hazardous use of drugs may impair driving skills.

However, evidence presented to the Inquiry suggests there are problems associated with the prescribing of some medications, which may result in drug dependency or diversion.

### The 'stewardship' of quality use of medicines

The procedures for best practice prescription and dispensation of medicines that are adopted by medical practitioners and pharmacists are governed by a variety of bodies, policies, regulations and guidelines. These bodies and policies include those summarised in the following table:

**Table 5.1a: Key organisations, schemes and policies governing access to pharmaceuticals**

Medicare Australia	Formerly referred to as the Health Insurance Commission (HIC). Medicare Australia is located in the Australian Government Department of Health and Ageing (DoHA). Medicare Australia is responsible for, among other things, Quality Use of Medicines (QUM), the Professional Services Review Scheme (PSR) and the Pharmaceutical Benefits Scheme (PBS).
The Department of Veterans Affairs (DVA)	The DVA has responsibilities related to the services (medical and pharmaceutical) provided to Veterans.
The Australian National Medicines Policy	This Policy guides the strategies to ensure access to safe and effective medications and prescribing and dispensing of these medications.
The Quality Use of Medicines (QUM)	QUM is a central component of the Australian National Medicines Policy. QUM identifies strategies and responsibilities to ensure safe and judicious use of medicines.
The Professional Services Review Scheme	The Australian Government facilitates compliance with the National Medicines Policy and the QUM. The PSR can involve scrutiny of a health care professional's practice and can implement restrictions if problems are identified.
The Pharmaceutical Benefits Scheme	The PBS is a central component of the Australian Government's management of prescribed medicines, governing access to and affordability of medicines. Specified medications are subsidised under the scheme. <sup>558</sup>

Some organisations and bodies that have a significant bearing on prescribing practices such as Medicare Australia and the Pharmaceutical Benefits Scheme (PBS) have already been discussed in the context of prescription drug monitoring in Section Four. It is not necessary therefore to repeat that discussion here. The rest of this section examines federal programmes that have a direct bearing on prescribing practices, most notably the Quality Use of Medicines programme (QUM) and the Professional Services Review Scheme.

<sup>558</sup> See also the role of the Therapeutic Goods Administration (TGA) and its various committees, as discussed in Chapter 3.1.

### **Quality Use of Medicines (QUM)**

In Australia, QUM is a cornerstone of safe and effective prescribing and is a critical component of the Australian National Medicines Policy. This includes core statements that medicines should be used:

- Judiciously – medicines, whether prescribed, recommended, and/or self-selected should be used only when appropriate, with non-medicinal alternatives considered as needed;
- Appropriately – choosing the most appropriate medicine, taking into account factors such as the clinical condition being treated, the potential risks and benefits of treatment, dosage, length of treatment, and cost;
- Safely – misuse, including overuse and underuse, should be minimised; and
- Efficaciously – the medicines must achieve the goals of therapy by delivering beneficial changes in actual health outcomes (Department of Health and Ageing (DoHA) 2000, p.3).

QUM involves a range of strategies related to policy development, education and training and strategic research, and emphasises the importance of routine data collection. However, as one pharmaceutical company representative stated to the Committee, in one sense the term 'Quality Use of Medicines' can be something of a misnomer as a crucial aspect of prescribing practice is 'knowing when not to use a medicine', particularly in an area such as pain management.<sup>559</sup>

The Australian QUM identifies the role of a number of people, including medical staff, pharmacists, other health staff, consumers, the media and the broad community. The National Strategy for Quality Use of Medicines describes specific responsibilities and roles for each group, and overall responsibilities which have been described in the following way:

All partners are responsible for:

- Improving medication use by recognising when and where problems exist, identifying factors that contribute to those problems, initiating interventions to improve medication use, and evaluating outcomes;
- Enhancing understanding of the risk and benefits associated with the use of all medicines (DoHA 2004, p.10).

Whilst the QUM is aimed at safe and effective use of all medicines, the aims are particularly relevant for drugs being considered as part of this Inquiry. As noted by Carr, this presents a practical clinical challenge, a theme that consistently emerges in international and national literature on this issue:

The aim is to try and prevent the prescription of drugs that are going to be abused rather than used in a controlled and reasonable way. Thus the aim is not to deny nitrazepam or temazepam to the regular patient who is known to be using one or two tablets a day (though there may be other appropriate management strategies here). The aim is the prevention of 'doctor shopping', the acquisition of multiple prescriptions and abuse of 20, 30 or more tablets a day (Carr 2000, p.2).

Adherence to the QUM is likely to reduce the risk of pharmaceutical misuse and reduce any unintentional impact on patients who may benefit from these medicines.

### **Professional Services Review Scheme**

The QUM also needs to be considered in relation to the Australian Government's Professional Services Review Scheme. This project aims to:

<sup>559</sup> Dr Greg Pearce, Medical Advisor, Alphapharm, in conversation with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Pharmaceutical Forum, Melbourne, 16 July 2007.



- protect the integrity of the Commonwealth Medicare Benefits and Pharmaceutical Benefits programs and in doing so:
- protects patients and the community from the risks associated with inappropriate practice; and
- protects the Commonwealth from having to meet the cost of services provided as a result of inappropriate practice (Medicare Australia 2005, p.1).

The Professional Services Review Scheme can examine the behaviour and procedures of individual practitioners who have been identified as potentially engaging in procedures that are not consistent with QUM. The Professional Services Review Scheme involves a process of peer review of practitioners as described in the following quote:

Medicare Australia, whose role and function is to administer the MBS (Medicare Benefits Scheme) and PBS, may request the Director of PSR [Professional Services Review] to review the provision of services by practitioners who are suspected of engaging in inappropriate practice.

Medicare Australia identifies practitioners whose MBS or PBS data indicates that their rendering, initiating or prescribing practice profiles appear different when compared with their peers. A Medicare Australia Case Management Committee (CMC) in each state regularly reviews these profiles and will decide if there is sufficient concern to commence Medicare Australia's practice profile review process (Medicare Australia 2005, p.1).

The review process consists of two stages. The first stage involves gathering information to ascertain how a medical practice operates. This stage also provides a practitioner who is under review an opportunity to respond to any concerns. If the response to these is adequate, the process can end at this point. The second stage involves an interview with the practitioner, resulting in a written report. Again the practitioner has the opportunity to respond in writing and if the concerns are dealt with, the process ends. However, the process may also result in a review of the practitioner's right to engage in certain practices or services, such as changing his or her prescribing authorities.

The above process relates to quality clinical practice. Of course occasionally clinicians may deliberately engage in fraud and under the *Medicare Australia Act 1973*, Medicare Australia can, alone and in conjunction with other agencies (for example, the police), investigate fraud by professionals and by members of the public.

In concert with other procedures to ensure adherence to the QUM, it is evident that these processes rely on quality information systems, both to alert the Professional Services Review Scheme to potentially risky practices and to inform judgements about the nature of individual practices and procedures.

### ***Implementing stewardship policies at a state level***

Translation of the relevant policies and procedures is overseen and/or facilitated by professional bodies at state level. Such bodies include the Pharmacy Board of Victoria, the Nurses Board of Victoria and the Medical Practitioners Board of Victoria. These Boards have developed standards of practice and procedures that include recommendations on the parameters within which certain drugs should be prescribed and dispensed. These aim to complement, and ensure application of, national and state policies and statutory requirements. The respective roles of these boards will be discussed at greater length later in this chapter. Other groups (for example, the Royal Australian College of General Practitioners (RACGP) and the Pharmaceutical Society of Australia (PSA)) have developed practice guidelines, learning objectives and training courses and resources that assist in the development of good prescribing and dispensing practices by the relevant professionals. A common theme communicated by these professional bodies is that they are stewards or custodians of drugs and poisons. For example, the PSA (Victorian Branch) has summarised this as follows:

In addition to contributing to the quality use of medicines, pharmacists have a major responsibility to be custodians of drugs, poisons and controlled substances for the community. They are expected to act honourably and carefully at all times to ensure that...(these substances)...are kept secure from unauthorised access and that they are supplied only to people who are lawfully entitled to receive them.

A difficult practical problem that regularly confronts all pharmacists from time to time is their responsibility for being vigilant for the possibility of forgery, employed as a means of obtaining drugs for illicit purposes (Lloyd, Guibert & Bell 2000, p.v).

Similarly, the Australian Medical Association's (AMA) submission to the Inquiry noted that:

In the most fundamental terms the most important principle underpinning medical practice is the ancient dictum, *primum non nocere*, first do no harm, whether this be by omission or commission...our primary concern is that we do not cause harm because of poor prescribing related to known patient allergies, predictable drug interactions, or likely side-effects given the expected disposition of the patient to such an outcome.

Medical practitioners also have real concerns about prescribing to patients, where it subsequently transpires there is no valid clinical reason to do so and the related problem of diversion of the prescriptions to non-medical uses...<sup>560</sup>

The AMA also noted the challenge in this latter task:

At a practical day-to-day level individual doctors face much more complex decisions about the treatment of some patients. A proportion of patients are deliberately, and often with considerable expertise, deceptively misrepresenting illnesses to doctors so as to access certain prescription pharmaceuticals such as opioid analgesics or benzodiazepines.<sup>561</sup>

The specific functions, duties and roles of these bodies with regard to the oversight of prescribing and dispensing practice will be discussed in greater detail later in this chapter.

### ***Drugs, Poisons and Controlled Substances Act and regulations***

Chapter 4.3 outlined the regulatory framework for drug control in Victoria and provided the legal context for prescribing and dispensing pharmaceutical medicines at state level. The following section examines the roles of medical practitioners and pharmacists in complying with these rules and regulations. In so doing, it is pertinent to revisit some of the key aspects of the *Drugs, Poisons and Controlled Substances Act 1981* and Regulations 2006 that have particular relevance to prescribing medicines, including those being considered in this Inquiry.

Access to, and advice about, drugs and poisons is determined by their classification or Schedule (as indicated in Chapter 4.3, there are nine Schedules of drugs and poisons) and whether or not they are considered to be 'drugs of dependence' by the relevant state/territory authorities. A person may become dependent due to non-medical use of drugs, including legal drugs (for example, alcohol) and illegal drugs (for example, heroin). A patient may also become dependent on drugs that have been prescribed for legitimate purposes (for example, pain management). Whilst there is some variance in the laws from jurisdiction to jurisdiction, it is not lawful to prescribe a drug simply to maintain a patient's dependence on a drug, except where special permission has been granted to an authorised medical officer (for example, those who prescribe methadone or buprenorphine for the purpose of pharmacological management of opioid dependence) for a specific patient.<sup>562</sup> This is to ensure coordinated treatment of the patient and to reduce the risk of 'doctor shopping' or over-prescription and diversion.

<sup>560</sup> Submission of the Australian Medical Association (AMA) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

<sup>561</sup> Submission of the AMA to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

<sup>562</sup> See Section 35, *Drugs, Poisons and Controlled Substances Act 1981*.



### Prescribing Schedule 4 (S4) and Schedule 8 (S8) drugs

There are limitations on the duration that Schedule 8 drugs can be prescribed without an authorisation – usually for no more than two months.<sup>563</sup> There are also usually limitations on the geographical origin of prescriptions. For example, in Victoria a pharmacist cannot supply a Schedule 8 drug on a prescription written by a practitioner who is not registered in Victoria.<sup>564</sup> There are also guidelines on how prescriptions are written – to avoid intentional or unintentional errors. For example, prescriptions must state amounts (that is, number of tablets or doses and dosage) in words and figures to reduce the chances of fraud, and the prescriber should not leave a space between the end of the prescription and the doctor's signature to avoid fraudulent additional entries (Bird 2006).<sup>565</sup> The practices expected of prescribers and pharmacists in relation to these drugs are clearly communicated. For example, the Guide to the Drugs Poisons and Controlled Substances (DPCS) Regulations 2006 provided by DHS Victoria states that prescribers and pharmacists should ensure that:

- Reasonable steps are taken to ascertain the identity of a patient; and
- Appropriate authorisations have been attached (for example, imprint of pharmacy stamp, completed PBS Repeat Authorisation) (DHS Victoria 2006a, p.2).

The Department of Human Services also develops and disseminates educational material for various groups of health professionals to clarify legislative responsibilities and to highlight the importance of complying with those legislative responsibilities.<sup>566</sup> For example, in relation to broader uses of these drugs, DHS Victoria has produced the following guidance:

Schedule 8 poisons (labelled Controlled Drug) are drugs with more strict legislative controls, eg. Morphine (Kapanol, MS-Contin), pethidine, oxycodone (Oxycontin, Endone), methadone (Physeptone), hydromorphone (Dilaudid), flunitrazepam (Hypnodorm), fentanyl (Durogesic). A permit might be required before prescribing Schedule 8 poisons...

Schedule 4 poisons (labelled Prescription Only Medicine) include all other drugs for which prescriptions are required, eg. Diuretics, oral contraceptives, antibiotics, some compound analgesics (Panadeine Forte) & many others.

The term 'drugs of dependence' is used to describe all S8 poisons plus those S4 poisons that are subject to misuse and trafficking....Doctors should take additional precautions before prescribing Schedule 4 drugs of dependence (DHS Victoria 2006b, p.1).

and

Before prescribing a drug of dependence, a prescriber must take all reasonable steps to ensure a therapeutic need exists and to ascertain the identity of a patient (DHS Victoria 2006b, p.2).

Statutory bodies in the various jurisdictions have requirements regarding notification of dependent patients. For example, in Victoria:

Where there is reason to believe a person is a drug-dependent person, a medical practitioner must notify the Department of Human Service (DHS) Drugs and Poisons Regulation Group (DPRG) in the prescribed form (DHS Victoria 2006c, p.1).

The Department of Human Services Drugs Policy and Services Branch have also communicated to the Committee that they take a pro active role with regard to prescription drug monitoring. In correspondence to the Committee the Department states:

<sup>563</sup> See generally Division 10 of the Drugs, Poisons and Controlled Substances Act 1981.

<sup>564</sup> See Regulations 15–17, Drugs, Poisons and Controlled Substances Regulations 2006.

<sup>565</sup> See generally Drugs, Poisons and Controlled Substances Regulations 2006.

<sup>566</sup> Correspondence from the Mental Health Division, Department of Human Services (Victoria) to the Drugs and Crime Prevention Committee, 13 November 2007.

Prescription-monitoring activities (ie, monitoring of the dispensing records in pharmacies) are carried out by DHS officers in order to identify medical practitioners who might be prescribing excessively or inappropriately as well as members of the public who are obtaining such drugs excessively. This activity typically leads to one or more of the following courses of action:

- Intervention to prevent a continuation of unlawful or inappropriate prescribing.
- Identification of inadequacies or competence issues among health professionals that might need to be referred to the relevant registration board.
- Preparation of prosecution briefs to enable DHS to initiate action against health professionals when contraventions are considered to be serious.
- Provision of evidence and advice to Victoria Police to enable that organisation to take action against offenders.

DHS [also] periodically requires licence holders (ie, wholesalers) and other authorised persons (eg, pharmacists) to provide records of transactions relating to selected drugs and/or selected types of client in order to identify atypical or excessive use of those drugs. Pharmacists and licence holders are also required to report excessive or atypical patterns of supply in individual cases.

These reviews enable DHS to direct its prescription-monitoring activities more efficiently.<sup>567</sup>

State and Territory governments therefore set policies and procedures for prescribing S8 drugs to include a clear focus on the need to adopt strategies to avoid/reduce misuse and diversion. One particular example of such a policy is the Victorian 'Policy for Maintenance Pharmacotherapy for Opioid Dependence' (DHS Victoria 2006d). This document states that various factors related to illegal drug use:

...can create a risk of diversion of prescribed doses for illicit or unsanctioned use (DHS Victoria 2006d, p.6).

Only authorised practitioners can prescribe for these purposes to specifically identified patients. The policy describes the necessary expertise and assessment processes for a medical practitioner to be authorised to prescribe methadone and buprenorphine and identifies the treatment procedures and context for safe practice (for example, maximum number of patients). The policy alerts practitioners to the risks of these drugs if not used in a manner consistent with the policy and other guidelines.

The policy also suggests preventive countermeasures such as:

- advise the patient of the considerable risks of misuse of psychoactive drugs (such as the benzodiazepines) and alcohol while on pharmacotherapy
- ask the patient to sign a Medicare Australia privacy release form to enable access to information about the provision of Pharmaceutical Benefits Scheme drugs from other doctors and pharmacists
- conduct a drug screen of supervised urine collections (DHS Victoria 2006d, p.12).

Specifically in relation to diversion and misuse, the policy emphasises a range of required and advised strategies, including dose dilution for methadone, supervised dosing for methadone and buprenorphine and the potential benefits of prescribing the recently available combination product of buprenorphine/naloxone.<sup>568</sup>

As discussed below, other national and state statutory bodies and professional organisations communicate similar advice. However, as indicated earlier in this chapter, implementation of such advice may be more challenging.

<sup>567</sup> Correspondence from the Mental Health Division, Department of Human Services (Victoria) to the Drugs and Crime Prevention Committee, 13 November 2007.

<sup>568</sup> If taken by a dependent opioid user, this latter product will result in withdrawal symptoms if diverted and injected, but not if taken orally as indicated. See Chapters 2 and 7.



## Professional practice, standards and accountability

In addition to the various processes available to the Australian and state/territory governments, national and state professional bodies have a significant role in ensuring safe and effective use of all medicines in general and specifically those that are the concern of this Inquiry. Three Victorian Boards are used to illustrate these roles:

The Pharmacy Board of Victoria;

The Medical Practitioners Board of Victoria; and

The Nurses Board of Victoria.

### *The Pharmacy Board of Victoria*

The Pharmacy Board of Victoria is established and appointed under the *Pharmacy Practice Act 2004*. It consults with and responds to the advice of the Minister for Health. The Board aims to promote safe dispensing and use of medicines, and minimise the community's exposure to health risks associated with the provision of pharmacy services. The Board has determined minimum standards of good practice, and monitors and administers duties and responsibilities under the relevant Acts and regulations. Recently it has developed the *Guidelines for Good Pharmaceutical Practice* (Pharmacy Board of Victoria 2004). These guidelines cover registration, training, responsibilities and management of drugs that are subject to misuse. For example, there are requirements to report prescribing of excessive quantities of S4 and S8 drugs to the DHS.

The Board has procedures and resources that are directed to ensure safe and effective dispensing. For example, the Board will conduct a thorough review of pharmacists who are identified as behaving outside of legislative and professional guidelines – in short, engaging in risky practices (Pharmacy Board of Victoria 2004). The Board also liaises with the Medical Practitioners Board of Victoria to ensure that pharmacists are informed about medical practitioners who have had prescribing limitations imposed. Other relevant activities include developing standardised procedures for reporting suspicious purchases of medicine (for example, pseudoephedrine which may be diverted for use in the manufacture of illegal amphetamines) and producing newsletters that advise on quality practices, including those that aim to reduce forgery and misuse of medicines.

### *Medical Practitioners Board of Victoria*

The Australian Medical Council and state medical boards have oversight of medical standards and registration of practitioners. The Council is an independent national standards body that accredits education and training programmes. Each jurisdiction has a Medical Board, which is responsible for medical registration. The Boards aim to ensure that only properly trained and skilled doctors are registered and that registered doctors perform within expected standards of conduct and competence. The Boards respond to complaints about individual practitioners and, under the relevant legislation, they can investigate and, where indicated, discipline medical practitioners, including limiting their rights to practise (Medical Practitioners Board of Victoria website).

In this context, the Medical Practitioners Board of Victoria is an independent statutory authority that has responsibility for professional standards, using non-disciplinary and disciplinary methods to work with medical practitioners who are not performing to established standards and expectations. One issue that may be a concern is that medical practitioners may be at an increased risk of prescribing for their own use.<sup>569</sup> The guidance on this is unambiguous:

Doctors are not permitted to prescribe Schedule 8 or Schedule 4 poisons for the purpose of self-administration (regardless of whether the treatment was initiated by another medical practitioner) (DoHA 2006b).

<sup>569</sup> See Chapter 2.2 for a discussion of the adverse consequences of pharmaceutical use and Chapter 2.3 for a brief discussion of misuse by health professionals.

Doctors who do experience problems in relation to their personal use of these drugs may be investigated by the Board and may also be referred to services established to help them. One such example is the Victorian Doctors Health Program. This is:

an independent legal entity that has been established to provide a full time professional service to meet the needs of sick and impaired doctors and medical students (Doctors Health Database (Victoria) website).<sup>570</sup>

### ***The Nurses Board of Victoria***

The Nurses Board of Victoria is a self-funded statutory authority, incorporated under the *Nurses Act 1993*. It consists of 12 members appointed by the Minister for Health.<sup>571</sup> The Board regulates the nursing profession, but also addresses the wellbeing of nurses. This latter point is relevant because, like medical practitioners, the nursing profession has been identified as potentially high-risk for pharmaceutical misuse due to a number of factors, including access.<sup>572</sup>

These examples indicate that various professional boards can have an important role in ensuring safe and effective use of pharmaceuticals and in preventing their misuse. Clearly the Boards discussed above have identified this as an important role, both in relation to their community responsibilities and to ensure the wellbeing of their members.

## **Professional practice guidelines and policies**

### ***General guidelines for prescribing***

In addition to legislative approaches and policies that determine standards of practice, various expert groups and professional bodies have developed guidelines, learning objectives, courses and other materials that aim to ensure safe and effective prescription of medicines. These may be important adjuncts to legislation and regulations.

### **World Health Organization**

International bodies such as the World Health Organization (WHO) have developed a Guide to Good Prescribing Steps. Although not specific to drugs that are the focus of this Inquiry, they clearly have relevance to them. These guidelines describe the following steps (adapted from Shakib & George 2003):

1. Make a diagnosis;
2. Set the therapeutic goal for the individual patient;
3. Decide on the therapeutic approach;
4. Choose a drug class;
5. Choose a generic drug within that class;
6. Individualise dose, formulation, frequency and duration (that is, for the individual patient);
7. Verify the suitability of the chosen drug;
8. Write the prescription;
9. Inform the patient;
10. Monitor for effects and adverse effects; and
11. If necessary alter the prescription.

<sup>570</sup> Further information with regard to doctors who may divert prescription drugs to their own use or otherwise abuse them is discussed in Chapters 2.3 and 7.2.

<sup>571</sup> Submission of the Nurses Board Victoria to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

<sup>572</sup> Further information with regard to nurses who may divert prescription drugs to their own use or otherwise abuse them is discussed in Chapters 2.3 and 7.2.



## Department of Health and Ageing (DoHA)

The Australian Government DoHA has also fostered the development of clinical guidelines, learning objectives and assessment procedures to ensure safe and effective treatment for opioid dependence (Allsop et al 1997; Allsop, Corry & Ernst 2004; Henry-Edwards et al 2003). As well as addressing issues such as assessment, induction and maintenance strategies for safe and effective pharmacological management of opioid dependence, these resources also identify the importance of responding to drug-seeking behaviour and diversion. For example, whilst acknowledging the potential benefits of 'takeaway' doses of methadone, the guidelines note that:

Uncontrolled access to takeaway doses is associated with greater diversion and adverse consequences including bringing the program into disrepute. The safety of takeaway doses of methadone is increased by:

- Careful selection of patients suitable for takeaway methadone (requiring close monitoring by the prescriber and dispenser).
- Education of the patient (Henry-Edwards et al 2003, p.20).<sup>573</sup>

Thus, the guidelines recommend that generally methadone should be consumed under supervision, and where takeaway doses are provided this should only occur with patients who are carefully selected and monitored. The number of consecutive takeaway doses should be limited. They note that the rationale for this caution is that:

Research into methadone related deaths has consistently shown that between one third and two thirds of all methadone related deaths occurred in persons not prescribed methadone treatment.

The major source of diverted methadone is take away doses prescribed for patients in MMT (methadone maintenance treatment) (Henry-Edwards et al 2003, p.30).

## Royal Australian College of General Practitioners (RACGP)

Similarly, the RACGP has developed Guidelines on the prescription and use of benzodiazepines. The stated rationale for these Guidelines is as follows:

These Guidelines were formulated to provide assistance to general practitioners in relation to appropriate prescribing of benzodiazepines in the context of general practice. The Guidelines are based on the evidence regarding the advantages and disadvantages, particularly the danger of dependence, associated with the use of benzodiazepines (Royal Australian College of General Practitioners (RACGP) website, p.1).

Key aims of the Guidelines included:

- ◆ Reducing deaths from drug overdose; and
- ◆ Reducing indiscriminate prescribing of benzodiazepines to polydrug users.

In addition to being consistent with the National Medicines Policy, the Guidelines 'state general principles based on the best available evidence' (RACGP website, p.1). The Guidelines are outlined below in Figure 5.1a.

<sup>573</sup> There are sometimes grounds to prescribe doses that are taken outside normal supervisory procedures – for example, for stable patients who are employed and who have difficulty attending every day for their pharmacotherapy (Henry-Edwards et al 2003).

**Figure 5.1a: RACGP guidelines on the prescription and use of benzodiazepines**

1. Wherever possible avoid prescribing benzodiazepines especially to known polydrug users, including those with dependence.
2. When a programme of benzodiazepine reduction is undertaken it should be with the patient's consent and co-operation.
3. All patients prescribed benzodiazepines should be advised of the risk of dependence associated with long-term use.
4. Patients receiving prescriptions for benzodiazepines should be advised to obtain all such prescriptions from the same doctor, wherever possible, so that risk of dependence may be monitored.
5. Treatment review should include a review of the indication(s) for continued use of the benzodiazepine, medication dose and possible adverse effects. For all patients receiving long-term benzodiazepines review is particularly relevant.
6. Non-medication management for conditions such as anxiety and insomnia includes clarification of the problem, counselling and specific advice, with referral where the diagnosis is uncertain, or where assistance in management is required.
7. Detoxification from benzodiazepines may be facilitated by changing patients to long half-life medications eg diazepam, and then slowly reducing the dose. One-to-one counselling may be supplemented by self-help support programmes during withdrawal.
8. The management of anxiety and insomnia should rely largely on non-pharmacological interventions.
9. When benzodiazepines are prescribed, the lowest dose to achieve the desired outcome for the shortest duration necessary should be provided.
10. For residents of aged care facilities, discontinuation of benzodiazepines can often be achieved gradually, provided patient, family and nursing staff are cooperative. Medication may occasionally be required to control anxiety, agitation or other disturbed behaviours. Staff should be knowledgeable in appropriate management of challenging behaviours.

Source: Royal Australian College of General Practitioners (RACGP) website, p.1.

To ensure compliance with the Guidelines, doctors are advised to undertake and keep a record of the following steps:

- ◆ Undertake a full patient history, including focus on other drug use and co-existing mental health problems;
- ◆ Conduct an adequate physical examination;
- ◆ Identify/diagnose problems; and
- ◆ Develop a management plan.<sup>574</sup>

#### **Pharmacy Board of Victoria**

Similarly, the Pharmacy Board of Victoria provides guidelines for pharmacists on methadone, buprenorphine and other opioid treatment. These guidelines identify the importance of close liaison with prescribing doctors, describe where dosing should take place and enunciate key procedural issues such as ensuring adequate security for medicines, providing an accessible written manual on procedures, establishing complaint resolution procedures and maintenance of proper record systems. The guidelines state that:

Pharmacies providing an Opioid Substitution or Antagonist Treatment Service shall maintain:

<sup>574</sup> The importance of developing a management plan was testified to by Dr Mike McDonough of Melbourne's Western Hospital when he gave evidence to the Committee in July 2006. He stated:

'I think a treatment plan is absolutely essential. Unfortunately, seeing some of the cases where things did go wrong, I cannot remember ever seeing a case where the doctors involved kept notes that indicated there was a treatment plan, and it is probably the most important and most commonly overlooked aspect of the care of these patients. These are, again, benzodiazepine-dependent patients who sometimes use multiple doctors or doctor shop and get into problems with the way they take these medications.

The treatment plan should always involve one doctor and one pharmacist – that is, one dispensing point – and ideally one or other pharmacies working around the clock or working different days, getting to know the patient and picking up on some days where the patient does not look well. [In such cases] they may choose not to dispense until the patient has been sent down to the GP. Something like that is a regularly used technique in the management of patients on a methadone program, but it is probably not that familiar to many GPs. So it is just an additional form of monitoring – checks and balances' (Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 13 July 2006).



- (a) a recording system which enables pharmacists to access client information including the dose from their current prescription and a photograph for identification;
- (b) day or incident reporting books or similar;
- (c) client treatment notes. It is recommended that pharmacists maintain written notes detailing dose alterations, missed doses, consultations with prescribers etc.;
- (d) drugs, harm minimisation and other appropriate literature for distribution by the pharmacists to the client; and
- (e) required references including the National Clinical Guidelines and Procedures for the use of buprenorphine in the treatment of heroin dependence, the National Policy on Methadone Treatment, Methadone Treatment in Victoria Pharmacy Board of Victoria – Guidelines 2004 (amended) (Pharmacy Board of Victoria 2004, p.32).

The guidelines also contain general comments about the role of the pharmacist in relation to medicines subject to abuse:

- a. Pharmacists must keep themselves aware of any drugs or medicines which are being abused or misused in the general community and in the area in which they usually practise and ensure that any requests received at their practices for such drugs or medicines are referred to a pharmacist who must be assured that the drug or medicine is to be used for a bona fide therapeutic purpose before supplying the drug or medicine.
- b. For the purpose of this guideline, pharmacists are expected to observe warnings or notices about drug or medicine misuse or abuse distributed to the pharmacy profession and to ascertain conditions in their local area by regular consultation with other pharmacists and other health professionals in the area (Pharmacy Board of Victoria 2004, p.62).<sup>575</sup>

<sup>575</sup> Prescription guidelines are also advisable in particular locations and for particular circumstances. For example, in its submission to the Inquiry, the Victorian Institute of Forensic Mental Health suggested consideration of the following potential guidelines for benzodiazepine use in prisons:

'Guidelines on the clinical use of benzodiazepines in prisons would seem to need to fall somewhere between a zero tolerance stance and what currently occurs in the community. With this in mind, the following guidelines are suggested for benzodiazepine prescribing within prisons:

1. Assessment of the clinical indications for benzodiazepines should take account of the possibility of a history of benzodiazepine abuse, including where possible information from previous prescribers.
2. Prisoners requesting benzodiazepines should be educated on the indications, risks and benefits of these drugs, including the risk of dependency. This has been shown to be effective in reducing use amongst patients in the community.
3. Prisoners should be provided with alternative ways of treating their presenting complaint such as sleep hygiene education for insomnia or talking therapies for episodes of distress and anxiety.
4. Benzodiazepines should only be prescribed for the conditions for which they are known to be effective, at the minimum effective dose, avoiding benzodiazepines with a relatively short half life, and rarely prescribed for a period of more than three to four weeks, preferably on an intermittent, rather than regular basis.
5. Prisoners who are long term users should be withdrawn from benzodiazepines in a humane way. This would involve them collaborating with prescribers to work out a reduction regime which they can reasonably adhere to and which gives them a more realistic chance of staying abstinent from use in the future. A typical withdrawal regime can be found in the document Typical Withdrawal Plan in 'Guidelines for the Prescription of Psychotropic Drugs in Victorian Prisons'...
6. Long term maintenance use of benzodiazepines is not possible given the problems of trafficking and diversion of psychotropic medication. It is also difficult to accurately identify those who are truly long term maintenance patients from those who are not.
7. Prescribers should be aware of trends in benzodiazepine abuse within the local prison system and avoid the use of agents that are known to be highly valued for the purposes of diversion and trafficking. For example, in Victorian prisons – alprazolam and clonazepam.
8. Current evidence suggests that the combination of buprenorphine and alprazolam is associated with an increased risk of mortality' (Submission of Mr Michael Burt, Chief Executive Officer, Victorian Institute of Forensic Mental Health, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006).

### *Limitations of guidelines*

It is important to note that guidelines are important, but limited, facilitators of evidence-based medicine (for example, see Allsop & Helfgott 2002; National Health Service Centre for Reviews and Dissemination 1999). As was discussed earlier in this chapter, they are not always embraced and do not always result in quality clinical practice. For example, one study (Mazza & Russell 2001) found that general practitioners (GPs) generally do not access or follow guidelines. Even when they are adhered to, guidelines alone might not result in quality practice. Allsop and Helfgott (2002) cited one commentator who eloquently described the limitations:

There is a fear that in the absence of evidence clearly applicable to the case in hand a clinician might be forced by guidelines to make use of evidence which is only doubtfully relevant, generated perhaps in a different grouping of patients in another country at some other time and using a similar but not identical treatment. This is evidence-biased medicine; it is to use evidence in the manner of the fabled drunkard who searched under the lamp for his door key because that is where the light was, even though he had dropped the key somewhere else (Grimley Evans 1995, p.461).

This limitation is acknowledged in the Victorian Policy for Maintenance Pharmacotherapy for Opioid Dependence:

The policy is not intended to replace professional judgment in individual cases (DHS Victoria 2006d, p.2).

The other problem is that whilst some policies and guidelines are specific and detailed, others are not so clearly enunciated. For example, at the public hearings for this Inquiry Dr Harcourt, the Chief Health Officer of the Health and Disability Strategy Programmes, Transport Accident Commission (TAC), noted that in relation to pain management:

...there needs to be some benchmarking on the management of non-malignant chronic pain...there is no broad consistent clinical policy framework which pulls all that together in the management of chronic pain.<sup>576</sup>

With regard to benzodiazepine prescribing, guidelines such as those produced by the RACGP are generally useful but do not give any specific guidance with regard to the amount of drug that should be prescribed or for exactly how long they should be prescribed.

Whilst it is acknowledged that there needs to be a certain amount of flexibility in how a doctor prescribes medicines for his or her patient, and that decisions need to be considered on an individual basis, some commentators have told the Inquiry that it is time for the rate and duration of prescribing to be reduced.

For example, Dr Alex Wodak of St Vincent's Hospital Sydney is chairing a subcommittee of the Royal College of Physicians currently looking at benzodiazepine use in Australia. When Committee members asked Dr Wodak whether there was a problem with individual doctors writing prescriptions for inappropriate amounts of benzodiazepines and other drugs, he responded:

In my view the problem is really bigger than you are suggesting. I think it is the whole system. We have problems with pharmaceutical industries that are not, in my view, sufficiently regulated and constrained. Then I think we have a problem with the professional bodies that should really be setting out guidelines here, writing clear and unambiguous guidelines so that the cowboys can be taken out and dealt with. Because we do not have the clear and unambiguous guidelines we have Departments of Health that are reluctant to spend the millions of dollars required to prosecute these cases. So there are multiple levels of problems [with regard to prescribing]. The easiest one I think to fix is to get the

<sup>576</sup> Dr Peter Harcourt, Chief Health Officer, Health and Disability Strategy Programmes, Transport Accident Commission, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 19 June 2006.



professional bodies to write clear and unambiguous guidelines. Once that is done, and we have consensus within the medical profession, then it would not take a genius to work out an adequate surveillance system, and the kind of thing you are describing where a doctor is behaving way outside the guidelines could be dealt with.<sup>577</sup>

Ms Gwenda Cannard, Executive Director of the prescription drug support group ReConnexion, had similar doubts about the efficacy of current guidelines relating to benzodiazepine prescribing and use. She told the Committee:

The whole area of GP prescribing and what influences prescribing is a really interesting one, and I often compare it to antibiotic prescribing. In Australia we have one of the worst rates of antibiotic prescribing in the world and quite frankly the horse has bolted, and we are now trying to shut the stable door [similarly benzodiazepines are over prescribed].

There have been guidelines for prescribing antibiotics for absolutely yonks in the same way that there have been guidelines for prescribing for benzodiazepines. All of the guidelines have very clear warnings on them and the warnings in MIMS are very clear [but they are still over-prescribed]. So guidelines do not have a big influence on prescribing; other things do, [including public demand for the drugs and a lack of training of GPs].

Sometimes the GP might be a bit stuck in terms of maybe they know they shouldn't be prescribing for that length of time, but they are a bit stuck on how to go.<sup>578</sup>

There is a need to develop strategies to improve the effectiveness of these guidelines, to increase the likelihood of them being used by the target audience, and to combine their development and dissemination with other strategies that ensure judicious application of pharmacotherapies. This means providing treatment in the context of the individual patient's unique circumstances; for example, by simultaneously increasing practitioner understanding and acceptance of the rationale for the guidelines and supporting the development of quality clinical skills and supervision/support in their application.

## Other contributions from professional organisations

Professional bodies often contribute in other ways to reduce the risk of pharmaceutical misuse, such as by conducting research and surveys to inform the development and implementation of quality practice.<sup>579</sup> As an illustration, the Pharmaceutical Society of Australia conducted research into prescription forgery (Lloyd, Guibert & Bell 2000). In a review of the data (from 1997–1999) they found that the majority of forgeries were for drugs considered by this Inquiry (eg. pethidine, temazepam, flunitrazepam, oxycodone, morphine tablets). They noted that whilst the majority of forgeries were for benzodiazepines, this could in part have been because the regulations governing access to most of these drugs may be lower than for S8 drugs (eg. morphine), as discussed earlier in this chapter and in Chapter 4.2.

577 Dr A Wodak, Director, Alcohol and Drug Service, St Vincent's Hospital, Darlinghurst, and Fellow of Chapter of Addiction Medicine, Royal Australasian College of Physicians, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 25 June 2007.

578 Ms Gwenda Cannard, Executive Director, ReConnexion, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007. ReConnexion was formerly known as the support group TRANX.

579 There are also other 'in house' programmes of note that facilitate a variety of best practice models for the training, education and practice of health professionals such as pharmacists. The Pharmacy Guild of Australia for example operates the Quality Care Pharmacy Program that requires pharmacies and their staff to have protocols in place that supports the QUM principles. For details of these and other professional organisation programmes, particularly in the area of education and training, see Chapter 6.1.

Another body of note is the Victorian Therapeutics Advisory Group (VICTAG). VICTAG comprises directors of pharmacy, clinical pharmacologists and other clinicians from Victorian hospitals who meet regularly to discuss a range of medication related issues:

'These include the decisions of their hospitals' Drug and Therapeutics Committees; the access to and funding of pharmaceuticals; the rational use of medicines; drug policies at local, state and national levels; medication safety; and drug usage data. With twenty-four hospitals or networks represented as full members of VICTAG and a further eighteen associate members, the group also has a significant lobbying role, both at an institutional and government level' (<http://www.victag.org.au/about>).

The PSA also noted that there was a lack of coordinated data-gathering (for example, they observed that police do not always record correct names of forged drugs in line with pharmacy reporting, creating difficulty for intelligence coordination). One of their conclusions was that there was a need to enhance the coordination of effort across the relevant statutory bodies and professional groups.

### **Contributions from pharmaceutical companies**

It has been noted throughout this Report that both the benzodiazepine class of drugs and a wide range of opioid analgesics when prescribed correctly and used properly are beneficial products in the pharmaceutical formulary. Similarly, the pharmaceutical industry through its individual companies and its peak bodies including Medicines Australia and the Generic Medicines Industry Association (GMIA) can play a valuable and constructive role in ensuring that prescription and pharmaceutical medicines and products are manufactured to the highest standards, prescribed appropriately and used safely.

#### ***Medicines Australia and the Code of Conduct***

Medicines Australia is the peak organisation for most pharmaceutical companies operating in Australia. It is responsible for developing and regulating the industry's internal code of conduct, the basis of self-regulation of the Industry.

The latest edition of Medicines Australia's Code of Conduct 'sets the standards for the ethical marketing and promotion of prescription pharmaceutical products in Australia'.<sup>580</sup> It complements the legislation requirements of the Therapeutic Goods Regulations and the *Therapeutic Goods Act*.

Established in 1960, the pharmaceutical industry Code of Conduct has been revised on a regular basis. To ensure that the Code continues to reflect current community and professional standards and current government legislation, an extensive review of Edition 14 of the Code was completed during 2005.

Consultations with, and feedback from, consumer groups, peak medical associations (eg AMA, RACGP, ADGP), Pharmacy Guild and Society, member companies, government and other independent groups have provided the Code Review Committee with valuable insights, recommendations and views on the amendments to the Code.<sup>581</sup>

Code provisions include standards for appropriate advertising, the behaviour of medical representatives and relationships with healthcare professionals. Medicines Australia describes the Code as follows:

The Code of Conduct has two arms, firstly the adjudication of complaints undertaken by the Code of Conduct Committee and secondly the proactive monitoring of promotional activities undertaken by the Monitoring Committee.

Areas covered by the Code of Conduct include:

- Nature and Availability of Information and Claims – false and misleading claims, level of substantiating data
- Types of Product Information
- Promotional Material – advertisements, brand name reminders, competitions, gifts and offers
- Company Representatives – medical representatives
- Product Starter Packs
- Involvement in Educational Symposia, Congresses and Satellite Meetings – trade displays
- Sponsorship

<sup>580</sup> See <http://www.medicinesaustralia.com.au/pages/page5.asp>  
Edition 15 of the Code took effect from 6 December 2006.

<sup>581</sup> <http://www.medicinesaustralia.com.au/pages/page5.asp>



- Research
- Relationship with the General Public
- Relationship with Healthcare Professionals – travel, hospitality, remuneration, entertainment, consultants and advisory boards
- Administration of the Code – complaints process, committee membership
- Sanctions
- Appeals
- Monitoring
- Compliance Procedures
- Reporting.<sup>582</sup>

### *The Generic Medicines Industry Association (GMiA)*

The Generic Medicines Industry Association (GMiA) was established in 2001 and is the trade association for the manufacturers of generic prescription pharmaceuticals (drugs no longer subject to a patent monopoly) listed on the PBS. GMiA is a member organisation of the Australian Pharmaceutical Advisory Council (APAC). Member groups employ around 300 people and according to the Department of Health and Ageing 'invest in R&D at a rate which is in the top tier of the pharmaceutical industry in Australia; and export generic medicines to around 26 countries'.<sup>583</sup>

The GMiA was established to:

- ♦ provide a unified voice to represent the interests of the generic prescription medicine industry in Australia;
- ♦ develop good relationships with all constituencies involved in ensuring the continued delivery of pharmaceutical care to the Australian community; and
- ♦ contribute to the long term sustainability of the PBS through observances of the principles of the National Medicines Policy.

GMiA through its Code of Conduct:

- support the PBS and its long term sustainability;
- support the quality use of medicines;
- support the development of policies to ensure access to pharmaceutical care for all Australians;
- encourage professional awareness and general knowledge of the safety and efficacy of generic medicines; and
- promote balanced and generic-friendly intellectual property rights in the pharmaceutical sector that enable timely access to markets for generic medicines.<sup>584</sup>

Many pharmaceutical companies provide guidelines and training related to quality use of medicines for medical practitioners and pharmacists. They may also provide financial or resource supports to facilitate training and quality practice initiatives by other groups. For example, in a submission to the Inquiry, Mundipharma made the following statement:

Mundipharma, for its part, takes its responsibility to educate all participants in the distribution chain for opioid analgesic medication very seriously. We believe strongly that the effectiveness of laws governing the prescription and supply of controlled prescription products is only as good as the ability of individuals to comprehend the requirements and comply. Education around the rationale and need for various regulatory controls provides the basis for positive moral and ethical decision making by all stakeholders to understand and comply with the requirements. It is important for all stakeholders to understand that

<sup>582</sup> For a copy of the preamble to the most recent Code, see Appendix 14. A full copy of the Code can be accessed at [www.medicinesaustralia.com.au](http://www.medicinesaustralia.com.au)

<sup>583</sup> See <http://www.healthconnect.gov.au/internet/wcms/publishing.nsf/Content/nmp-advisory-apac-gmia>

<sup>584</sup> <http://www.healthconnect.gov.au/internet/wcms/publishing.nsf/Content/nmp-advisory-apac-gmia>

regulatory requirements imposed are not a bureaucratic exercise but, rather, are there to encourage modified behaviour to achieve desired societal outcomes.<sup>585</sup>

## **Current general concerns with regard to the prescribing of prescription drugs**

The following section examines a number of contentious issues pertaining to the practice of contemporary medicine and pharmacy, particularly in the area of prescribing and dispensing medications. Much of the discussion throughout this section is informed by the views of experts in this field with whom the Committee met or received submissions from.

### *The role of the pharmacist and the general practitioner*

#### **Health professionals as 'police officers'**

One of the issues that has arisen in the course of this Inquiry has been the respective roles of the general practitioner or other health professional in prescribing medicines, the role of the pharmacist and the relationship between the two. As is noted later in this chapter, doctors and pharmacists have both a statutory and a common law fiduciary duty of care to the patients they serve. But how far does that fiduciary duty extend? Does it require a health professional to intervene to protect a patient from his or her own bad choices and decisions?

For example, a particular issue that has been raised with regard to the role of the doctor in prescribing and the pharmacist in dispensing has been their respective reluctance to act as a 'police officer', especially when it comes to questioning the actions of possible 'doctor shoppers'. For instance, Ms Mary Sharpe, Deputy Chief Pharmacist of the Tasmanian Department of Health, remarked to the Committee:

Doctors – their profession is to trust the patient and it is very hard for them to put the policeman hat on and think, 'Is this patient telling me exactly what is going on? Is the level of pain they're indicating, the level of anxiety, is that real or do I have to question and call into judgment what they're saying? Is that right or wrong?' I think doctors find that very hard and they tend to believe what the patient is saying. It is in a sense an ability for them to be able to discern what is said as being right or wrong and it is very difficult.<sup>586</sup>

Ms Sharpe's colleague, Chief Pharmacist John Galloway agreed that both doctors and pharmacists are put in an invidious position in some circumstances when writing or dispensing prescriptions:

It is certainly true that doctors feel very uncomfortable about confronting patients. They are often very unwilling to do it unless they have very reliable information which is indisputable. When it comes to what people are doing with their drugs it is often very hard to get reliable information. A lot of it is unexpected. Even what you would term good, regular doctors are very reluctant to go looking for injection sites on people and patients. They feel quite uncomfortable with that particular role. They are not really doing enough to deal with the safety issues. I think they are prescribing in the hope that they are doing the right thing rather than with caution and safety.<sup>587</sup>

Whilst Ms Sharpe and Mr Galloway specifically talk about doctors, the same dilemmas face pharmacists, according to a number of commentators. Peter Halstead, Registrar of the South Australian Board of Pharmacy, stated to the Committee:

585 Submission from Mundipharma to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, August 2006.

586 Ms Mary Sharpe, Deputy Chief Pharmacist, Pharmaceutical Services Branch, Department of Health (Tasmania), Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Teleconference, Melbourne, 18 June 2007.

587 Mr John Galloway, Chief Pharmacist, Pharmaceutical Services Branch, Department of Health (Tasmania), Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Teleconference, Melbourne, 18 June 2007.



We have a situation where pharmacists, we feel, are starting to end up in a policing action to a large extent, which detracts from our original aim in life and I do not think it benefits the community much at all.<sup>588</sup>

This is also the way some pharmacists 'at the coal face' feel according to Ms Toni Riley of Toni Riley Pharmacies in Bendigo:

It [confronting or questioning patients] is a big issue for pharmacists because we feel a bit like we are expected to be the policeman. We are expected to make judgments on people that are sometimes not fair. Then we are left holding the baby. What the heck do we do with this situation, because there is no-one really who can help us out of it.

Conversely, doctors have got a tough road to drive along too because they potentially have people come in with legitimate reasons for having such medication prescribed, but they are not going to use it legitimately. Once again the doctor is put in the role of being the judge and the jury too.<sup>589</sup>

The latter point is one that a doctor currently practising in alcohol and drug treatment in Warrnambool says happens all too often:

I do not believe that my job is to be a policeman. My job is to be a doctor and to err on the side of relieving symptoms. I do make mistakes. I am absolutely sure of that. I am sure that many of the prescriptions that I write end up on the market. My problem is that I do not know which ones.<sup>590</sup>

### The relationship between doctors and pharmacists

Another issue that impacts upon good prescribing and dispensation practice is that the individual roles of doctor and pharmacist are sometimes affected by the relationship or lack thereof between the two professional groups.<sup>591</sup> For example, Dr Con Constantinou, Health Manager of the Medical Practitioners Board of Victoria, believes that a good professional relationship between doctor and pharmacist is essential in promoting and safeguarding patient health. It should be a relationship based on mutual professional respect in which a pharmacist should not feel shy about questioning what he or she feels is inappropriate, negligent or even unethical prescribing on the doctor's part. Unfortunately, this ideal is not always apparent in practice:

Unfortunately some of the time-constrained doctors do not act very kindly to such calls [questioning a prescription] and consider them interference, and so the exchange can be short and brutal and not very productive. A sensible medical practitioner will regard the local pharmacist as a friend and colleague and will go out of his way to meet with them and socialise with them so that they understand each other, and they can be of great benefit to each other. Yes, I think there can be more action taken to foster that relationship between the two professionals.<sup>592</sup>

Ms Beth Wilson, Victoria's Health Commissioner, also indicated to the Committee that better working relationships need to be forged between prescribers and dispensers, particularly given the expanding role of the community pharmacist in recent times:

588 Mr Peter Halstead, Registrar, Pharmacy Board of South Australia, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Adelaide, 18 May 2007.

589 Ms Toni Riley, Pharmacist, Toni Riley Pharmacies, Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Bendigo, 30 May 2007.

590 Dr David Richards, Addiction Medicine Physician, Western Region Alcohol and Drug Centre, Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Warrnambool, 29 May 2007.

591 A recent Report by the Collaborative Centre for e-Health at the University of Ballarat that examined dispensing practices of scheduled drugs found that there was 'a need to identify an efficient communication mechanism between general practitioners and pharmacists', particularly with regard to prescribing, dispensing and counselling protocols with regard to Schedule 4 and 8 drugs that have dependency properties (Lynton-Moll 2006, p.10). (Emphasis in original)

592 Dr Con Constantinou, Health Manager, Medical Practitioners' Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 9 July 2007.

Pharmacists already do much more than just putting pills into a bottle with a label over the top; they have a very important community education role...The communication between doctors and pharmacists has been an interesting one over the years, and there has certainly been some paternalism on the part of the medical fraternity who look down on pharmacists and do not want them interfering too much. Certainly I know pharmacists who find doctors very rude and angry if they ring up to verify a prescription. Doctors just have to get over that. Once it was considered funny that doctors had lousy handwriting, which in fact can be a life or death matter. Many of the drugs sound very similar. Pharmacists have taken that active role, but they have done so with some trepidation because some medical professionals get very stropky about that.<sup>593</sup>

Clearly, a good working relationship between prescriber and dispenser is essential. Many interested parties, from whom the Committee took evidence, are of the view that the responsibility for ensuring safe and therapeutic ingestion of medicines is jointly that of the doctor who writes the script and the pharmacist who fills it, and that both have a duty of care in this regard.<sup>594</sup>

The responsibility is of both. It has to be both, because the prescriber in fact needs to provide some information about what the drug is, what it is going to be used for, and how often they need to take it. The pharmacist needs to reinforce that....When a pharmacist asks, 'What did the doctor tell you?', all too often people tell you, 'Nothing'. So you might say, 'Okay, well this is an antibiotic'. 'Oh yes, he told me that'. 'You need to take one twice a day'. 'Yes, he told me that'. So they need the recall triggers to prompt what is sitting back there. Sometimes they will forget [what the doctor has told them], so pharmacists have got to give a lot more information.<sup>595</sup>

There have been, however, some differing views expressed as to just who is ultimately responsible for providing detailed information about the properties and effects of medications to the patient. For example, Dr Con Constantinou believes such responsibility 'should always fall upon the doctor', whilst Ms Beth Wilson's view is that 'Pharmacists have de facto in practice taken on the role of explaining to patients things that their doctor actually should have done'.<sup>596</sup>

Sometimes a breakdown in communication can occur not only between professions such as pharmacist and doctor but between practitioners in different settings such as specialist and generalist doctors or a doctor in a hospital setting with one in general practice. Ms Mary Sharpe explained to the Committee how a difference in approach in prescribing practices in various settings sometimes could have negative repercussions for the patient:

[Hospital] doctors will probably prescribe, on discharge, certain amounts of medication. Where we see the problem is that a patient will go to hospital and because the condition in hospital is acute, they often need a higher dose of medication. They can then present to their GP and say, 'Look, whilst I was in hospital I was on 200 milligrams of that drug'. That might have been fine while they were in hospital but that was the acute phase. The chronic phase needs a much lower dose. There is often no interface, a proper communication back to the

593 Ms Beth Wilson, Health Commissioner of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse and Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 9 July 2007.

For further discussion of the role of the pharmacist in community education and information provision, see Section Six.

594 This begs the question as to what extent pharmaceutical companies are responsible for supplying information to consumers on the properties of their medicines and their effects and side effects. For further discussion of this topic, see Section Six.

595 Mr Steve Marty, Registrar, Pharmacy Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007.

596 Dr Con Constantinou, Health Manager, Medical Practitioners Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 9 July 2007; Evidence of Ms Beth Wilson, Health Commissioner of Victoria, given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 9 July 2007.



GP of what the long-term dose needs to be. The GP often then tends to prescribe that high, acute phase dose which the patients no longer need, then they have extra medication they can use or divert.<sup>597</sup>

It has been argued that such a breakdown may become even more acute as a greater number of health professionals are given a licence to prescribe certain drugs.

### *Widening the net of prescribers*

Traditionally, rights to prescribe medications have been restricted to general and specialist medical practitioners, psychiatrists, dentists, and veterinarians. In the last decade these rights have been extended to nurse practitioners, ophthalmologists and most recently podiatrists.<sup>598</sup> These changes have not necessarily been unilaterally welcomed, particularly by medical and pharmacy organisations.

For example, a submission from the Victorian Pharmacy Board stated:

The increasing number of persons being granted prescribing rights will exacerbate the problem [of medical misinformation, misadventure and prescription monitoring] given that [non-traditional] prescribers currently practice in isolation from other practitioners, unaware of what others have prescribed, possibly placing patients at risk of medical misadventure including death.<sup>599</sup>

The AMA (Victoria) has been particularly critical of allowing podiatrists restricted prescribing rights. In a submission to this Inquiry it states:

While there are some programs and safeguards in the system to protect the community and medical practitioners from harm caused by benzodiazepine and opioid misuse and abuse, few of these safeguards exist for podiatry prescribing. Further, medical practitioners have significant experience prescribing for many years before entering community practice, while podiatrists lack this experience.

Consultations are generally not covered by Medicare or subject to the Professional Services Review Scheme; podiatry is not mentioned in the *Australian National Medicines Policy* or the *National Strategy for Quality Use of Medicines*; and prescriptions are not counted by the Pharmaceutical Benefits Scheme. Podiatrists prescribing of benzodiazepines and opioids will be uncounted and unaccountable.

Medical practitioners prescribing benzodiazepines and opioids do so within a Medicare and Pharmaceutical Benefits system that monitors consultations and prescriptions. Medicare Australia has sophisticated tracking systems to identify both medical practitioners and patients who [prescribe] outside normal patterns. These data collection and monitoring systems are not available for podiatry consultations or prescribing.

All prescriptions require a standard set of information to allow a pharmacist to accurately dispense medication. Prescriptions are written by medical practitioners on a standard form supplied by Medicare Australia, easily identifiable, and are designed to discourage forgery. Medicare Australia prescription pads are not available to podiatrists, who will have many and varied ways of writing prescriptions. Forging a podiatrist prescription will be a simple matter of a suitable letterhead, a prescriber number and a signature...

AMA Victoria has significant concerns about podiatrists prescribing schedule four substances, in particular benzodiazepines and opioids. The risks of misusing these drugs are considerable, and the costs to the community are significant. Podiatrists lack the training, support, experience and regulatory structure to adequately reduce the risk of harm to the community.<sup>600</sup>

597 Ms Mary Sharpe, Deputy Chief Pharmacist, Pharmaceutical Services Branch, Department of Health (Tasmania), Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Teleconference, Melbourne, 18 June 2007.

598 See the *Drugs Poisons and Controlled Substances Act 1981* and *Drugs Poisons and Controlled Substances Regulations 2006* and the discussion in Chapters 3.2 and 4.3.

599 Submission of Pharmacy Board of Victoria to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

600 Submission of the AMA (Victoria) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

## Specific concerns with current prescribing practices

As stated earlier in this chapter, the DCPS Regulations have outlined some fairly strict provisions that practitioners must observe in prescribing controlled substances. These requirements become less stringent, however, with prescription drugs that are placed in lower schedules. This is particularly the case with benzodiazepines. Many witnesses to this Inquiry have observed that there should be a stronger regime when it comes to the prescription and dispensing of benzodiazepines. Concerns have particularly centred on the amount of time that it is permissible to prescribe the drug, the amount of the drug that can be prescribed at any one time and, related to this point, the general issue of package size of certain prescription drugs. Issues have also been raised as to how surplus prescription drugs should be disposed of. Each of these issues will be dealt with in turn.

### *Constraints on good prescribing practices*

Almost all the people with whom the Committee met remarked that the overwhelming majority of practitioners, be they doctors, dentists or other allied health professionals were conscientious and responsible, trying to do the right thing by their patients:

I think in any jurisdiction, most prescribers are very responsible, cautious, most prescribers are responsible ethical prescribers, I think most of the inappropriate prescribing is done by a small group of people in any jurisdiction [but]...a small group of willing prescribers can do enormous damage.<sup>601</sup>

Nonetheless, the good intentions or otherwise of prescribers aside, there are a number of cultural, structural and administrative issues pertaining to the practice of pharmacy or medicine that also have a bearing on how pharmacists and doctors relate to both their patients and each other.

### **Time constraints for medical practitioners**

A key example of this is addressing treatment of chronic pain. As will be discussed in Section Seven, with a few exceptions, at least at general practitioner level, treatment of pain is almost invariably through pharmacological interventions. This is partly a cultural phenomenon. Since the early 1990s and due to the release of drugs such as OxyContin® on the market 'the culture of prescribing [pain] drugs has changed...every Australian doctor [found it] suddenly acceptable...to prescribe opiates for non malignant pain'.<sup>45</sup> But the reasons are also structural. For example, Mr John Galloway, Chief Pharmacist of the Tasmanian Department of Health told the Committee:

One of the issues is that anxiety, chronic pain, withdrawal issues are chronic conditions. A 10-minute session with a GP is not going to touch the surface of a problem like that. People cannot be managed on this particular medical model and really improve. All doctors really are left with is, 'What do I do now?' There is not a practical strategy in withdrawing people, other than to say no, and the patient moves on to another doctor. A lot of doctors feel very unhappy about all this because the doctors set out to do good but they eventually end up doing harm with these particular drugs. I guess all of us in the health system feel very uncomfortable about this.<sup>602</sup>

In Mr Galloway's view insufficient time allowed by Medicare for a general practitioner to do a thorough treatment analysis into the patient's pain disorder (or anxiety or sleeping disorder) combined with a lack of specialist clinics contribute to excessive or inappropriate prescribing practices by the general practitioner. This is also the view of pain treatment specialist Dr Malcolm Hogg, as expressed in his evidence to the Inquiry:

<sup>601</sup> Dr Mike Tedeschi, ANU Medical School, Canberra Hospital, Meeting with Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Canberra, 16 May 2007.

<sup>602</sup> Mr John Galloway, Chief Pharmacist, Pharmaceutical Services Branch, Department of Health (Tasmania), Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Teleconference, Melbourne, 18 June 2007.



There are serious access issues: the Australian Pain Society did a waiting-in-pain project. We did questionnaire surveys...essentially Victoria is under serviced for places in pain management clinics, and this is historical. Our wait time has improved though, but there are more positions for pain management clinics in South Australia than there are here...<sup>603</sup>

According to Dr Hogg these time limit issues can seriously impact on the quality of the service general practitioners can afford their patients presenting with pain-related symptoms:

I think GPs are treading water. I think the idea of 'I want to give a five-year plan to this patient, or a one-year plan, and we are going to work over 10 visits', I do not think that comes about. It is crisis management or keeping them the same; they are not challenging them and giving them a medium to long-term plan...

It worries me to just send patients out of the hospital on opioids. We have started them off [on higher doses] expecting the GP to drop them down. It does not get dropped down, and the GP just keeps prescribing them, saying, 'Oh well, if you have still got pain, this [drug] will stop it'. He or she is not going to challenge them. He is not going to push them into rehab. He or she is not going to push them back to the specialist to say, 'Let's get them off it'.<sup>604</sup>

### State level organisational issues affecting medical practitioners

Other structural impediments according to Dr Hogg are the way pain treatment services are organised at state level and how they coordinate or rather fail to coordinate with other services such as alcohol and drug treatment:

There is also a real problem at the policy level at DHS. The clinic that I run is SACS-based, as is Caulfield, but we run on a different funding model to Geelong. We run on grants and Medicare clinics. The Austin runs on Medicare clinics, St Vincents runs on federal grants. We cannot benchmark against each other. We do not know about catchment areas, essentially the big public ones get given those. We lose out on some of the compensable patients, so we lose income. There is a real issue there. There are holes in all our services. Our hole is psychiatry, but we have a good drug and alcohol service; versus Caulfield's hole, which is drug and alcohol services. We need some consistent approach from the DHS so that we can develop along those lines.<sup>605</sup>

### Corporatisation of medical clinics

Other factors pertaining to the organisation of medical practice that can impact upon prescribing (and over-prescribing) include the 'corporatisation' of medical clinics. For example, Dr Mike Tedeschi informed the Committee that the situation in the Australian Capital Territory (ACT) is catching up to Victoria in terms of the number of corporate and bulk-billed clinics that have opened in recent years. According to Dr Tedeschi, ACT doctors can be seeing on average up to 60 patients a day. Such a workload impacts on good clinical practice, including prescribing practice.<sup>606</sup> Drug and alcohol workers in Ballarat made similar comments to the Committee. In their view the rotating system in the 'mega clinics' can sometimes mean that one doctor (or pharmacist) will not necessarily have a complete understanding of the patient's history and will not always have the time to review the patient's file to check his or her interactions with other medical staff.

603 Dr Malcolm Hogg, Australian Pain Society, Royal Melbourne Hospital, Fellow of Australian and New Zealand College of Anaesthetists, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007.

604 Dr Malcolm Hogg, Australian Pain Society, Royal Melbourne Hospital, Fellow of Australian and New Zealand College of Anaesthetists, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007.

605 Dr Malcolm Hogg, Australian Pain Society, Royal Melbourne Hospital, Fellow of Australian and New Zealand College of Anaesthetists, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007.

606 Dr Mike Tedeschi, ANU Medical School, Canberra Hospital, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Canberra, 16 May 2007.

We have the Eureka Medical Clinic now that is open from probably seven in the morning till 10 at night seven days a week. It is bulk-billed. The doctors are on a rotating system there...people can rock up there and wait for an appointment with doctors. There has been a little bit of a shift away from people having their [own] general GP [who] follows that person all the way through...People can go in, take a number like at the supermarket and sit and wait and it is potluck who you get. Then it is up to the honesty of the person that is seeing the doctor to tell them what is really going on. It probably leaves a little bit of a window of opportunity for that to be abused because a client can go in and say, 'Look, I've been on this medication for such-and-such a time', and tell them a story, 'I normally see my usual doctor but I'm out of a script and you're open so' – in some cases, doctors may initially prescribe on the basis of if the person is telling the truth.<sup>607</sup>

### Impediments to pharmacists 'counselling'

Pharmacy groups who gave evidence to this Inquiry believe that pharmacists also face structural constraints that may impact upon their practice. For example, although pharmacists do receive a dispensing fee under the Community Pharmacy Agreement pharmacy remuneration scales may not be sufficient to allow pharmacists to spend more than a minimal amount of time 'counselling' a patient as to the nature of the drugs dispensed for him or her and how to take them safely. Nor will individual pharmacies necessarily be able to afford the luxury of setting aside a separate area to be used as a private 'counselling area'.<sup>608</sup> Similarly, they were concerned that financial matters may prevent pharmacists from dispensing daily 'pick up' doses of medications, particularly opiate pharmacotherapies, even if they were initially willing to do so.<sup>609</sup> However, the constraints for pharmacists and practitioners may not just be economic. Some health professionals have stated to the Committee that in cases where a patient may have a history of 'doctor shopping' and/or prescription drug abuse, a useful adjunct to good practice is to put a note on the prescription to the effect that the drug must only be dispensed at X pharmacy.<sup>610</sup> But

607 Mr Ray Beacham, Team Leader, Alcohol and Other Drug Centre Co-ordinator, Ballarat Community Health Centre, Evidence given to Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Ballarat, 29 May 2007.

608 The basic dispensing fee for pharmacists is currently \$5.15. There is no separate fee for counselling a patient/consumer nor is any component of the dispensing fee allocated specifically for such a purpose. A recent Report on dispensing practices with regard to scheduled 4 and 8 drugs with dependency properties has recommended that:

*'Based on the key finding that there is a need to facilitate appropriate communication between consumers and pharmacists it is recommended that: Pharmacies providing the service of dispensing [in instalments] should have a designated private area in the pharmacy where appropriate consultation between pharmacist and consumer can take place' (Lynton-Moll 2006, p.10). (Emphasis in original)*

609 See, for example, Evidence of Mr Irvine Newton, Pharmaceutical Society of Australia (Victoria), given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 19 June 2006; Evidence of Mr Darren Tyrell, Australian Nursing Federation (Victoria), given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 9 July 2007; and Evidence of Dr Mark Stoové, Turning Point Alcohol and Drug Centre, given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 9 July 2007.

610 See for example, Evidence of Dr Roger Brough, Drug and Alcohol Physician, South West Healthcare; and Mr Norm Ferrier, pharmacist, Monaghans Healthywise Pharmacy, given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Warrambbool, 29 May 2007.



such a practice in most circumstances would rightly rely on the consent of the patient.<sup>611</sup>

### Lack of prescribing skills training

Finally, a major constraint on good clinical and prescribing practice is the lack of appropriate undergraduate, postgraduate and ongoing education and training for doctors, pharmacists and other health professionals. The following remarks from Shakib and George (2003) are illustrative of the insufficient attention given in both undergraduate training and ongoing practice to the skills needed to prescribe:

Think back to your medical student training, and try to remember how much time was spent teaching prescribing. For most of us, it was usually a single lecture or two on basics such as putting the date at the top and signing your name on the bottom. In fact until recently the majority of medical school curricula have spent less than 1% of total teaching time on prescribing issues, with the majority of teaching time being spent on making a diagnosis.

Unfortunately, many do not appreciate that good prescribing is a skill, and one that needs to be learnt. Teaching therapeutics in medical schools has usually been drug centred, focussing on indications and side effects of different drugs and prescribing is something one picks up by watching the behaviour of others. There has been little focus on the process of prescribing which involves making correct decisions about the choice of medication and individualising it for the patient sitting in front of you (Shakib & George, 2003, p.35).

Shakib and George present the following table as a guide for optimal prescribing practices.

**Table 5.1b: Characteristics of good and bad prescribing**

Good prescribing	Bad Prescribing
Effective	Ineffective
Safe	Unsafe
Patient centred and individualized	Not patient centred
Acceptable to patient	Not suitable for patient
Appropriate (not too little or too much)	Inappropriate
Addresses expectations of patient	Causes patient distress and harm
Judicious use of resources	Higher cost
Well informed (evidence based)	Poorly informed
Based on unbiased information	Based on biased information
Low vulnerability to outside influence	Vulnerable to outside influence

Source: Shakib & George 2003, p.36.

<sup>611</sup> One way the use of such a practice could become more common is through the use of a 'drug contract', between doctor, patient and, where appropriate, pharmacist. Such a system exists in the ACT, particularly with regard to the prescription of benzodiazepines to those patients with a history of abusing the drug. 'Benzo contracts' were explained to the Committee when it met with drug and alcohol clinician Dr Mike Tedeschi of Canberra Hospital/ANU Medical School in May 2007:

'In the ACT we've got a really good system...we've got about 200 patients in the ACT where they sign what's known as a benzodiazepine contract. That contract then confines the patient to one doctor, one pharmacy, and that list is distributed monthly to every pharmacist and every doctor in the ACT. So unless they [the patient] want to drive to the coast at Bateman's Bay they've got to comply and that can work quite well...It is known as core compliance...every doctor has that list, every practice has and would know 'you're [the patient] on contract with Dr X' and only I can prescribe it and only certain [nominated] chemists can dispense it...'

Whilst Dr Tedeschi believes this system works very well given the demographics and geography of the ACT, he told the Committee he was not so sure it could work in larger population centres like Melbourne where there are many more doctors surgeries and pharmacies available to the 'doctor shopping' patient (Dr Mike Tedeschi, Canberra Hospital/ANU Medical School, in conversation with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 16 May 2007).

Training and educating doctors and pharmacists in prescribing and dispensing respectively will be discussed in Chapter 6.2.<sup>612</sup>

### *Duration of prescription and amount prescribed*

One of the issues that has arisen throughout this Inquiry both in Victoria and during the Committee's travel interstate and abroad has been whether the current stipulations with regard to the allowable quantity of a prescribed drug and time period it is prescribed for are appropriate. This is generally not so much a problem with regard to opioids as the prescribing of these drugs is relatively well regulated. Benzodiazepines, however, are not subject to the same restrictions.

In Victoria, evidence has been given to the Committee that stricter rules are needed regarding the length of time that benzodiazepines can be prescribed. Whilst Schedule 8 drugs certainly have stringent provisions for the periods in which they can be supplied,<sup>613</sup> generally there are no firm rules pertaining to the period other classes of drugs, including benzodiazepines can be prescribed.<sup>614</sup> Ms Cheryl Sobczyk, Clinical Nurse Manager at Bendigo Community Health Services, said there were certainly cases she knew of where the recommended duration for prescribing benzodiazepines was 14 days, yet prescribers were writing scripts for 50 plus tablets, that is, in excess of therapeutic requirements:

You do not need 50 tablets if you are only going to have 14 days of treatment.

...You do not need that many and that is part of the problem. The doctor might say, 'Only take so many', but they still have the packet there and their problem has not necessarily gone away. They get the feeling that it helped them sleep or whatever, so they take the whole packet and go back the next time, 'That helped me, doc. I'm still having these problems', so the doctor often will give them another packet. But now they have had 100 tablets when initially the guideline says...what is the use of a guideline if it is not enforceable or the doctors do not receive backup to support them? So they have got two packets out of

612 Albeit to state at this point that one example of deficient training that can lead to bad prescribing practices is found in the area of pain management. For example, in a submission to this Inquiry Mr John Galloway, Chief Pharmacist of the Tasmanian Department of Health, and his colleague Ms Mary Sharpe, stated:

'Essentially, it is our view that the issue is not that doctors should not prescribe these drugs but that they need to have the skills and training to appropriately select those patients who can be treated safely and effectively and who are very unlikely to sell or misuse their drugs' (Submission of Mr John Galloway, Chief Pharmacist, and Mary Sharpe, Deputy Chief Pharmacist, Pharmaceutical Services Branch, Department of Health (Tasmania), to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007).

This was a view also expressed by Dr Malcolm Hogg, a specialist pain clinician, when he gave evidence to the Committee at Public Hearings. (Dr Malcolm Hogg, Australian Pain Society, Royal Melbourne Hospital, Fellow of Australian and New Zealand College of Anaesthetists, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007. See also discussion in Section Seven.

613 And even in these cases some observers are critical that these rules can be more observed in the breach. For example, Ms Sobczyk of Bendigo Health Services was most critical that in the case of controlled substances there were certainly incidences she was aware of where practitioners were not bothering to obtain the relevant authorisation to continue prescribing after two months or the period required under the permit.

This was a practice that her colleague Ms Toni Riley of Toni Riley Pharmacies believed happened far too often. Not only in her view do some doctors not apply for the relevant permits, but 'Nobody follows up whether they do it or not' (See comments of Ms Cheryl Sobczyk, Clinical Nurse Manager, Bendigo Community Health Services, and Ms Toni Riley, Toni Riley Pharmacies, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Bendigo, 30 May 2007).

As indicated in Chapter 4.3, concerns have already been expressed by the Transport Accident Commission (TAC) that 51 per cent of doctors who had prescribed Schedule 8 drugs to TAC clients did so without having obtained the relevant permits (See Submission of the TAC to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006).

614 There are limitations on the amount of PBS drugs that can be prescribed per script. But as Peter Muhleisen, Pharmacist with Turning Point Alcohol and Drug Centre, remarked to the Committee, these limitations will not apply to cases where people access private scripts. In any case, according to Mr Muhleisen, the PBS limitations are still relatively generous. For example, diazepam can be prescribed on the PBS in amounts of 50 tablets per script (Evidence of Mr Peter Muhleisen, Pharmacist, Turning Point Alcohol and Drug Centre, given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 9 July 2007).



that doctor. The doctor says next time, 'I don't think you need it any more'. But the person says, 'Well, doc, I can't sleep without it'.<sup>615</sup>

Ms Bev McIlroy of the Glenelg and Southern Grampians Drug Treatment Service believes that time limit should be regulated through a permit system, although she acknowledges that before any arbitrary time period can be set there needs to be consensus as to what the therapeutic timeframe for a drug such as Valium is, and that consensus then written into appropriate guidelines.<sup>616</sup> In her words 'therapeutic value should be able to be measured'.<sup>617</sup>

Even if guidelines are in place advising doctors to minimise the amount of benzodiazepines, some people are of the opinion that many prescribers are either not aware of them or choose not to follow them. According to Mr Ange Vassallo, whilst state guidelines may advise a practitioner not to prescribe excessive amounts of alprazolam (Xanax®), neither state regulations nor Therapeutic Goods Administration regulations prohibit the packaging or the prescribing of the drug in large and arguably therapeutically unnecessary amounts:

If you are meant to take it [a benzodiazepine] for a 21-day period then you should be prescribed just that – 21 days of tablets. The longer a person takes benzodiazepines, the greater the risk of becoming dependent on the drug...If a patient is prescribed 50 tablets and takes them for the two to three weeks and then experiences tolerance or withdrawal within that time frame, the patient can mistakenly assume that his or her problems are increasing and that therefore he or she needs to continue taking the pills. So rather than going back to the GP and asking for more scripts the patient sees that there are enough tablets remaining for another course of two to three weeks, finishes the remaining tablets and before they know it they may have become dependent on the medication.<sup>618</sup>

Mr Vassallo's criticism was not based on mere academic considerations, it stemmed from personal experience. He testified to the Committee how, in his opinion, his partner who had a longstanding addiction to benzodiazepines had often been inappropriately prescribed benzodiazepines far in excess of therapeutic dosages:

Susan was prescribed Xanax on a number of occasions, scripts with two to three repeats — that is, 150 tablets. That is five months worth as compared to the recommendation of two to three weeks.<sup>619</sup>

Similar concerns were expressed by Mary Smith, a woman suffering from a long-term addiction to benzodiazepines. Until very recently Mary has attempted to obtain large amounts of benzodiazepines through 'doctor shopping' methods. As Mary indicates to the Committee in the following quote, it is not difficult to stockpile large quantities of prescription medications from relatively few prescribers. The instance cited by Mary, for example, shows how a huge amount of temazepam could be obtained from two doctors working in the same general practice over a one-week period:

615 Ms Cheryl Sobczyk, Clinical Nurse Manager, Bendigo Community Health Services, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Bendigo, 30 May 2007.

616 To a certain extent this is in fact done, see discussion below.

617 Ms Bev McIlroy, Service Manager, Glenelg and Southern Grampians Drug Treatment Service, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Warrnambool, 29 May 2007.

618 Evidence of Mr Ange Vassallo given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007.

619 Evidence of Mr Ange Vassallo given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007.

During the period April 22–29 – a matter of only 7 days – [I] attended 7 medical clinics including X<sup>620</sup> medical clinic ...The details of the X clinic scripts prescribed during the period are as follows:

April 22 Dr Jane	25 Temaze (Computer script)
April 26 Dr John	50 Temaze (Computer script)
April 26 Dr John	25 Temaze (Handwritten script in the name of another clinic)
April 29 Dr Jane	50 Temaze (Computer script).

All prescriptions were written at the same clinic, including the paper script which was post-dated. This script was written at the same time as the computer generated a prescription for 50 temazepam.<sup>621</sup>

It is interesting to note that two doctors at the same clinic were prescribing the medication.

Ms Rosemary McLean of the Australian Drug Foundation gave similar anecdotal evidence to the Committee on the inappropriate prescribing of large amounts of benzodiazepines:

I was with friends the other night and said I was coming [to the Public Hearing], and this woman said she had been put on benzos short term because her back was in spasm, but even though she was only on it for five days, she could not remember if it was 50 or 100 tablets she got on the one prescription. She said: 'There is a problem, because if I use a fraction of that, they are around, if I had teenage children or someone else who could access them'. 'Why do they have to prescribe them in such huge amounts when I only needed a few?'<sup>622</sup>

In Ms McLean's view the above anecdote reflects 'a systemic problem in how they [doctors] prescribe'.<sup>623</sup>

Finally, in the context of prescription drug misuse among young people the community and youth service provider *Youth Projects* strongly recommended to the Committee that:

The maximum number of tablets/scripts prescribed at any one time be reduced (eg it is currently acceptable to give a script for 50 diazepam tablets)...[This reflects] an increasing tendency for patients presenting with anxiety and panic disorders to be medicated without GPs exploring the reasons behind the anxiety and other methods of addressing such issues.<sup>624</sup>

On the other side of the ledger, it has been stated by medical groups that such bad prescribing practices are relatively rare. According to the AMA (Victoria), a combination of the guidelines issued by the RACGP on the prescribing of prescription drugs, including benzodiazepines,<sup>625</sup> and the regulations issued by the Drugs and Poisons Unit of the DHS ensure that most doctors prescribe safely and appropriately. The AMA does recognise, however, that there may be a need for greater education of general practitioners on prescribing benzodiazepines, particularly with regard to patients who may be potentially misusers of these drugs.<sup>626</sup>

620 Details of the clinic in question have been omitted.

621 Submission of 'Mary' to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007. The name of the witness has been changed to protect her confidentiality.

622 Ms Rosemary McClean, Policy and Program Adviser, Australian Drug Foundation, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007.

623 Ms Rosemary McClean, Policy and Program Adviser, Australian Drug Foundation, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007.

624 Submission of Youth Projects Inc to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2007.

625 These guidelines have been discussed earlier in this chapter.

626 See evidence of Dr Mark Yates, Former President AMA (Vic) given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007. Further discussion of state regulation of benzodiazepines and the education and training needs of general practitioners is found in Chapters 4.3 and 6.2 respectively.



### The South Australian experience

In South Australia there are limits on both the amount of drugs that can be prescribed and the duration of the prescription. Even more stringent requirements are placed on the prescribing of controlled substances. Mr Keith Evans, Chief Executive Officer, Drugs and Alcohol Services of South Australia (DASSA), explained the system to the Committee:

In terms of our process, if a person turns up today to see their medical practitioner, the medical practitioner can prescribe for up to two months, assuming that it is not a drug-dependent person, in which case they need an authority right away. They are effectively permitted to treat for two months but in that period they have to obtain an authority from us. We do not make a clinical judgment about that application for authority, it is an administrative decision, and the people that we have who carry out that function are almost exclusively either pharmacists or people with training and background in the area, and with training in pharmacology.<sup>627</sup>

Thus in South Australia, after two months of treatment with any prescription drugs an authority must be obtained by the doctor to keep prescribing those drugs.

In addition, at the dispensing end, despite the quantity of drug prescribed in a prescription, a maximum of two days supply only can be provided unless the person for whom the drug is prescribed is known to the pharmacist or the pharmacist recognises the signature of the prescriber or the pharmacist has verified the prescription with the prescriber. According to a submission from DASSA to this Inquiry:

This ensures 'unfamiliar' prescriptions to the pharmacist are confirmed before dispensing but provides a minimum quantity if the prescription is presented after hours or on weekends when the surgery may not be able to be contacted.

Pharmacists cannot hand over the medication until the patient has signed and dated for receipt of the drug and if the person for whom the drug is dispensed, or the agent, is not known to the pharmacist they must provide satisfactory evidence of their identity. Signatures, with supporting identification, of the person collecting the medication assist in the identification of that person in cases of fraud.

Pharmacists who have reasonable cause to suspect they have been presented a forged prescription or document or fraudulently altered document must deliver any such document or prescription to the Commissioner of Police (Section 30 of the *Controlled Substances Act* 1984). Thus pharmacists have no discretion in their handling of a suspected or known forgery, must not return it to the person, which is usually demanded back if dispensing refused. The police and the Unit have developed a standard report form for this reporting with the original being forwarded to a central desk in the Drug and Organised Crime Section of the police for monitoring and then forwarding to the relevant police area for follow up and the pharmacists faxes a copy of the form to this Unit.<sup>628</sup>

### Package sizes

As can be seen from the previous discussion, obviously linked to the amount of the drug prescribed is the issue of how those drugs are packaged. Some information has been given to the Committee that pharmaceutical companies encourage pharmacists to buy larger packets of drugs and give them discounts if they do so:

I have had a couple of issues with some of the drug companies in recent times about their promotion of products...For example, we have a major problem with Nurofen Plus. The company involved there I think is totally irresponsible. They are always trying to push pack sizes of 72 onto us – 'We'll sell you 72s'. We refuse to buy the 72s, so they then cut us out

627 Mr Keith Evans, Chief Executive Officer, Drugs and Alcohol Services of South Australia, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Adelaide, 18 May 2007.

628 Submission of Mr Geoff Anderson, Manager and Chief Pharmacist, Drugs of Dependence Unit, Drug and Alcohol Services South Australia, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2007.

of the discount scheme. They say, 'No, you've got to buy the 72s or we won't give you the discount'. We try and sell only the 12s and 24s, but there are a lot of people who come in for the codeine in the Nurofen Plus and they say, 'How come you don't sell the 72s? I want to get the 72s'.<sup>629</sup>

It should be noted that Nurofen Plus is a pharmacy-only drug rather than one that must be prescribed by a doctor. Nonetheless, Ms Toni Riley told the Committee that whilst the profit motive of the pharmaceutical companies cannot be discounted, it is the PBS on the advice of the Pharmaceutical Benefits Advisory Council (PBAC) that ultimately sets the limits of prescription amounts and drug packaging:

Package sizes for things that are on the PBS are governed by the PBS. If the PBAC made a decision that 20 tablets or 10 tablets is the size, the pack sizes would change overnight. It has to be at that level. We would be able to influence the drug companies, but the reality of the matter is, why would they change them when the PBS quantities are 50 or 25?<sup>630</sup>

Pharmaceutical companies also claim that PBS rulings and directives circumscribe many of the issues pertaining to size and packaging. In addition, current packaging, particularly through foil blister packages and the like, guarantee that the product will be safe and contamination free. For example, during the Pharmaceutical Company Forum held by the Committee in July 2007, Dr John Whitlam of Mundipharma stated:

I was a hospital pharmacist more than 30 years ago and we used to count every single capsule and tablet from bottles of a thousand or more. That was considered to be inefficient, it was considered hazardous because we were handling capsules and tablets, and [there was a risk of] contamination. Single pack dispensing came in, unit dose came in...I understand the way the PBS is set up at the moment [a pharmacist] can break a pack.

[Drug packaging] of opioids is really dictated by the Pharmaceutical Benefits Branch. It is not legislated and they decide what quantities of products will appear on the PBS.<sup>631</sup>

Dr Greg Pearce, Medical Advisor with the pharmaceutical company Alphapharm, remarked to the Committee that if anything 'The trend is now for us to package in smaller units'. He continued:

Recently we have repacked zolpidem. We used to have them in 20s. We now, on request from the TGA, have repackaged them as sevens. So there is a tendency [to] standardise presentations into smaller pack sizes.<sup>632</sup>

Dr Pearce stated further that most pharmaceutical companies attempt to do the responsible thing, but it would also be helpful not to have unfavourable pricing arrangements that favour big packs against small packs. Currently, as with most unit cost pricing, it takes a greater share of overhead to produce a smaller volume of product than a larger size.

Clearly, pharmaceutical drug companies can play a responsible and constructive role with regard to issues such as the packaging of prescription drugs. Another area in which the pharmaceutical industry can also be good 'corporate citizens' is in reformulating their products to minimise abuse.

629 Mr Norm Ferrier, Pharmacist, Warrnambool, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Warrnambool, 29 May 2007.

630 Ms Toni Riley, Pharmacist, Toni Riley Pharmacies, Bendigo, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Bendigo, 30 May 2007.

631 Dr John Whitlam, Director of Medical Affairs, Mundipharma, Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Pharmaceutical Company Forum, Parliament House, Melbourne, 16 July 2007.

632 Dr Greg Pearce, Medical Advisor, Alphapharm, Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Pharmaceutical Company Forum, Parliament House, Melbourne, 16 July 2007.



### *New formulations and products*

With the expressed intention of improving therapeutic outcomes and reducing side effects, pharmaceutical companies are constantly developing new products and revised formulations for existing products. New products may have medical benefits, but they should also be examined to assess the risk for deleterious and unforeseen consequences. This issue is now being recognised overseas and has already been discussed in the context of the American experience in Chapter 4.1 of this Report. Nonetheless, it is pertinent to point out that in the United States currently:

Nearly every [new] product of abuse is required to have at least an evaluation of risk at the time of application...Risk management programs may address elements such as the package insert, proper patient selection, education of patients and healthcare providers, assessment for diversion along the distribution chain to the patient, post-marketing surveillance, and definition of and specific restrictions on marketing practices. The intensity of the program is generally tailored to the degree of perceived risk (McCormick 2006, p.566).

Another deliberate strategy to reduce the abuse potential is the reformulation of drugs by pharmaceutical companies. Reformulation can include:

...combination products with an oral formulation of opioid with antagonist, formulations with other aversive characteristics...physically impenetrable formulations, and drug device combinations with patient recognition capability (McCormick 2006, p.566).

Common examples of such strategies include:

- ◆ formulations that affect the solubility of a drug (thereby reducing the potential for injection);
- ◆ adding a drug such as naloxone to buprenorphine. This means that if such a drug is injected an opioid dependent person will experience withdrawal symptoms, but will not experience such an outcome if the drug is taken as intended; or
- ◆ adding a dye, to prevent surreptitious administration of a drug by a sexual predator.

In the American context there has been much lobbying for the drug regulatory, scheduling and approval process to provide incentives to pharmaceutical companies to 'develop formulations of current and future drugs with reduced potential for abuse' (Grudzinskas et al 2006, p.81). Certainly the evidence in the United States is that pharmaceutical companies are increasingly devoting much research time, money and energy to reformulating drugs to make them 'tamper proof' or at least less likely to be abused by recreational drug users (Muir 2006).

This issue of reformulation was also discussed in Chapter 4.1 and as such does not bear repetition here, albeit to state that it may be worthwhile to consider the merit of such strategies in Australia. Certainly this is the view of some organisations that gave evidence to this Inquiry. For example, the Victorian Alcohol and Drug Association (VAADA) believes that guidelines should be developed by the Victorian government in collaboration with expert advisers to assist pharmaceutical companies assess the abuse potential of pharmaceutical drugs and the possibility of reformulating where appropriate to increase their safety and therapeutic value. In a submission to this inquiry, VAADA stated:

The guidelines would consider

- Whether ingredients of any new pharmaceutical products are currently associated with misuse
- Whether component ingredients of any new pharmaceutical products have properties that would make them likely to attract misuse (are psychoactive, analgesic, addictive, etc)
- Encourage the design of new pharmaceutical products that contain ingredients less likely to attract misuse, specifically assisting them to
  - Avoid product designs associated with misuse, such as

Easily injectable substances, including gels, liquids, soluble powders

Large dosage sizes

Leading information on package inserts

- Select product designs likely to deter misuse, such as

Including antagonist substances within the product, where feasible.<sup>633</sup>

Developing new products and reformulating drug formulae presents some challenges, and indeed historically drug misusers have ignored some of these strategies or otherwise found ways around such preventive measures. For example, as a study by Schuster found:

Although medicinal chemists are continuing to develop new medications with the hope of separating their therapeutic actions from their abuse potential this approach has not been successful for important indications such as pain, anxiety and ADHD. There appears to be promise in the development of formulations that will decrease the abuse potential of medications for such indications. It is unlikely, however, that any formulation can be developed that cannot be altered by 'street chemists' into a more abusable form. Hopefully, however, the 'cost' in time and effort to do this will act as a serious deterrent to the diversion and abuse of such formulations (Schuster 2006, pp.13–14).

As promising as such developments may be, it is beyond the scope of this Report to examine these various methods in detail, but certainly this is an issue that merits further research in the future.

### *Disposal of medications*

The issue of medications disposal was brought to the attention of the Committee during the Inquiry. Concerns have been expressed on two levels. First, there is an issue with regards to medication that is either in excess of need or no longer required by the patient (for example, because they have died or recovered from their illness).

Second, what impact does the inappropriate discarding of surplus medicines have on environmental systems?

### **The dangers of surplus or stockpiled medications**

The Committee has received evidence from a number of agencies and individuals as to the lack of appropriate guidance consumers receive with regard to prescription drugs that are surplus to their requirements or no longer needed. This may particularly be the case where a patient has died and family members or carers are unsure what to do with any remaining medications.

Often the situation may arise where a hospital discharges a patient with medications for use during the convalescent period at home. Sometimes the amount of medicine dispensed may be for fairly long periods and if the patient either dies or makes a speedier recovery than expected there is a chance that the drugs can be stockpiled.<sup>634</sup> The following evidence provided to the Committee by Mr Darren Tyrell, an officer of the Australian Nursing Federation, is fairly typical of the type of accounts the Committee received in this regard:

I am speaking from personal experience. I had a relative who passed away a while ago and I was quite concerned about the amounts of opiate-based medication she was sent home with and the way it was secured in the home. There was a relative about whom I was concerned who might be vulnerable and use it. I actually spoke to the family. I took them aside and said, 'I think you need to be careful about how you store that medication', and I

633 Submission of Victorian Alcohol and Drug Association to the Drugs and Crime Prevention Committee Inquiry into the Misuse/Abuse of Benzodiazepines and other Forms of Pharmaceutical Drugs in Victoria, June 2007.

634 There is also the related problem that such stockpiles may be used for diversion and drug trading, either by the relative of a deceased patient or in some tragic circumstances the patient. This is particularly a risk with opioid drugs used to treat cancer and/or chronic pain. See, Evidence of Ms Mary Sharpe, Deputy Chief Pharmacist, Tasmanian Department of Health, given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Teleconference, 18 June 2007. See also the discussion of drug diversion in Chapter 2.4 of this Report.



told them why. They had not made the connection. I guess I had concerns for the safety of this person. In that instance when the hospital sent this relative home on medication...I was not satisfied with the way it was just put in the cupboard for anyone to access.<sup>635</sup>

Mr Tyrell also stated that these relatives were unsure of what to do with the medication once the person in question had died.

Mr Tyrell's colleague Ms Jill Clutterbuck told the Committee it is true that there is a fair amount of uncertainty as to what should be the correct procedure in storing and disposing of medications in these circumstances. The uncertainty is felt not only by patients and their relatives but also by members of the nursing profession:

Our organisation [The Australian Nursing Federation] has actually had queries from nurses working in community areas around that issue of returning drugs of dependence. We have not had a lot of queries, but we have had some, and I think it probably is an area of concern – not just about knowledge of how it gets returned but about practices around its being transferred on for other use, which is not good.<sup>636</sup>

The last point raised by Ms Clutterbuck refers to the issue of transferring or reusing the medication of one person by another. Some anecdotal evidence has suggested that this may be a prevalent practice among some family members, particularly inter-generationally.<sup>637</sup>

The Committee has received very little evidence as to whether there are official programmes, protocols or advisories for patients and their families on the safe and responsible return or disposal of prescription drugs. Whilst the National Prescribing Service has produced some useful and informative online material giving details about safe storage and disposal of medicines, such information is not as readily available as it could be, requiring the consumer to have advance knowledge of the National Prescribing Service and its materials.<sup>638</sup>

Given concerns raised with the Committee as to the relatively high levels of deaths and illness through medical misadventure this would seem to be a significant oversight in community health approaches. Whether such information comes from a hospital on discharge, a community health centre, doctor's surgery or local pharmacy, it is imperative that guidelines or protocols be developed and, more importantly, disseminated through networks easily accessed by patients, their families and carers.

One project that is, however, of significant merit from both a safety and environmental perspective is the National Return and Disposal of Unwanted Medicines Project, known as the RUM Project.

635 Mr Darren Tyrell, Drug and Alcohol Nurse/Professional Officer, Australian Nursing Federation (Victoria), Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 9 July 2007.

636 Ms Jill Clutterbuck, Senior Professional Officer, Australian Nursing Federation (Victoria), Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 9 July 2007.

637 For example, mothers passing on their benzodiazepines for their daughters to use. This particular aspect of the problem and the wider issue of accessing drugs through the use of another's prescribed medications are discussed in Chapter 2.3.

638 See National Prescribing Service website at [www.nps.org.au](http://www.nps.org.au)

In particular the online information forum *Medicines Talk* and the current campaign run by the National Prescribing Service, *Get to know your medicines*, whilst not specifically pertaining to disposal of medicines, are informative with regard to the safe use of medicines generally. For further discussion of these projects, see Chapter 6.1.

### Disposal of medicines and their effect on the environment

There is an increasing concern that inappropriate discarding or disposal of unwanted or surplus prescription and other drugs can have a deleterious effect on environmental and ecological systems.

This has certainly been an issue of growing concern in the United States, where a variety of state and federal information projects have been devised to make consumers more aware of the effects of inappropriate disposal of their medicines on environmental systems.<sup>639</sup>

Data collected in Australia by the RUM Project shows that 'more than 300 tonnes of medicines are being inappropriately thrown out in Australia each year...[and] find their ways into waterways and landfill...' (National Return and Disposal of Unwanted Medicines n.d.).<sup>640</sup>

The most common means of disposal – down the sink or toilet, or in the bin – can all lead to poor environmental consequences. Simon Appel, Project Manager for the RUM (Return of Unwanted Medicines) Project states in this regard that:

Where the dangers associated with disposing chemical waste are well understood, many people don't associate the same danger with medicines, and thus, large volumes continue to be discharged to the environment via the garbage, drains or toilet. The fact is sewage treatment plants aren't designed to treat all the substances contained in medicines so when they go down the toilet or the sink, some of these chemicals could end up in our rivers and creeks where they may cause harm.<sup>641</sup>

For example, Mr Appel lists some of the key medicines or their key components that can cause environmental damage including:

- Oestrogen, which even at low levels can have a feminisation effect of male fish, which could cause great harm to future breeding populations of the affected species.
- Antibiotics, which have acute effects on bacteria, yet can alter microbial community structures in nature and thereby affect the higher food chain. Their use in aquaculture results in eventual human consumption.
- Antidepressants/Obsessive-Compulsive Regulators, which has subtle, but possible profound effects on aquatic species, such as affecting the fighting behaviour of lobsters.
- Retinoids, which have profound effects upon the development of various embryonic systems, especially in amphibians, where retinoic acid receptors have been hypothesized to play a role in frog deformities.<sup>642</sup>

To address these and other environmental and safety issues, the RUM Project was formed in the late 1990s. The project was initially developed as a result of there being 'no consistent means of [drug] disposal which meet state environment and hazardous waste guidelines' (National Return and Disposal of Unwanted Medicines n.d.).<sup>643</sup>

639 For example, see the Federal Guidelines on the Proper Disposal of Prescription Drugs produced by the Office of National Drug Control Policy (ONDCP) and attached as Appendix 15. For an example at state level, see the leaflet, Return of Prescription Drugs to a Pharmacy, developed by the Kentucky Board of Pharmacy.

The Committee also received anecdotal evidence that the environmental consequences of unsafe disposal of prescription and other medications was an issue of growing concern during its fact-finding tour of North America in July/August 2007.

640 Accessed at <http://www.returnmed.com.au/>

641 The RUM Project, Press Release – Environmental Spotlight on Unwanted Medicines, 28 March 2002. Accessed at <http://www.returnmed.com.au/>

642 The RUM Project, Press Release – Environmental Spotlight on Unwanted Medicines, 28 March 2002. Accessed at <http://www.returnmed.com.au/> See also Pharmaceuticals and Personal Care Products in the Environment: Agents of Subtle Change? *Environmental Health Perspectives*, Volume 107, Supplement 6, December 1999

643 Accessed at <http://www.returnmed.com.au/>



The National Return and Disposal of Unwanted Medicines Ltd is a national not-for-profit company set up to enable consumers to return unwanted or out-of-date medicines to any pharmacy, at any time. The medicines returned are not reused or recycled but disposed of through high temperature incineration. The RUM project is jointly supported and funded through the Commonwealth government, the Pharmaceutical Society of Australia, the Pharmacy Guild of Australia, the Council on Ageing and the Australian Institute of Environmental Health. A copy of the current RUM project community information brochure is attached as Appendix 13.

Whilst programmes such as RUM are to be commended, it may be that this issue will definitely need a watching brief in future years. Further research definitely needs to be undertaken to determine the extent of the problem before any comprehensive strategies can be implemented to address it.

### ***Information and monitoring systems***

As consistently indicated in this chapter, ensuring compliance with regulations and guidelines, ensuring QUM, and enhancing quality practice by prescribers and pharmacists are reliant on establishing and maintaining quality information and monitoring systems. Although such information and monitoring systems are in place in Australia there are questions around their comprehensiveness and effectiveness, as indicated in Chapter 4.2. For example, implementation of the PBS involves gathering information and data on prescribing practices. Based on this information the Professional Services Review Scheme may examine health professionals whose practices have raised concerns. Medical practitioners can register with the Prescription Shopping Program to access patient information that can reduce the risk of pharmaceutical misuse. However, it appears there are limitations with these current systems.

### ***The effect of monitoring on prescribing practices***

Although the issue of prescription drug monitoring and review at both national and state levels has already been discussed in Section Four of this Report, it is pertinent in the context of this chapter to ascertain the effect, if any, monitoring systems and legal controls have on prescribing practices. There is little empirical data in this area and few qualitative studies outside the United States (Room 2007). However, in the context of that country's experience, as Room indicates, 'It is clear that prescription registration systems, along with the limitations on dose and duration of prescription usually associated with them, substantially affect doctors' prescribing behaviour' (Room 2007, p.26).

In North America it does seem to be the case that drug monitoring and regulation has led to a shift from one form of drug to another, with the substitute drug sometimes being as dangerous as the original drug being regulated, if not more so:

As a number of the studies underline, the result is often not much a reduction in prescriptions as a substitution of prescriptions for substances which are not so heavily controlled. In the case of barbiturates, it is clear that, from the perspective of drug-related deaths, the switching which resulted from their inclusion in the prescription registration systems was beneficial. It remains an open and interesting question whether this change happened equally completely and equally as fast in jurisdictions which did not make this regulatory change. A guess would be that, though the change happened in the end, it was probably not so fast. In the case of benzodiazepines, the outcome of inclusion in prescription registration systems in terms of drug-related adverse events is much more questionable, since the switching was often to drugs with a worse record...

Shifting a prescribed drug onto a special prescription register, in conjunction with guidelines which limit prescriptions, usually results in a substantial drop in prescriptions of that drug. The effect seems to be partly from the extra trouble involved in a registered prescription, and partly from the deterrent effect on the physician of the threat of sanctions. However, a large part of the prescriptions will be replaced by prescriptions for a substitute drug which is less

controlled. In some cases, where the substitute drugs are less harmful, the result is a clear gain from a public health perspective. In other cases, it has been argued that the result of the shift was a net loss for public health (Room 2007, pp.26, 31).

For example, when regulation of benzodiazepines by means of triplicate prescription was introduced into New York State in 1989 'the subsequent reduction in benzodiazepine prescribing was mirrored by a rise in the use of older, more hazardous compounds in long term care facilities' (Quigley 2001, 332).

It would be useful to have local research undertaken as to the flow-on effect of regulation, monitoring and/or rescheduling of drugs in Australia. This could become particularly important if a benzodiazepine such as alprazolam was moved into a higher schedule in the future.<sup>644</sup>

#### **Information systems and data collection**

Some of those who made submissions to the Inquiry also raised concerns about the limited coordination of data and occasionally the poor use of information by key personnel, including coroners.<sup>645</sup> Whilst it is not possible to quantify these concerns, they did reflect a high degree of distress and dissatisfaction with the current systems of information coordination, especially in the event of a drug-related death.

As stated, however, both monitoring and information systems and their respective strengths and weaknesses have been comprehensively canvassed in Section Four of this Report.

### **Conclusion**

It is evident that in Australia, as in other countries, the risk of prescription medicine diversion and misuse has been recognised and a range of responses have been developed. Regulatory processes have been established to ensure quality use of medicines in general and to reduce the risk of diversion and misuse in particular. State and Territory statutory bodies have developed procedures to reduce a range of risks from 'drugs of dependence', and professional boards and groups have produced guidelines that support such aims.

The brief review in this chapter suggests that such procedures are consistent with international practice and, in general, procedures and guidelines have been comprehensively developed using credible processes and involving representatives from the key professions and agencies. However, the evidence base to assess the effectiveness of these strategies is limited. This is a concern for two reasons. First, it limits the ability to direct investment to those strategies that are cost-efficient and away from those that are ineffective. Second, there is some concern that strategies may have unintended impacts on patients who have 'genuine need' and whose care may be compromised.

These approaches all rely on quality information and monitoring systems. There is currently insufficient information available that can inform the Committee as to whether these systems can be improved. It is, however, important to note that other countries are reviewing and attempting to improve their systems. This chapter has focused very much on the health services. As noted in this Inquiry, pharmaceutical diversion and misuse has relevance for health and other groups such as law enforcement. Lessons from overseas, and local reviews, suggest that it may be appropriate to review the information and monitoring systems in concert with developing a coordinated intelligence system that can guide practice across the various systems, whilst at the same time ensuring patient care and patient confidentiality are not compromised.

Finally, although various statutory bodies and professional groups have responsibilities to review the context and nature of professional practice, no evidence was found on the

<sup>644</sup> See discussion in Chapters 2.2 and 3.1.

<sup>645</sup> See for example submission from Mr Leon Hain to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, April 2006.



effectiveness of these initiatives. It may be timely to review the adequacy of such procedures and in particular assess whether adequate resources are allocated to ensure effective implementation of compliance strategies. As such, the Committee will be interested to see whether a forthcoming review of benzodiazepine use and prescribing by the Royal Australian College of Physicians expresses similar viewpoints and concerns.

The Drugs and Crime Prevention Committee believes that most members of the medical professions responsible for drug prescribing perform their duties in a responsible and conscientious manner. Nonetheless, the Committee also has serious concerns with regard to the evidence presented to it that on occasion prescribing practices, particularly with regard to benzodiazepines, can be inconsistent or at worst, careless. For example, unless clinically necessary or appropriate, there seems to be no reason for doctors to prescribe benzodiazepines, particularly those of high potency such as Alprazolam, for more than the shortest period commensurate with good clinical practice. As such, the Committee believes the Medical Practitioners Board of Victoria should be responsible for developing appropriate standards and the distribution of authoritative information to doctors in relation to safe prescribing of benzodiazepines and opioid analgesics.<sup>646</sup>

<sup>646</sup> For further discussion with regard to the information and education needs of doctors and other health professionals in prescribing and/or dispensing benzodiazepines and other prescription drugs, see Chapter 6.2.

## 5.2 Health Information Technologies: The Electronic Prescribing of Medicines

### Introduction

In a time of advanced technological communications, the use of the Internet to promote health and wellbeing is clearly attractive. Electronic prescribing is currently in use in the United States and other countries, and has been put forward by a number of witnesses to this Inquiry as a mechanism that can address many of the problems associated with prescription drug misuse and abuse. In particular, electronic prescribing and the technology that supports it can be buttressed to address issues such as 'doctor shopping', prescription fraud and medical misadventure. In addition, the proponents of e-health and tele-health systems argue that such technology can clearly be of benefit to people in remote and rural parts of the country where access to a pharmacy may be difficult. There are, however, also serious problems associated with accessing drugs from the Internet, particularly through illegal means, which will be discussed in the following chapter.

### Electronic prescribing in the United States

The oversight of electronic prescribing in the United States is the responsibility of the federal Drug Enforcement Administration (DEA), Office of Diversion Control. Currently, whilst there are a number of commercially operated prescribing systems that electronically transmit prescriptions for non-controlled drugs, until relatively recently it was not permissible to prescribe controlled substances using electronic means. Over the past five years the DEA has been in the process of overhauling its regulations to allow for electronic transmission of prescription medicines, including controlled substances.<sup>647</sup> This process is being undertaken through the Electronic Prescriptions for Controlled Substances (EPCS) Project.

According to the DEA the EPCS is 'expected to bring numerous benefits to both the healthcare community and the patients they serve' (DEA 2006, p.1).

**[Such benefits reduce] medical mistakes** – There have been numerous reports concerning the impact of prescription mistakes. Some reports estimate that prescription drug errors kill over 7000 patients each year in the United States. The DEA understands that automating and electronically transmitting prescriptions not only benefits the health care industry in terms of cost reduction and increases in efficiency, but such a system also provides tangible benefits to the patient community.

**Improve healthcare efficiency** – Electronically prescriptions not only reduce the amount of time spent processing prescriptions in the pharmacy; they also improve practitioner efficiency when these systems are linked to patient records and drug utilization review. By prescribing electronically, practitioners get fewer call-backs and patients receive their prescriptions faster.

<sup>647</sup> For a list of controlled and regulated substances under the US Controlled Substances Act 1970, see Chapter 4.1.



**Reduce prescription forgery** – Pharmacists are routinely faced with the problem of determining the validity of controlled substance prescriptions – has the prescription been altered or is it a forgery? EPCS prescriptions will be secured using strong digital signatures thereby enabling pharmacists to quickly determine whether a prescription has been altered or if the prescriber is DEA-registered (DEA 2006, p.1.)

The use of electronic prescribing and dispensing will not be mandatory for prescribers or pharmacists under the envisaged new system. Given the significant costs expected in implementing the technology, doctors and pharmacists registered to prescribe or dispense controlled substances with the DEA will have the option of continuing with the current process of manual 'paper prescribing'.

### **Technical and security provisions**

The DEA describes the envisaged system for securing electronic prescriptions as follows:

Frequently, the last business processes [such as prescription writing] to be automated are those that require a 'wet signature' [handwritten signature]. In the electronic world, Public Key infrastructure (PKI) can replace the traditional approach with a more robust method that delivers both message integrity and non repudiation. The solution combines a 'document fingerprint' with public key cryptography. Public key cryptography provides a mechanism for encrypting information. It is an important tool used in creating a digital signature. The encryption algorithm is asymmetric – that is, it uses two distinct keys, or numbers. The owner keeps one key private and makes the other public. What one key encrypts, only the other can decrypt. Because neither key can be derived from the other, there is no vulnerability in sharing the public key.

**Signing a document** – First, the sender's computer runs the document through a complex algorithm to generate a fixed-length message digest – the unique document fingerprint. If even one letter in the document changes, the fingerprint also changes. Now the sender can use his or her private key to encrypt the digest. The encrypted digest, called a 'digital signature', is then sent along with the message.

**Verifying a signature** – Upon receiving the digitally signed document, the recipient uses the sender's public key to decrypt the signature and obtain the original message digest. If the signature can be decrypted with the sender's public key, then only the sender could have sent it (the sender's private key was used to encrypt the digest). This provides the service of non repudiation. The recipient then calculates a new message digest and compares this with the one that has just been decrypted. If they match, the document has not been changed. This provides the service of message integrity. This process is instantaneously and transparently performed by PKI-enabled systems (DEA 2006, p.2.).

As a further step in the security process, electronic prescribing in the United States must be subject to stringent checking from a Certification Authority (CA):

A Certification Authority (CA) is an entity that issues digital certificates to applicants. It also makes certificates, status information available to relying parties. In this capacity, it acts as a credible and neutral trusted third party. Subscribers implicitly trust any information that is digitally signed by the CA. The CA performs a number of important duties, including:

**Enrolment** – Before issuing a digital certificate, the CA verifies the identity of the applicant to ensure that the digital certificate is being 'bound' to the correct individual and not to an impostor. Depending on the intended application, some CAs require in-person enrolment while others may allow enrolment over the web. Such procedures are defined in the Certificate Policy (CP).

**Revocation** – Digital certificates can be revoked for a number of reasons including loss or compromise. The CA lists these un-trusted certificates on a Certificate Revocation List (CRL) in the same way that credit card companies once published list of invalid credit cards. The CRL is digitally signed by the CA and is valid for a specific time period (DEA 2006, pp.2–3).

Only registered DEA medical practitioners will be eligible to apply for and obtain an Electronic Prescribing for Controlled Substances (EPCS) digital certificate. This will be valid for one year and then must be renewed. Receipt of such a certificate will enable the doctor to electronically transmit controlled substance prescriptions.

### ***Obligations of pharmacists***

Unlike DEA registered medical practitioners, pharmacists as 'relying parties' will not receive EPCS certificates of their own:

However, the electronic prescription system they use will be required to be EPCS-compliant. This means that the software must perform the EPCS-defined relying party obligations – identified below – prior to accepting the controlled substance electronic prescription (DEA 2006, p.7).

Upon receipt of a digitally signed prescription, 'relying parties' such as the pharmacist must ensure that the digital certificate used to digitally sign the message has not expired (DEA 2006, p.4.).

The pharmacist must also check the status of the practitioner's EPCS digital certificate to ensure that the practitioner is still a DEA registrant by verifying the practitioner's EPCS digital certificate is not listed on the CRL. The pharmacy must also verify that the practitioner is authorised to prescribe the appropriate schedule of controlled substances. The pharmacy must reject the prescription if the practitioner's digital certificate has been revoked, or if the practitioner does not have the proper privileges to prescribe the class of medication...For valid EPCS prescriptions, the pharmacist must electronically sign the electronic prescription so that the pharmacist can be bound to the act of filling the prescription (DEA 2006, p.8.).

According to the DEA, authorised computer systems can be programmed to perform all of these functions automatically.

The pharmacy must also maintain an electronic archive of all controlled substance prescriptions received for at least two years. DEA regulations regarding the management of electronic records will be formulated and updated over the next two years.

### ***Oversight of the system by the Drug Enforcement Administration***

To ensure the integrity of electronic prescribing systems, a raft of new DEA regulations pertaining specifically to the use of the new technology will be put in place. In particular, the DEA will operate the root Certification Authority (CA) under which all other CAs, such as commercial or governmental departmental authorities, will be subordinate:

While the DEA has the authority to take action against registrants, it was unclear how DEA regulations would apply to commercially or institutionally [government] operated CAs. In the event that a CA operates in an improper manner – inconsistent with the DEA's EPCS Certificate Policy – the DEA desires the ability to terminate the CA's ability to issue the EPCS certificates and to revoke all certificates issued by it. By operating a root CA, the DEA would have a mechanism to do this. While such a step would be drastic, it would only occur after discussions between the DEA and the CA, or after some form of legal action.

The DEA's current role as a registrar naturally positions it to perform a similar – yet reduced role – in the EPCS environment. Therefore, the DEA anticipates that it will implement the EPCS Root Certification Authority...Under this framework, commercial or institutional Subordinate CAs that agree to operate in accordance with the DEA's Certificate Policy – and who receive approval from the DEA – would be granted the authority to issue EPCS Digital Certificates to DEA registered practitioners and institutional authorised practitioners. To facilitate this, the EPCS Root CA will issue certificates to DEA approved Subordinate CAs (DEA 2006, p.5).

In addition to the security measures outlined above, vendors of approved software, practitioners and pharmacists 'will be required to perform a yearly audit of their



application to ensure that the software correctly performs the pharmacy obligations' (DEA 2006, p.6).

As the DEA itself notes, the EPCS has not been established as a reporting or monitoring system similar to those outlined in Chapter 4.1.

[i]t merely provides a PKI framework that will support the secure and trusted electronic transmission of controlled substance prescriptions between practitioners and pharmacy systems. However, since the prescription will be transmitted in an electronic form, this should make transaction reporting or monitoring easier when required by state laws or regulation (DEA 2006, pp.7–8).

In addition to this potential benefit of being an adjunct to Prescription Drug Monitoring Systems, the DEA argues that the EPCS process will bring the following advantages:

- Reduce the amount of paper in the process
- Speed transaction times
- Lower costs per transaction
- Introduce [higher] security services into the process (DEA 2006, p.2).

Clearly, the use of technological systems for electronic prescribing is at a fairly advanced stage in the United States. The next section of this chapter examines the extent to which similar developments are being replicated in Australia.

### Current developments in electronic prescribing in Australia

In the last few years the Commonwealth Government in consultation with the states has developed a number of initiatives that will eventually result in a fully integrated network for electronic prescribing across the country. In July 2006 the last legal impediments to the implementation of electronic prescribing for Pharmaceutical Benefits Scheme (PBS) medicines were removed with the passage of the National Health (Pharmaceutical Benefits) Amendment Regulations 2006. These laws became effective on 1 March 2007. In addition to changing the Commonwealth laws, state and territory legislative barriers have been identified and are currently in the process of being amended to complement the Commonwealth regulations and to provide the rules for electronic prescribing and dispensing in each jurisdiction. The development of key model technical and other standards, and the establishment of a national health information regulatory framework are also currently in the process of development (Department of Health and Ageing 2007a).

The impetus for the new regime has partly come from the Australian Council for Safety and Quality in Health Care's *Second National Report on Patient Safety* which, according to the Department of Health and Ageing:

[e]stimated 400,000 adverse drug incidents occur in Australia each year. Electronic prescribing will help eliminate those incidents that occur due to poorly handwritten paper prescriptions and transcription errors. It will also support long term moves to reduce waste in the PBS and improve patient safety stemming from duplicate prescriptions and adverse interactions between different medicines (Department of Health and Ageing 2007b, p.1).<sup>648</sup>

Other improvements the Commonwealth envisages as a result of introducing electronic prescribing include:

- Improved confidentiality and security of medication information;
- Better clarity and communication of prescription information;
- Rapid information exchange;
- More time with health professionals due to less paperwork;

<sup>648</sup> See also McInnes, Saltman and Kidd 2006 for a discussion of the benefits of health information technology, including electronic prescribing to address issues such as adverse drug events in general practice settings.

- Reduction in medication and dispensing errors;
- Decline in adverse drug events; and
- Mitigate against fraud risks present in the paper-based process (Department of Health and Ageing 2007a, p.1).

Whilst the legislative changes introduced and implemented in 2006 and 2007 have removed the main barriers to introducing electronic prescribing there are, according to the Commonwealth Department of Health, 'a number of additional steps that will need to be taken before the vision becomes a reality' (Department of Health and Ageing 2007a, p.1).

In addition to the required legislative and policy changes at state level, the Department believes that all governments:

[w]ill need to work with Medicare Australia, the National E-Health Transition Authority, IT suppliers and professional bodies representing doctors and pharmacists to put in place arrangements to ensure the successful operation of electronic prescribing. Key considerations to be addressed will include:-

- the need to ensure security of prescribing information and protect patient confidentiality;
- procedures to validate the identity of prescribers;
- mechanisms to allow patients choice over where and when they have their medicines dispensed;
- integration with doctors' and pharmacists' existing computer systems; and
- arrangements for secure archiving of prescription details (Department of Health and Ageing 2007b, p.1).

In Victoria, pursuant to Regulation 26 of the Drugs, Poisons and Controlled Substances Regulations 2006, the Secretary of the Department of Human Services has already given general approval for an authorised prescriber to issue computer generated prescriptions in circumstances that meet the following criteria:

1. The computer program will restrict access to the prescription-printing module to authorised persons.
2. Prescriptions will be generated only by authorised persons.
3. The prescription will be either printed with the prescriber's name, address and contact telephone number OR with the address and contact telephone number of the practice.
4. The prescription will be personalised to the prescriber by the addition at the time of printing of the name of the prescriber below the last prescribed item when the prescription is being generated.
5. The prescriber will sign, in his or her own handwriting, the prescription form beneath and as near as practicable to the last item prescribed on the form.
6. The prescription will not be pre-signed.
7. The total number of items prescribed on the prescription will be either stated on the prescription or the area on the prescription below the prescriber's signature will be scored, hatched or otherwise marked in some way to prevent any other item being printed in that area.
8. The particulars of any prescription issued will be included in the clinical or medication record of the person or animal for whom the prescription was generated.
9. The clinical or medication record of the person or animal for whom the prescription was issued will be preserved for at least one year from the date on which the prescription was generated and will be capable of being accessed when required.
10. Alterations will not be made to printed prescriptions. Where alteration is required a new printed prescription will be generated and the other prescription will be immediately destroyed.



In addition, in the case of drugs of dependence (which includes all Schedule 8 poisons and some Schedule 4 poisons):

11. Only one item appears on a prescription.
12. In addition to the printed particulars on the prescription, the prescriber will in his/her own handwriting write all of the particulars required under the Regulations (other than the date and the patient's or animal owner's name and address), namely:
  - the name of the substance or the proprietary product containing it,
  - the strength where more than one strength is available,
  - the quantity being prescribed (in both words and figures),
  - adequate directions for use,
  - the number of repeats authorised (in both words and figures).

The software program will automatically indicate that such handwriting is required (Department of Human Services (DHS) Victoria 2006f, pp.5–7).

### *How will the system work?*

It is envisaged the new system will enable all stages of the prescribing and supply of medicine to be completed electronically as an alternative to the current paper based system.

The new, streamlined process will allow for a prescription to be entered electronically by a medical practitioner, authenticated via an electronic signature, and transmitted securely for dispensing by a pharmacy. The pharmacy can then make claims electronically to Medicare Australia. There are a number of potential electronic prescribing and dispensing business models. No one solution will be mandated at this time because key work on standards and health information regulation are still being finalised (Department of Health and Ageing 2007c, p.1).

Nonetheless, a basic framework has been established that incorporates many features similar to the American DEA model described earlier in this chapter. Medical practitioners will 'sign' the prescriptions using an individual digital certificate that then will be transmitted electronically using approved prescribing software. Pharmacists will securely decrypt and download the prescription for dispensing. Consumers will still have the choice of where they have their prescriptions filled and at least initially whether they want to have prescriptions sent electronically or remain with a paper based system. It is envisaged that even after the programme is finalised it will be some years before a sufficient body of pharmacies and medical surgeries<sup>649</sup> will be equipped to utilise the electronic model (Department of Health and Ageing 2007c).

## **Views on electronic prescribing**

The Committee has sought the views of the relevant groups and individuals in the community as to the benefit or applicability of electronic prescribing systems in this state as a mechanism to reduce the misuse and abuse of prescription drugs. These opinions were usually expressed in meetings with the Committee, public hearings, or interstate visits. Most witnesses generally had favourable opinions with regard to new information technologies being employed in the health sector, including the use of electronic prescribing.

### *Support for electronic prescribing*

Mr Peter Halstead, Registrar of the South Australian Pharmacy Board, was of the view that if security issues could be addressed, electronic prescribing makes 'perfect sense':

<sup>649</sup> Although a recent Australian survey of general practitioners' use of computers to manage their medical practices has shown that 'Australian general practice has achieved near-universal clinical computerisation' (McInnes, Saltman & Kidd 2006, p.88).

I initially thought it was a fantastic idea. I have heard feedback that it has not been totally tied down yet security-wise, but I still would have thought in this day and age, again, if it allows greater scripting surveillance, and at the same time provides information, it would be the way to go. I know we have been looking at that at a state government level for some time here, and I continue to get reports that ultimately there are still issues around the security of electronic prescriptions.<sup>650</sup>

Certainly, electronic scripts would for the most part exclude excuses by 'doctor shoppers' such as 'it got lost', or 'the dog ate it', or 'it was destroyed in the wash'<sup>651</sup> as the electronic format would preclude a hard copy being given to a patient.

Mr Chris Lynton-Moll of the Collaborative Centre for e-Health at the University of Ballarat believed the technology is already in existence to make electronic prescribing a workable option for most doctors and pharmacists.

Some of it is related to technology and some of it is related to where the patient wants to go. Ideally, all pharmacies should be hooked up to some on-line system. All GP practice systems should be revised and rebuilt so that they can produce electronic prescriptions. A lot of them can produce prescriptions at the moment but they print it. There are various secure messaging systems by which these systems can produce an electronic form of a prescription and send it to a selected pharmacy, or one of the big ideas which is coming out – and this is being pushed by the National e-Health Transition Authority [NETA] – is to look at some web services approach where the prescription can go to a central repository.<sup>652</sup>

Mr Lynton-Moll envisaged a system where a patient would consult with the doctor and the doctor would fill out a web based prescription form that is linked to a unique Patient Identifier Number (PIN). When the patient presents at the pharmacy he or she would need to provide identity that would include the PIN and then the pharmacist could download the script prescribed by the doctor and fill that prescription. If the patient goes to another chemist and attempts to use their code to get another prescription, the computerised system would give an alarm to the second chemist enabling that chemist to say: 'Unfortunately, I can't give you this prescription it has already been prescribed and recorded in the system'.

The medical and allied health professions for the most part were supportive of an electronic prescribing system. For example, Dr Alex Wodak from St Vincent's Hospital in Sydney remarked when he gave evidence to the Committee:

Do doctors and medical organisations support electronic prescribing? The answer to that is yes; yes, for a number of reasons: it saves time, solves the problems of doctors' handwriting and the errors and deaths that can occur in that situation, and I suppose litigation as well. It has lots of benefits, and in terms of building up better data records of patients it offers a lot of improvements, so there is a lot of attraction there.<sup>653</sup>

Similarly, Dr Con Constantinou, Health Manager with the Medical Practitioners Board of Victoria (MPBV) stated to the Committee that:

I have no problem with electronic scripts. In a way they are better than handwritten ones because (a) they are legible and (b) it feeds into an electronic database that will tell you

<sup>650</sup> Mr Peter Halstead, Registrar, Pharmacy Board of South Australia, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Adelaide, 18 May 2007.

<sup>651</sup> Mr Peter Halstead, Registrar, Pharmacy Board of South Australia, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Adelaide, 18 May 2007.

<sup>652</sup> Mr Chris Lynton-Moll, Collaborative Centre for e-Health, University of Ballarat, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Ballarat, 29 May 2007.

<sup>653</sup> Dr Alex Wodak, Director, Alcohol and Drug Service, St Vincent's Hospital, Darlinghurst, and Fellow of Chapter of Addiction Medicine, Royal Australasian College of Physicians, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 25 June 2007.



whether that patient is allergic to that medication or that class of medication, or whether there are any restrictions on the prescribing of that medication. If you are doing it by hand, that is not available to you unless you have got a good memory or unless you have read the patient records. Electronic records and electronic prescriptions – I have no problem with that.<sup>654</sup>

In a submission to this Inquiry the Pharmacy Board of Victoria said:

A secure electronic prescribing system that can provide for the consumer to determine the pharmacy where they would like to have their prescription dispensed, free of alteration or interdiction, and supplied only on the number of occasions authorised and with patient privacy maintained. This would virtually eliminate prescription fraud, reduce medication misadventure and therefore unnecessary treatment and/or hospitalisation.<sup>655</sup>

Mr Steve Marty, Registrar of the Victorian Pharmacy Board, also spoke to this submission when he gave evidence to the Committee at public hearings. He stated he totally supported the establishment of an electronic prescription system with appropriate safeguards. Having commented to the Committee that some hospitals in Melbourne are using closed intranet systems to send prescriptions quite successfully he continued:

The technology has been there for 10 years. I participated in the first electronic prescriptions Standards Australia workshops back in 1995, also with the Health Insurance Commission and their security unit looking at what sorts of encryption standards you could put into place. The problem I see is that people come up with all sorts of reasons why you cannot do something, rather than looking at it the other way to say, 'This is the desired outcome, how do we get there?' Everybody is full of reasons to say, 'You cannot do that because...' of privacy concerns for example.

If people really are worried about privacy you could make an interim step and say, 'If you want it on the national health scheme, which is funded by taxpayers, your name goes into the database. If you don't want it to go on there, get it as a private prescription'.

However, of course, having said that, we have to recognise that these people will take it down the private path because they want to avoid the scrutiny of the system. But you could wipe out prescription fraud if you had an electronic system. There are only three things you really have to worry about. Firstly, that it has been generated by an authorised person; secondly, that it has not been intercepted and altered along the way; and thirdly, that consumers have got the choice to take that prescription to the pharmacy of their choice so that it is not channelled and under any arrangements that are contrary to the public interest, so that the public can take it to whichever pharmacy in Australia they wish to.<sup>656</sup>

### *Concerns about electronic prescribing*

However, electronic prescribing was seen by some to have problems. According to some respondents it could possibly even increase the risk of 'doctor shopping'. For example, according to pharmacist Ms Toni Riley from Bendigo:

As a downside of e-prescriptions, there is a potential for people to be able to pharmacy-shop better. You go to the doctor, the script goes into the electronic mailbox and then it is retrieved in the pharmacy, so it will be easier for people to go to different pharmacies because that prescription will be out there in the ether for it to be picked up wherever. It will be potentially easier for people who should be dealing with a particular service, be it a particular pharmacy or perhaps drug and alcohol services, to get their prescription and take

654 Dr Con Constantinou, Health Manager, Medical Practitioners Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 9 July, 2007.

655 Submission of Pharmacy Board of Victoria to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

656 Mr Steve Marty, Registrar, Pharmacy Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007.

it somewhere else. Some of those daily pick-up controls that we have that work reasonably well with people we know of may well be open to abuse.<sup>657</sup>

Ms Kerry Deans, Executive Officer of the Pharmaceutical Society of Australia, whilst generally supportive of the concept of electronic prescribing, did raise the point with the Committee that there would be a number of problems pertaining to functionality and access that would need to be considered at a national level. In particular, she noted that although the electronic transmission of prescriptions would be 'the key means of avoiding forgeries' there would be difficulties associated with the dispensing of the prescription because not every patient will go to a particular pharmacy they have nominated to their doctor. Some form of 'secure box' would need to be installed in the system to allow the dispenser to fill the prescription and fill it only once.<sup>658</sup> As noted earlier in this chapter, these types of technical and connectivity issues are currently being addressed at both Commonwealth and state level.

### ***MediConnect e-prescription trial***

To a certain extent there have been trials of e-prescriptions in Australia, including the MediConnect trial located in Ballarat and Launceston. Ballarat pharmacist Mr Colin Dorn explained the MediConnect trial when he met with the Committee in May 2007:

The way that system worked the customer would turn up with a printed prescription which had a big barcode down the bottom. When we scanned that bar code it would lock onto the central repository we talked about, pull that script down and all the details would be there, along with the history. If, for example, the first script from the doctor we dispensed and then they went to another pharmacy and they dispensed it, they would be able to see our dispensing, plus do theirs and then we would be able to see theirs the next time they came back to us, that sort of thing. The doctor could see the whole thing unfold. Medicare Australia had the central repository. Each pharmacy had their own database.<sup>659</sup>

However, Mr Lynton-Moll told the Committee that MediConnect was not a success and folded after the 18-month trial, for several reasons:

It was very poorly supported by pharmacies who had a lack of technology. They did not have broadband access. It was poorly supported by patients because they had the choice of opting in. It also took the GP software vendors a long time to get the process right. It took them nearly two years to get it right and in the end the money dried up and the trial was abandoned.<sup>660</sup>

<sup>657</sup> Ms Toni Riley, Toni Riley Pharmacies, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Bendigo, 30 May 2007.

<sup>658</sup> See comments of Ms Kerry Deans, Chief Executive Officer, Pharmaceutical Society of Australia, Meeting with Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Canberra, 17 May 2007.

<sup>659</sup> Mr Colin Dorn, UFS Pharmacy Ballarat, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Ballarat, 29 May 2007.

<sup>660</sup> Mr Chris Lynton-Moll, Collaborative Centre for e-Health, University of Ballarat, Evidence to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Ballarat, 29 May 2007.



## Conclusion

Clearly the use of sophisticated health information technologies, including electronic prescribing systems, will increasingly be a major part of medical and pharmacy practice over the next decade. It is logical to surmise that paper based prescriptions will eventually become obsolete. Web based technologies can be highly beneficial to reduce prescription fraud and minimise the number of medical misadventures or adverse reactions that occur in Australia each year.

There is, however, a negative aspect to the use of the Internet as it relates to prescription medications. The issue of illegally accessing prescription drugs and the use of rogue 'cyber-pharmacies' is certainly a serious problem in the United States and arguably an increasing one in Australia. Any interventions to address prescription drug misuse and diversion in this country must come to terms with the growing use of the internet to access and supply pharmaceutical drugs.

## 5.3 The Internet: Accessing Drugs and Online Prescriptions – The dilemmas of e-pharmacy

### Introduction

There are both benefits and dangers posed by the Internet as it relates to the advertising, purchase and distribution of prescription drugs. On the one hand 'cyber pharmacy' can benefit people who find it difficult to have their drugs prescribed and those prescriptions filled, particularly for people living in rural and remote areas. Conversely, severe harms can result from the unregulated use of the Internet to illegitimately gain access to a wide range of pharmaceuticals and prescription drugs. There are no guarantees that these drugs are manufactured safely or even contain the properties they are represented as having. The experience of the United States in developing strategies to counter the risks associated with Internet pharmacies is particularly valuable.

### Accessing drugs on the Internet

One issue pertaining to both advertising<sup>661</sup> of and access to drugs and medicines that has raised concerns in recent years is the use of the Internet and e-commerce. Whilst the current advertising restrictions of the *Therapeutic Goods Act* and its associated regulations and codes apply to all advertising that is broadcast or otherwise disseminated in Australia, including the Internet, neither the Commonwealth nor state governments have a great capacity to regulate 'spam' advertising that originates overseas. Unfettered access to drugs and medicines over the Internet poses dangers on three main levels. Firstly, there may be doubts as to the purity and safety of the drugs in question. Secondly, even if the drugs are therapeutically 'safe', without the intervention of a qualified third party such as a doctor or pharmacist to advise on their usage, consumers may either wilfully or through ignorance take these medicines incorrectly and unsafely. Thirdly, as an American commentator has remarked, 'Internet sales ...become a concern because they constitute an unmeasured component of supply in each state' (Simione & Holland 2006, p.7).

As the Galbally Review into prescription drug regulation in Australia noted: 'This is an international problem and one which the Commonwealth Government and the governments of other countries are attempting to resolve' (Galbally 2000a, p.50).<sup>662</sup> Whilst it is undoubtedly a problem that affects international borders, most of the literature on Internet sales of pharmaceutical drugs and strategies is American. The next section therefore discusses the experience of the United States and the parameters of the problem in that country.

661 That is advertising in the sense of promoting the drugs illegally on websites. Advertising of prescription drugs generally through legitimate channels such as television or magazines is for the most part prohibited in Australia, unlike the United States. See discussion in Chapters 3.1 and 4.1.

662 See also the discussion in Chapter 3.1.



## The Internet and prescription drug use and abuse in the United States <sup>663</sup>

The United States has a huge problem with the use of the Internet to illegally purchase prescription drugs. The main reason for this is that unlike Australia or Canada (with some minor exceptions) the United States has no universal subsidised scheme for the prescription and purchase of medicines comparable to the Pharmaceutical Benefits Scheme (PBS).<sup>664</sup> Many American citizens who are legitimately in need of pain relievers or other medicines turn to the Internet because they cannot otherwise afford to purchase them. Such customers are to be distinguished from those who 'surf' the Internet to purchase prescription drugs for recreational purposes or even obtain 'recipes' to manufacture prescription drugs or to 'tamper' with those already in their possession.<sup>665</sup>

### *How easy is it to access prescription drugs on the Internet?*

As previous chapters have indicated, accessing comprehensive data on prescription drug use and misuse even when supplied through legitimate channels is difficult in both the United States and Australia. However, establishing good data on the magnitude of the problem of accessing prescription drugs via the Internet is almost impossible. Nonetheless a number of American studies attempting to explore the availability of controlled prescription drugs on the Internet have been conducted. These are detailed as follows:

#### **The Center on Addiction and Substance Abuse Studies 2004-2007**

In 2004 the National Center on Addiction and Substance Abuse (CASA) conducted a study to explore the availability of controlled prescription drugs on the Internet. In a one-week period, the study identified 495 sites offering controlled prescription drugs, with 41 per cent being those drugs with the highest potential for abuse (Schedule II in the United States system). The most frequently offered controlled drugs were benzodiazepines (found on 144 sites), followed by the opioids, including drugs like hydrocodone, fentanyl and oxycodone (103 sites). Ninety-four per cent of 157 anchor sites – sites that sell drugs, differing from portal sites which simply link to anchor sites – studied did not require a prescription. The researchers found that there were no mechanisms in place to block purchase by underage buyers. Forty-four per cent of the sites said drugs would be shipped from the United States, 20 per cent did not specify, and 47 per cent said they would be shipped from other countries (one of which was Australia). A replication of the original study, conducted one year later, found few differences. Whilst the second study identified only 409 sites, 95 per cent of the 160 anchor sites did not require a prescription, and considerably more offered opioid medications (CASA 2005).

CASA noted that regulation is difficult because websites can appear, move, or be removed in a very short time, making it difficult to monitor or close those that are operating illegally (CASA 2005).

The CASA study was updated again in May 2007 using the same methodology as for the previous two. The Report for this study reported that 'access to controlled prescription drugs online continues unabated' (CASA 2007, p.i). The findings showed that between 2006 and 2007 there had been a 70 per cent increase in the number of web sites identified that advertise or sell controlled prescription drugs. Moreover, the Report found that eighty four percent of the sites offering controlled prescription drugs:

[d]o not require that the patient provide a prescription from his or her doctor. Of those sites that do require prescriptions, 57 per cent only require that the prescription be faxed allowing significant opportunity for multiple use and other types of fraud (CASA 2007, p.i).

<sup>663</sup> For a good general account of the problems posed by Internet pharmacies, particularly in the early days of their establishment, see United States General Accounting Office 2000, *Internet Pharmacies: Adding Disclosure Requirements Would Aid State and Federal Oversight*. For a more recent account see United States General Accounting Office 2004, *Internet Pharmacies – Some Pose Risks for Consumers*.

<sup>664</sup> There is much that could be discussed about the American health care system and the difficulties American consumers have in accessing pharmaceutical and prescription drugs, but whilst such issues are important they are largely peripheral to this Inquiry. For a general discussion, see Singh and Shi 2004.

<sup>665</sup> For a discussion of tampering, see below.



As in the previous two studies benzodiazepines were the controlled drugs most frequently offered for sale with 79 percent of the sites offering these drugs in 2007 (CASA 2007, p.5). The most frequently offered benzodiazepines for sale were alprazolam (xanax®) and diazepam (valium®). The second most frequently offered class of drugs for online sales were opioids with 64 per cent of the sites offering these drugs for sale in 2007. Hydrocone formulations such as Vicodin® or Lortab® were the most frequently offered opioid drugs. As in previous years, there were only infrequent mentions of the stronger opioids such as OxyContin® for sale.

Of most concern to CASA was that as in previous years, there were still no apparent controls in place limiting access of these sites to children. It was also of concern that of the 187 sites [that CASA was aware of] that sold prescription drugs only two were VIPPS certified or legitimate sites.<sup>666</sup>

Finally, the various CASA studies including the most recent from 2007, found that there was a very short 'lifecycle' for websites selling controlled prescription drugs. Such sites have an 'extremely high turnover' and often avoid detection or scrutiny by changing their web names and/or addresses:

Of the non VIPPS [authorised] sites identified in 2004 (152), only 19 percent (29 sites) remained in business one year later. Only seven percent (11 sites) were still operating when CASA conducted this year's [2007] study –four years later. CASA also found that it was not unusual for sites to have multiple names or to disappear entirely even within the period of analysis. This fluidity in web sites increases the difficulty of tracking and closing down rogue sites (CASA 2008, p.8).

#### **The Government Accounting Office Study 2004**

The United States General Accounting Office (USGAO) made similar findings in its 2004 study. The USGAO spent several months buying prescription drugs online, tracking the Internet pharmacies and drugs delivered in response to their online orders, and then testing the delivered drugs to ascertain if they were actually the medications ordered. The USGAO obtained 68 samples of 11 drugs, each from a different website in the United States, Canada, Mexico or other foreign country.<sup>667</sup>

It was found that:

Five U.S. and all 18 Canadian pharmacy sites from which GAO received samples required a patient-provided prescription, whereas the remaining 24 U.S. and all 21 foreign pharmacy sites outside of Canada provided a prescription based on their own medical questionnaire or had no prescription requirement. Among the drugs GAO obtained without a prescription were those with special safety restrictions and highly addictive narcotic painkillers.

GAO identified several problems associated with the handling, FDA approval status, and authenticity of the 21 samples received from Internet pharmacies located in foreign countries outside of Canada. Fewer problems were identified among pharmacies in Canada and the United States. None of the foreign pharmacies outside of Canada included required dispensing pharmacy labels that provided instructions for use, few included warning information, and 13 displayed other problems associated with the handling of the drugs. For example, 3 samples of a drug that should be shipped in a temperature-controlled environment arrived in envelopes without insulation. Manufacturer testing revealed that most of these drug samples were unapproved for the U.S. market; however, manufacturers found the chemical composition of all but 4 were comparable to the product GAO ordered. Four samples were determined to be counterfeit products or otherwise not comparable to the product GAO ordered. Similar to the samples received from other foreign pharmacies, manufacturers found most of those from Canada to be unapproved for the U.S. market; however, manufacturers determined that the chemical composition of all drug samples

<sup>666</sup> Verified Internet Pharmacy Practice Sites. See discussion below.

<sup>667</sup> Including Argentina, Costa Rica, Fiji, India, Mexico, Pakistan, Philippines, Spain, Thailand, and Turkey (USGAO 2004, p.5).



obtained from Canada were comparable to the product GAO ordered (USGAO 2004, p.ii).<sup>668</sup>

One relatively positive aspect of the USGAO project was the fact that narcotic pain medications such as OxyContin® were less readily available over the Internet:

Despite extensive searching of Internet pharmacy sites, we found few that sold these drugs without prescription. Other factors also hindered our ability to purchase these drugs. For example, some pharmacies that advertised the narcotics did not actually sell them. Rather, they attempted to substitute a different, often less potent and non narcotic, drug once the order was placed. In addition, several pharmacies that offered narcotics required payment by means that were beyond our scope, such as check, bank transfers, or 'e-gold' exchanges. We were able to place orders for the generic version of Vicodin at several U.S. pharmacies; however, some of these pharmacies required not only an online medical questionnaire, but also a telephone consultation with a pharmacy-designated physician in order to obtain a prescription. Finally, we were able to place only one order for a drug purporting to be OxyContin, and only after locating the source by paying a membership fee and joining an Internet pharmacy drug club, which referred us to the site (USGAO 2004, p.14).

### **Studies by Forman and colleagues 2006**

To ascertain the accessibility of websites offering opioid medications, Forman and colleagues (2006) conducted 47 Internet searches using Google and Yahoo with terms including 'codeine', 'no prescription Vicodin®' and 'OxyContin®'. More than 50 per cent of the resulting hits were sites that would sell opioids without a prescription (n=302). The study employed the standard search tools that Internet users would employ to search for information about these drugs and/or their availability on a non-prescription basis. They found that sites offering to sell opioid medications without a prescription were 'pervasive' and more prevalent than sites offering information, suggesting that the Internet seems to facilitate access to these drugs (Forman et al 2006).

A preliminary study was conducted to gauge the extent to which people with substance use problems were accessing the Internet to purchase drugs (Gordon, Forman & Siatkowski 2006). Semi-structured interviews were conducted with 100 patients in a private drug treatment programme in eastern Pennsylvania from July 2003 to March 2004. The study found 29 per cent of patients knew the Internet could be used to locate drugs, and nine had done so – six had purchased pharmaceuticals and three 'party drugs'. Among the total sample, the most frequently cited sources for obtaining drugs in the past month were drug dealers (77%), friends/family/colleagues (43%), health care professionals (24%), the Internet (11%), home production (6%) and theft (5%) (Gordon, Forman & Siatkowski 2006). The authors concluded that the Internet has become a source of controlled drugs for some addicted individuals.

Whilst the studies reviewed in this section are by no means exhaustive or conclusive they do give a disconcerting snapshot of how relatively easy it is for some consumers to illegitimately access prescription drugs.

### ***Internet 'pharmacies'***

#### **Legitimate Internet pharmacies**

It is also a fact that the Internet can be a convenient and sometimes inexpensive means of accessing medications, particularly for patients in remote and rural districts, where access to a 'bricks and mortar' pharmacy may be difficult. As the United States Drug Enforcement Administration (DEA) noted:

<sup>668</sup> To identify the Internet pharmacies, the USGAO used a list of Internet pharmacy websites compiled by a private consultant and provided to it by FDA; used Internet search engines, including Google, Yahoo and Excite; and joined Internet pharmacy members-only websites, which provide enrolled members with lists of websites selling various prescription drugs (USGAO 2004, p.4).

There are strong societal benefits to allowing individuals with a valid prescription to get their prescriptions over the Internet, as long as the pharmacy that fills these prescriptions is a legitimate one and there is a legitimate doctor-patient relationship. This may be helpful in rural areas or for individuals who are homebound due to illness or other factors. However, the anonymity of the Internet, and the proliferation of websites that facilitate illicit transactions in controlled substance pharmaceutical drugs, have given drug abusers the ability to circumvent both the law and sound medical practice.<sup>669</sup>

In the United States there are legitimately run Internet pharmacies that are regulated and certified by state boards of pharmacy and registered with the National Association of Boards of Pharmacy (NABP) Verified Internet Pharmacy Practice Sites (VIPPS) programme.

The VIPPS program was developed in 1999 by a coalition of state and federal regulatory associations, professional associations, and consumer advocacy groups in order to protect the viability and safety of prescription drug supply through the internet.

To be VIPPS accredited, a pharmacy must comply with the licensing and inspection requirements of their state and each state to which they dispense pharmaceuticals. In addition, pharmacies displaying the VIPPS seal have demonstrated to NABP compliance with VIPPS criteria including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists.<sup>670</sup>

VIPPS pharmacy sites are identified by the VIPPS hyperlink seal displayed on their websites. By clicking on the seal, a visitor is linked to the NABP VIPPS site where verified information about the pharmacy is maintained by NABP.

The Food and Drug Administration has commended the VIPPS programme as one method to 'minimize the risks of getting bad quality drugs from disreputable sources'.<sup>671</sup>

#### **The use of Internet pharmacies to access and divert prescription drugs**

Whilst safeguards such as VIPPS accreditation are clearly an essential strategy in minimising risks associated with Internet pharmacy, they do not of themselves stop or address Internet scams or 'rogue Internet drug sellers'. Apart from purchasing prescription drugs legitimately from legal Internet pharmacies, there is a substantial problem in the United States with providing often spurious online prescriptions which can then be filled or supplied via the Internet. Often such sites give deceptive and inaccurate advice that the actions in accessing drugs from such sites is perfectly legal.<sup>672</sup> Whilst such practices are by no means unknown in Australia, it is much more common in the United States because of the higher price of drugs in that country and the lack of a subsidised pharmaceutical benefits scheme. The United States Department of Justice commented in this regard:

Prescription drugs are increasingly diverted via the Internet because many Internet pharmaceutical distributors – often referred to as Internet pharmacies – offer prescription drugs to customers without requiring prescriptions or physician consultation or verification. Estimates as to the number of Internet pharmacies vary widely. For example, the National Board of Pharmacy estimates that the number of Internet pharmacies has increased from none in the mid- to late 1990s to between 400 and 1,000 in 2003. However, in January 2004 the National Center on Addiction and Substance Abuse (CASA) identified only 157 Internet

669 Mr Joseph T Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Department of Justice. Testimony to the House Government Reform Committee, Subcommittee on Criminal Justice, Drug Policy, and Human Resources, 26 July 2006, Hearings, *Prescription Drug Abuse: What is Being Done to Address This New Drug Epidemic*, accessed at <http://www.dea.gov/pubs/cnrgtest/ct072606.html>

670 National Association of Boards of Pharmacy VIPPS Program, accessed at <http://www.nabp.net/index.html?target=vipps/intro.asp&>

671 Food and Drug Administration, Press Release, 13 July 2004 accessed at <http://www.nabp.net/index.html?target=vipps/intro.asp&>

672 For example, see Mr Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Department of Justice. Testimony to the House of Representatives Energy and Commerce Committee, Subcommittee on Oversight and Investigations, 13 December 2005, accessed at <http://www.dea.gov/pubs/cnrgtest/ct121305.html>



sites distributing controlled pharmaceuticals to individual users, although an additional 338 Internet sites provided links to one or several of the 157 pharmaceutical distribution sites. Nevertheless, of the 157 Internet sites identified by CASA, 64 (40.8%) did not require any prescription or physician consultation to purchase prescription drugs. Moreover, 77 (49.0%) of the Internet sites only required customers to report their symptoms in an online questionnaire before they could receive the prescription drug – there was no requirement for personal physician verification of the symptoms. Faxed prescriptions were required by seven (4.4%) and mailed prescriptions were required by three (1.9%) of the sites. The remaining six (3.8%) sites made no reference to any prescription requirement. CASA further reports that the Internet pharmacy sites most often offered benzodiazepines (alprazolam and diazepam), followed by narcotic analgesics (fentanyl, hydrocodone, and oxycodone), and stimulants (methylphenidate). *None of the 157 Internet sites included security procedures restricting children from purchasing prescription drugs.*

FBI reporting indicates that many unscrupulous Internet pharmacy operators recruit corrupt physicians to write fraudulent prescriptions for their customers. The FBI further reports that unscrupulous physicians are paid as much as \$1,500 per day for writing fraudulent prescriptions for Internet pharmacy patients (United States Department of Justice 2005, p.9).<sup>673</sup> (Committee emphasis)

The USGAO has described three different types of Internet pharmacies currently operating in that country and abroad:

First, some Internet pharmacies operate much like traditional drugstores, selling a wide range of prescription drugs and requiring consumers to submit a prescription from their physicians before their orders are filled. In some instances these Internet pharmacies are affiliated with traditional chain drug stores. Second, other Internet pharmacies may sell a more limited range of drugs, often specializing in certain lifestyle medications, such as those that treat sexual dysfunction or assist in weight control. These Internet pharmacies typically require consumers to fill out an online medical history questionnaire in place of a traditional examination by a physician, and issue a prescription after a physician affiliated with the pharmacy reviews the questionnaire. Still other Internet pharmacies dispense drugs without a prescription (USGAO 2004, p.8).

The American Pharmacists Association (APhA) expressed particular concerns to a Senate Special Committee on Ageing with regard to the second and third types of operation mentioned by the USGAO. Making allowance for the fact that American pharmacies would undoubtedly feel their economic viability threatened through the growth of Internet pharmacies, they also have strong feelings about the lack of safeguards associated with Internet prescriptions and the ease with which patient care can be jeopardised:

Illegitimate Internet drug sellers operate outside these [VIPPS] protections and pose safety risks to patients. A sample of the safety risks that exist with purchasing prescription medications through Internet drug sellers include:

- Failing to provide access to pharmacists and offering medications 'without a prescription', a serious breach of our regulatory system.
- Removing current assurances pharmacists and patients have that products are effective, safe, or have been produced under U.S. quality control requirements to protect against contamination.
- Delaying treatment of adverse drug reactions or side effects if a health care provider does not know what the patient is taking. The actual appearance or name of some foreign medications is different from the U.S. manufactured counterpart.
- Increasing the likelihood of drug-to-drug interactions because patients do not tell their local pharmacist about the medications they purchased from an Internet drug seller

<sup>673</sup> The USGAO surveyed all American state medical boards to ascertain whether the practices of physicians employed by online pharmacies were legal and/or ethical. Thirty-nine of the 45 boards surveyed 'indicated that a physician who issued a prescription on the basis of an online questionnaire would not satisfy the standard of good medical practice required under the [respective] states laws' (USGAO 2004, p.10).

that conflict with an acute prescription. It is always best for patients to use one pharmacy to reduce the likelihood of these occurrences.

- Prescribing medications without a physical examination, or any interaction with the patient, bypassing the traditional prescriber-patient relationship. As a result, consumers may receive inappropriate medications because of a misdiagnosis.<sup>674</sup>

The APhA has stressed the dangers associated with importation of prescription drugs and those accessed via the Internet and the potential negative impact it will have on patient care:

Because of the stigma involved in importing medications, many patients do not tell their physician or pharmacist about medications they are securing outside of the U.S. This is understandable, but dangerous. When a patient obtains medications from multiple sources – in this case through importation [via Internet] and a local pharmacy – neither the domestic nor international pharmacist has the patient's complete medication profile unless the patient provides this information.

Not knowing a patient's entire medication regimen or the content and strength of a particular drug can also cause problems when a patient suffers unexpected complications or does not respond as expected to a medication. Consider a patient working with their local physician and pharmacist to treat their high blood pressure. The patient imports a faulty medication that has no, or little, active ingredient. It is unlikely the patient will physically feel anything different; unlikely he would actually notice any difference in the product. Later the patient visits the physician and his blood-pressure reading shows that the medication is not working. Because of our trust in the medication supply, it is highly unlikely that the physician will consider that there was a problem with the medication. Rather, the physician will likely assume that the medication did not work and will consequently either increase the dose or choose another medication. This sets the stage for using a stronger, but potentially unnecessary, medication and increasing overall health care costs.

Also consider the scenario where a patient is in need of a prescription medication on a short timeframe – such as an antibiotic for an infection or a pain medication to treat symptoms from an injury. If that patient has been importing his or her medications, the pharmacist is unable to determine whether the new prescription will conflict with any other medications the patient takes, has ingredients that duplicate a current prescription, or whether its mere presence suggests other medical problems for the patient that should be followed-up with the patient's physicians. This 'blindness' compromises the ability of physicians to care for their patients and the ability of pharmacists to partner with patients to improve medication use and advance patient care.<sup>675</sup>

Similar concerns were expressed by Mr Joseph Rannazzisi of the Office of Diversion Control, DEA:

Perhaps most disturbing is that many of these Internet pharmaceutical sites – calling them 'pharmacies' gives them more credit than they deserve – are hiding behind a façade of legitimacy by pretending to ask customers health questions. After customers fill out a superficial questionnaire, which is given an even more cursory review (if any) by a doctor employed by the internet pharmacy, these sites provide pharmaceutical products with no face-to-face medical examination, no tests, no drug interaction screening, and no follow-up care.<sup>676</sup>

674 American Pharmacists Association (APhA), Testimony to the Senate Special Committee on Ageing, Hearings; *Internet Pharmacy and Importation: Exploring Risks and Benefits*, 26 January 2005, Accessed at [www.aphanet.org/AM/Template.cfm?Template=/CM/ContentDisplay.cfm&ContentID=7840](http://www.aphanet.org/AM/Template.cfm?Template=/CM/ContentDisplay.cfm&ContentID=7840)

675 American Pharmacists Association, Testimony to the Senate Special Committee on Ageing, Hearings; *Internet Pharmacy and Importation: Exploring Risks and Benefits*, 26 January 2005, Accessed at [www.aphanet.org/AM/Template.cfm?Template=/CM/ContentDisplay.cfm&ContentID=7840](http://www.aphanet.org/AM/Template.cfm?Template=/CM/ContentDisplay.cfm&ContentID=7840)

676 Mr Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Department of Justice. Testimony to the House of Representatives Energy and Commerce Committee, Subcommittee on Oversight and Investigations, 13 December 2005, accessed at <http://www.dea.gov/pubs/cngtrtest/ct121305.html>



At a later hearing before Congress in 2006, Mr Rannazzisi, stressed that for the DEA 'the most potentially dangerous and increasingly used method for the diversion of controlled pharmaceuticals is through the Internet'<sup>677</sup> Mr Rannazzisi testified further that:

As the number of Americans with Internet access has increased, so too have opportunities for individuals to acquire controlled substance prescription drugs over the Internet...There are legitimate pharmacies that provide services over the Internet and that operate well within the bounds of both the law and sound medical practice. The National Association of Boards of Pharmacy has established a registry of pharmacies that operate online and meet certain criteria, including compliance with licensing and inspection requirements of their state and each state to which they dispense pharmaceuticals.

By contrast, other websites used by Internet facilitators will often advertise themselves as pharmacies, but they do not operate in the same manner as brick-and-mortar pharmacies. Many of these websites advertise controlled substances without a prescription, and none include an in-person medical examination from a licensed physician.

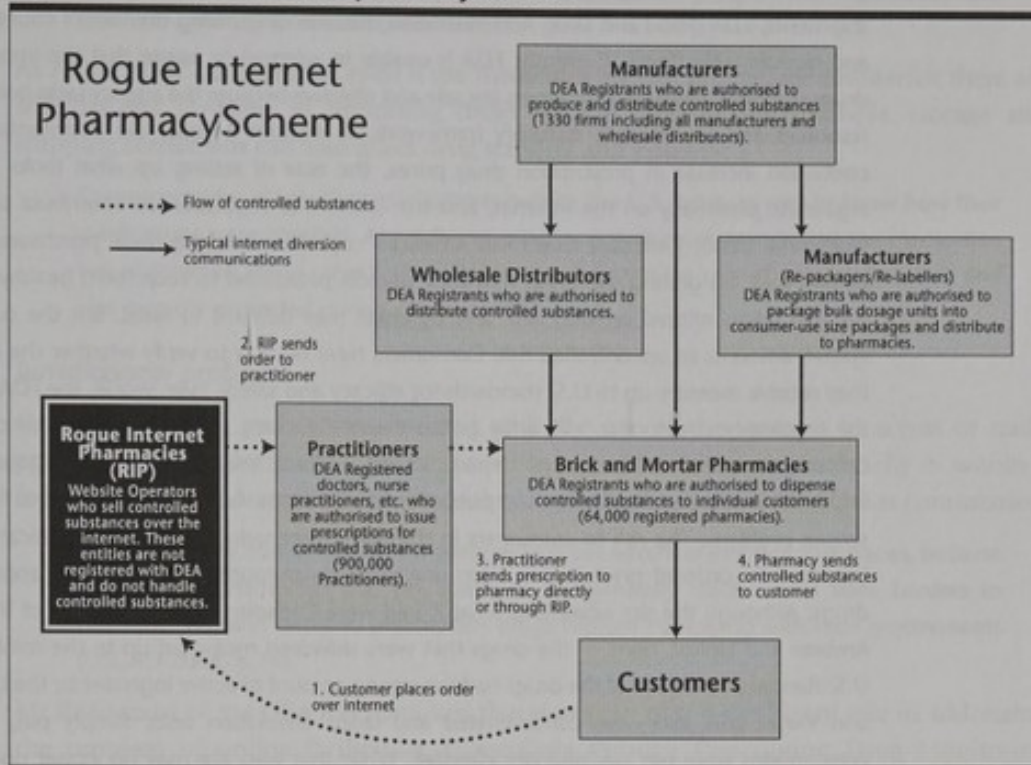
Of particular concern is the cursory and abbreviated nature of the medical interaction. Often, if there is any interaction with a medical professional at all, the Internet facilitator will provide only a cursory doctor consultation by computer or telephone for customers. This brief interaction is not meant to elicit meaningful health information, and is generally done by way of a 'questionnaire' filled out by the 'patient' without any face-to-face meeting between the doctor and the patient. Without this face-to-face interaction, it is not possible for the doctor writing the prescription, who has never met the patient, to verify the information provided by the individual and assess legitimate medical need. This is particularly troubling in the context of youth drug abuse. Unlike when the patient visits the doctor, a minor can easily log onto a website and provide an inaccurate age.

Doctors, who are often paid by the number of prescriptions they sign in these situations, have no incentive to spend time seeking additional patient information. Law enforcement has discovered website-affiliated doctors who sign hundreds or thousands of prescriptions a day. After receiving the prescription from the doctor, the facilitator will then submit the prescription to a cooperating pharmacy. Because there is often no identifying information on these rogue websites, it is very difficult for law enforcement to track any of the individuals behind them.<sup>678</sup>

<sup>677</sup> Mr Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Department of Justice. Testimony to the House Government Reform Committee, Subcommittee on Criminal Justice, Drug Policy, and Human Resources, 26 July 2006, Hearings – Prescription Drug Abuse: What is Being Done to Address This New Drug Epidemic, accessed at <http://www.dea.gov/pubs/cngrtest/ct072606.html>

<sup>678</sup> Mr Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Department of Justice. Testimony to the House Government Reform Committee, Subcommittee on Criminal Justice, Drug Policy, and Human Resources, 26 July 2006, Hearings – Prescription Drug Abuse: What is Being Done to Address This New Drug Epidemic, accessed at <http://www.dea.gov/pubs/cngrtest/ct072606.html>

Figure 5.3a: Rogue Internet pharmacy scheme



Source: Drug Enforcement Administration 2007.

Mr Rannazzisi reiterated these observations and concerns when he met with members of this Committee during its fact-finding trip to North America in July 2007, adding that an even greater concern from a public health perspective is the fact that a percentage of the drugs being purchased from Internet sites, particularly those based abroad, have proven to be counterfeit.<sup>679</sup>

### Counterfeit drugs

One particular concern expressed in the United States and elsewhere is the possibility that drugs received after purchase from Internet pharmacies may be counterfeit or impure, leading to illness or even death in those who consume them. Whilst this is rarely a problem with regard to drugs imported from Canada (unless those drugs themselves have originally been imported from elsewhere), drugs imported from countries such as India, Mexico, Thailand or China have been known to be impure or completely counterfeit.<sup>680</sup> The Federal Bureau of Investigation (FBI) has noted that counterfeits of popular brand name prescription drugs and pharmaceuticals obtained from the Internet often contain inactive ingredients, incorrect ingredients or improper dosages. According to the FBI, most counterfeit pharmaceuticals are produced in India and China and as much as 60 per cent of the pharmaceuticals from China are counterfeit (United States Department of Justice 2005).

Dr David Kessler graphically described this serious problem in his testimony to Congress in 2005:

In the past couple of years, there has been an exponential increase in the number of prescriptions brought into the United States from Canada and other countries. The Department of Health and Human Services has estimated that the number of shipments has

679 Mr Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Department of Justice, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Washington, 27 July 2007.

680 Indeed, the World Health Organization has estimated that between 5 to 8 per cent of all pharmaceuticals produced are counterfeit. Quoted in [www.aphanet.org/AM/Template.cfm?Template=/CM/ContentDisplay.cfm&ContentID=7840](http://www.aphanet.org/AM/Template.cfm?Template=/CM/ContentDisplay.cfm&ContentID=7840)



grown from 2 million packages in 2001 to 10 million in 2004. With this explosion in shipments, FDA (Food and Drug Administration) has seen a growing number of counterfeit and questionable drugs. Currently, FDA is unable to adequately assure that the imported drugs reaching American consumers are safe and effective because the agency lacks both the resources and an effective statutory framework to regulate or stop the shipments. The continued increase in prescription drug prices, the ease of setting up what looks like a legitimate pharmacy on the Internet, and the absence of regulation all contribute to this worrisome trend. I am sure that most American consumers making these purchases truly believe they are getting the drugs that their doctors prescribed to keep them healthy. And the low prices offered on web sites and by email may be hard to resist. But the current system amounts to uncontrolled risk. Consumers have no way to verify whether the drugs they receive measure up to U.S. standards for efficacy and safety. Even worse, the FDA lacks the regulatory structure to efficiently police the marketplace. Mr. Chairman, the choice before you is not the choice of imports or no imports. We already have a system of importation of drugs that jeopardizes public health. Congress has the responsibility to fix this serious problem. The risk to consumers in the current scenario is not just theoretical. FDA Investigators ordered prescriptions from one web site purporting to be selling approved drugs. Although the site advertised what it said were Canadian generic versions of Viagra, Ambien and Lipitor, none of the drugs that were delivered measured up to the minimum U.S. standards. All three of the drugs had the wrong amount of active ingredients; the Lipitor and Viagra pills also were contaminated and failed dissolution tests. Simply put, these prescriptions were not safe and not effective. While that web site may no longer operate, there are literally hundreds of other web sites that exist today without any regulatory oversight whatsoever.<sup>681</sup>

The APhA has expressed similar concerns:

Even with the comprehensive U.S. system, counterfeit drugs have penetrated our system.

According to the Food and Drug Administration (FDA), the number of counterfeit drug investigations has increased four-fold since the late 1990s. For example, in 2003, 11,000 boxes of counterfeit Epogen and Procrit were found on pharmacy shelves and in patients' homes. Three months later, the FDA discovered five lots of counterfeit Lipitor. And more recently, the FDA warned of counterfeit Ortho Evra contraceptive patches that contain no active ingredient and were being sold online by a company based in India. These examples support the need for review and refinement of our existing safety net, not the expansion of efforts to circumvent or relax that system. A poorly constructed importation proposal would relax our current system and damage our safety net. Opening the door to importation increases the risk of counterfeit medications infiltrating our drug supply.

Even when a patient receives a 'legitimate' drug, there are differences between drugs that are sold in the U.S. and other countries. Medications obtained outside of the U.S. may contain different formulations – with differences in the amount of active ingredient or differences in the type of inactive ingredients – both of which can affect the product's stability and how the product works. Because of these differences, any safe importation system must limit importation to products approved by the Food and Drug Administration,

681 Testimony of Dr David Kessler, Former Commissioner of the United States Food and Drug Administration, US Senate Committee on Health, Education, Labor and Pensions Hearings S.334: *An Approach to Drug Importation*, 19 April 2005, accessed at [http://help.senate.gov/Hearings/2005\\_04\\_19/2005\\_04\\_19.html](http://help.senate.gov/Hearings/2005_04_19/2005_04_19.html)

There have been several congressional hearings held in the United States on the issue of Internet Pharmacy. In addition to the Senate and House of Representatives Inquiries heretofore mentioned the following hearings and Inquiries have taken place:

Senate Committee on Governmental Affairs – *Buyer Beware: The Danger of purchasing pharmaceuticals over the Internet*, 17 June 2004.

House of Representatives, Subcommittee on Oversight and Investigations, *Safety of Imported Pharmaceuticals: Strengthening Efforts to Combat Controlled Substances over the Internet*, 13 December 2005.

Senate Committee on the Judiciary, *Rogue Online Pharmacies: The Growing Problem of Internet Drug Trafficking*, 16 May 2007.

not merely products that contain the same, or similar, active ingredients. Medications are different – and minor differences matter.<sup>682</sup>

As APhA point out however, even if the medicines are not themselves counterfeit there are still dangers involved in importing drugs via the Internet. For example, storage and shipping conditions can also affect drug stability and potency:

Consumers who obtain their medications outside the U.S. have no way to know how their medications were handled. Any safe importation system must ensure that the medication was maintained at the correct temperature, was stored in the correct type of container, and was properly protected during shipment.<sup>683</sup>

### *Jurisdictional problems*

One of the major problems associated with the use of the Internet to access or trade prescription drugs is that the Internet knows no borders either internationally or within a federation such as Australia, Canada or the United States. As the USGAO has commented:

State regulatory boards face new challenges with the advent of Internet pharmacies, because they enable pharmacies and physicians to anonymously reach across state borders to prescribe, sell, and dispense prescription drugs without complying with state requirements (USGAO 2004, p.14).

Mr Rannazzisi of the DEA has remarked that states can play a significant role in addressing the problem of online facilitators, particularly through Prescription Drug Monitoring Programs (PDMPs):

As part of the Administration's work with states regarding PDMPs over the next several years, states will be encouraged to consider addressing, either by statute, regulation, or interstate agreement, a number of scenarios that primarily involve pharmacies dispensing or delivering controlled substance prescription drugs to patients across state lines. To be effective, laws must be updated to reflect the changing ways people live and in which business is conducted.<sup>684</sup>

To a certain extent these jurisdictional problems, at least within the United States, are starting to be addressed through the use of National All Schedules Prescription Electronic Reporting (NASPER) and cross-border information sharing agreements, as discussed in Chapter 4.1 of this Report.<sup>685</sup> Moreover, the federal government has the 'ability to shut down illegal sites nationwide quickly, whereas each state having to challenge individual sites would be a slow process' (Kraman 2004, p.16).

Nonetheless, this does not solve the problems of Internet pharmacies or surfing the net to purchase pharmaceuticals across international borders. Much of the 'trade' done through Internet sites takes place between countries such as Australia and the USA or the USA and Mexico or Canada. Currently there are insufficient resources, legal agreements or strategies to address these issues at international level.

As a result of the seriousness with which American law enforcement authorities view illegal Internet trading, the DEA established an Internet Investigation Unit. This Unit investigates Internet pharmacy and illegal trading of prescription drugs and has used its powers to issue suspensions or revocations of DEA registrations of doctors and pharmacists who have

682 Testimony of Dr David Kessler, Former Commissioner of the United States Food and Drug Administration, US Senate Committee on Health, Education, Labor and Pensions Hearings S.334: *An Approach to Drug Importation*, 19 April 2005, accessed at [http://help.senate.gov/Hearings/2005\\_04\\_19/2005\\_04\\_19.html](http://help.senate.gov/Hearings/2005_04_19/2005_04_19.html)

683 APhA, Testimony to the Senate Special Committee on Ageing, Hearings – *Internet Pharmacy and Importation: Exploring Risks and Benefits*, 26 January 2005, accessed at [www.aphanet.org/AM/Template.cfm?Template=/CM/ContentDisplay.cfm&ContentID=7840](http://www.aphanet.org/AM/Template.cfm?Template=/CM/ContentDisplay.cfm&ContentID=7840)

684 Mr Joseph Rannazzisi Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, accessed at [www.dea.gov/pubs/engrtest/st072606.html](http://www.dea.gov/pubs/engrtest/st072606.html)

685 Although, despite NASPER, the Council of State Governments state there is still 'disagreement as to the level of federal regulation necessary to assist states in effectively controlling Internet prescribing and dispensing'. Some states favour federal legislation to establish national minimum standards such as compulsory contact information for Internet pharmacies. Other states do not. See Kraman 2004, p.16.



operated illegally via the Internet.<sup>686</sup> The US Department of Justice has also prosecuted doctors and pharmacies who illegally distribute via the Internet, and has taken an active role in 'busting' international or offshore Internet drug rings.<sup>687</sup> However, as discussed in the next section, both the resources and the legal frameworks to combat international prescription drug crime are relatively scarce.

### *Problems with interdiction*

The DEA believes there are huge problems associated with 'policing' the importation of drugs accessed from the Internet.<sup>688</sup> Federal police agencies, Customs and the DEA itself simply do not have the resources or manpower to sufficiently inspect packages coming into the United States from online pharmacies services abroad (USGAO 2004). Australian authorities have made similar observations (St George, Emmanuel & Middleton 2004). Senator Carl Levin, giving testimony to a Senate Committee on Internet drug trading, stated how customs screening practices in the USA were insufficient to deal with the suspected volume of trade crossing the borders:

The Subcommittee examined operations at three U.S. ports of entry in New York, Chicago, and Miami to evaluate how federal agencies screen parcels containing pharmaceutical products and originating from foreign countries. The investigation determined that tens of thousands of dangerous and addictive controlled substances are streaming into the United States on a daily basis from overseas and that, at ports of entry such as the John F. Kennedy International Airport (JFK) in New York and Miami International Airport, Customs agents are being overwhelmed as they attempt to prevent potentially hazardous materials from entering our borders.

For example, at JFK Airport, Customs officials estimated that over 40,000 parcels containing pharmaceutical products passed through its facility every day. Miami International Airport saw 30,000 packages a day. Neither facility had sufficient personnel to screen these parcels. For example, JFK had an average of 50 Customs agents and just 6 FDA inspectors working at its facilities during the course of a day, which means each person was responsible for screening more than 700 pharmaceutical parcels every day. And, remember, these agents and inspectors had lots of other responsibilities too – they were also charged, for example, with screening packages for firearms, nuclear material, counterfeit currency, and other contraband items.

Millions of packages containing pharmaceutical products were imported into the United States last year and in 2003, and an estimated \$1.1 billion worth of prescription drugs were imported into the U.S. solely from Canada. Internet pharmacies have contributed to this increase and to the ongoing strain on our enforcement resources. While some of these Internet pharmacies are based in the United States, many others are based in foreign countries which makes them harder to investigate, inspect, and shut down. Recent research indicates, for example, that the top countries of origin for imported medications include Brazil, Canada, India, Mexico, the Netherlands, Pakistan, Portugal, Romania, and Spain.

686 Instances of this happening were cited to the Committee by Mr Joseph Rannazzisi of the DEA when they met with him in Washington in July 2007.

687 For an example of such a 'bust', see Operation Cyber Chase conducted by the U.S. Organised Crime Drug Enforcement Task Force (OCDETF). As a result of this massive joint investigation:

'[a] number of significant insights were gained into the operation of the Bansal organization, an India-based group that supplied controlled substances to rogue pharmacies operating Internet Facilitation Centers (IFCs) in the United States.

The indictment...indicates that during the period from "August 2004 to March 2005 the defendants and others sold at least 400,000 dosage units of controlled substance pharmaceutical drugs in Schedule 2 at least 2,700,000 dosage units of controlled substance pharmaceutical drugs in Schedule 3, and at least 12, 287,000 dosage units of controlled substance pharmaceutical drugs in Schedule 4" to IFCs' (Simione & Holland 2006, p.8).

688 As related to the Committee by Mr Joseph Rannazzisi of the DEA when it met with him in Washington, July 2007. In Sacramento, the Committee was also told by Ms Renee Zito, Director of the California Department of Drug and Alcohol Programs that for 'every internet pharmacy the California regional office of the DEA close down, two more will soon open up – it's that rapid' (Comments of Ms Renee Zito, Director, California Department of Drug and Alcohol Programs to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Sacramento, 2 August 2007).

While federal agencies such as FDA, Customs, DEA and the Department of Justice have successfully taken enforcement actions against both domestic and foreign Internet pharmacies and associated physicians in the past, these agencies face a host of enforcement issues with scarce resources. In an age of global terrorism where these same agencies are charged with protecting the public from dirty bombs, heroin sales, and chemical and biological weapons, it is tough to believe that stopping Internet pharmacies will become a top priority.<sup>689</sup>

Similar problems in detecting or interdicting prescription drug contraband distributed via the Internet have been observed in Australia. Data on pharmaceutical drug detections by Customs authorities at the Australian borders suggest that levels of importation are relatively small. The Australian Crime Commission (2007) reports that in 2005–2006, Customs detected 447 unauthorised importations of benzodiazepines (compared to 341 detections in 2004–2005 and 544 detections in 2003–2004) and 46 detections of pharmaceutical opioids (compared to 18 detections in 2004–2005 and 31 in 2003–2004). The majority of detections were in parcel post. There were 14 detections of postal shipments of more than 300 benzodiazepine tablets. Twenty-five of the opioid detections involved morphine, 3 contained moderate quantities of methadone, 11 contained codeine, and 4 contained dihydrocodeine tablets. One postal detection contained 1,170 morphine capsules and four detections contained between 114 to 360 morphine tablets each (Australian Crime Commission 2007).

However, it is difficult to know whether these statistics represent only a small fraction of the pharmaceutical drugs being mailed into the country from Internet pharmacies and other sources. In 2004, St George, Emanuel & Middleton wrote:

We could not determine what actions these authorities were pursuing in regard to this issue. Australia Post does not have the authority to open postal articles because of privacy issues (Sal Perna, Group Manager, Australia Post, personal communication). Customs informed us that their surveillance capacity has been increased over the past 2 years to meet the challenges posed by Internet purchases of medications and other restricted goods. Customs also regularly prosecutes those who attempt to import prohibited goods without permits. At present all international mail and 70% of air cargo arriving in Australia is examined either physically or by x-ray (JH Jeffery, Acting Chief Executive Officer, Australian Customs Service, personal communication) (St George, Emmanuel & Middleton 2004, p.119).

When the Committee heard evidence from Mr Steve Marty, Registrar of the Pharmacy Board of Victoria, he stated in this regard:

In theory customs examines 100 per cent of inward mail. However, the realities are they cannot possibly check every single packet. Quite commonly pseudoephedrine has come in as vitamin preparations...That is a major subject of the national chemical precursor diversion group that I am on and there is some intelligence about that sort of issue...

The Australian ones [Internet sites] we certainly look at; it is pretty hard to pick up overseas ones unless you get some intelligence, because they are there one day and changed the next. Even if they have got a dot-au extension on them it does not mean that they are based in Australia; they could be anywhere. Of course, the risks are for people buying things over the Internet; you have got no idea what you are buying, where they are from, or who is supplying them.<sup>690</sup>

689 Statement of Senator Carl Levin, to the Senate Committee on Governmental Affairs, *Buyer Beware: The Danger of purchasing pharmaceuticals over the Internet*, 17 June 2004.

690 Mr Steve Marty, Registrar, Pharmacy Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007.



*The Internet as an 'educator' – Prescription drugs for recreational abuse*

The Internet facilitates not only knowledge of prescription drugs that are available but also how to abuse these drugs for recreational purposes. In such cases the people using the Internet are not those with a genuine need for the drugs who are trying to access them more cheaply, as is particularly the case among American consumers, but as a forum, particularly by young people, in order to access the drugs themselves or information about them for use as recreational drugs. As Heye et al note: 'The Internet has served to accelerate the education of abusers' (2002, p.2).<sup>691</sup>

Experts giving evidence to this Inquiry have observed the Internet being used this way. For example, Mr Ray Beecham, a drug and alcohol worker from the provincial rural town of Ballarat, told the Inquiry:

[f]or a lot of young people these days because of the access to internet...they can go to doctors and can tell the doctors what they want to hear to get the medications – Those that we see are just as well educated as some of the workers in the field. What initially starts off as, 'I'll tell the doctor or the psychiatrist or somebody a story'...

You can access the MIMs [Prescription drug guide] off the internet or you can go in and look at the different disorders. You could go on to a Google search and put in 'anxiety disorders' and there would be different links. Rather than go to the doctor and try and tell them a story to get the medications, they can go in and explain, 'I've got this symptom' or 'I've got that symptom'.

We have one client in particular that I am thinking of and he was a wealth of knowledge because as a young kid he was isolated in a little rural town and [used the internet extensively]; he had a massive benzo problem from about the age of 14 or 15 and it was prescribed – because he used to tell them about the symptoms – and you would not think a 14 or 15-year-old would be able to fake those symptoms.<sup>692</sup>

Similarly, Mr Steve Marty stated:

[That is] the challenge for health practitioners today...because often members of the community will know more about their particular condition and drug than perhaps the health practitioner does because they have done a Google...Of course they will know all the things about the drugs. If you cannot find out [through other means], particularly for illicit purposes, you will find that on the internet as well.<sup>693</sup>

The Internet can also be viewed as a particularly useful tool to learn how to 'tamper' with prescription drugs, that is altering the formulation of a drug to get a bigger 'high':

'If you just swallow them you will not be getting the full effects.' Instead, the website tells abusers of a common prescription drug to crush the time-release beads and snort them, or swallow the powder in a piece of tissue paper to get a longer-lasting 'hit'.

These words could kill. Yet tampering with prescription drugs to amplify their effects is a growing health hazard. A study published this month suggests that droves of people are turning to the internet to search for and swap advice on how to tamper with prescription drugs, for instance, by snorting those prescribed for hyperactivity disorders, or chewing skin patches containing potentially lethal painkillers.

The appearance of websites detailing the recreational use of these drugs, which even post recipes on how to heighten the hit, is the latest twist in this trend...The traffic on some of

691 For some examples of Internet activity pertaining to prescription drug recreational abuse that the authors uncovered during their internet surveillance see Appendix 16.

692 Mr Ray Beecham, Team Leader, Alcohol and Drug Centre, Ballarat Community Health Centre, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Ballarat, 29 May 2007.

693 Mr Steve Marty, Registrar, Pharmacy Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007.

the sites is enormous. One, which includes around 3000 personal accounts of experiences with a wide range of legal and illicit drugs, receives an average of 420,000 hits a day.

For instance, some sites suggest ways of tampering with skin patches designed to slowly release the opioid painkiller fentanyl. Users sometimes extract the drug from a patch to eat, inject or smoke. Yet a single patch can contain enough fentanyl to kill several people, according to toxicologist Bruce Goldberger from the University of Florida in Gainesville. 'It's like Russian roulette – you just don't know how much drug you're going to get', he says.

Goldberger says the tampering problem began to escalate in the mid-1990s when OxyContin came on the market. OxyContin, made by Connecticut-based company Purdue Pharma, is a sustained-release formula of oxycodone, another powerful opioid painkiller. Recreational users quickly realised they could defeat the sustained-release formula by chewing the tablets, or crushing them to snort or inject.

Surveys by the US Drug Abuse Warning Network (DAWN) suggest the number of emergency hospital visits involving oxycodone misuse increased about 10-fold between 1996 and 2004. Estimates suggest that in 2004 there were more than 36,000 admissions involving misuse of the drug, now nicknamed 'hillbilly heroin'.

There are no official US national statistics on how often drug tampering leads to a fatal overdose. But tampering is implicated in roughly 200 deaths each year in Florida alone, according to Goldberger, whose lab oversees much of the state's post-mortem investigations. He adds that because the circumstances of a drug overdose are often unclear, that is probably the tip of the iceberg.

Goldberger says he was reluctant to discuss the problem of drug tampering publicly several years ago, for fear of planting the idea in someone's head. 'But today, the information is already out there', he says. 'If you don't know how to tamper with a product all you have to do is a Google search' (Muir 2006, p.6).

In the United States a comprehensive academic study of tampering and the use of the Internet to support it was recently undertaken by Cone (2006). The study examined tampering methods reported on the Internet for selected pharmaceutical and prescription drugs and found that:

The Internet appears to be a prime source of information for misusers interested in tampering with drug/formulations. A plethora of websites provide users with advice, tips, procedures and specific recipes on drug/formulation tampering.

The Internet provides broad and varied guidance on tampering methods that are specific to drug classes and unique formulations. Instructions are available on crushing, separating, purifying and chemically altering specific formulations to allow changes in dosage, route of administration, and time course effects. Many pharmaceutical formulations contain features that serve as 'barriers' to tampering. The nature and effectiveness of formulation barriers vary widely with many being overcome by adventurous misusers. Examples of successes and failures in tampering attempts are frequently described on Internet sites that support recreational drug use (Cone 2006, p.31).

Cone lists four main methods by which tampering can be effected. These are:

- Separating narcotic drugs (codeine, hydrocodone, oxycodone) from excipients and non desirable actives (aspirin, acetaminophen, ibuprofen)
- Overcoming time-release formulations
- Removing active drugs from high dose formulations (particularly in patches and pills)<sup>694</sup>
- Altering dosage forms for alternate routes of administration (Cone 2006, p.31).

694 Alprazolam (Xanax) is a benzodiazepine particularly susceptible to this form of tampering (Cone 2006).



Cone argues that pharmaceutical manufacturers need to take into account when developing or reformulating their products 'the scope and practice of tampering methods available to recreational drug users on the Internet':

To discount the importance of Internet information on drug tampering seems unwise in all regards. A therapeutic product should provide the highest level of safety and efficacy possible. Review of tampering practices offers ethical drug developers an opportunity to assess the strengths and limitations of their products in light of how recreational drug users may approach their products (Cone 2006, p.38).<sup>695</sup>

Other academic studies on the use of Internet to access and trade prescription drugs for illicit purposes have expressed similar concerns. For example, a study published last year in the *American Journal of Psychiatry* (Forman et al 2006) found the use of non-prescription websites could be viewed as worrying new methods for initiating opioid use among young people, particularly as individuals aged 21 and younger are the most frequent users of the Internet in the United States (Lenhart, Madden & Hitlin 2005). The authors concluded their study with a timely warning:

Three national drug use monitoring studies have cited significant increases in prescription opioid use over the past 5 years, particularly among young people. The emergence of NPWs [non-prescription websites] introduces a new vector for unregulated access to opioids...

Search engines such as Google make NPWs readily available to the public without any medical guidance or control. This unregulated access is likely to increase use and contribute to abuse, dependence and overdose. Young people – the heaviest users of the Internet – appear to now have an unsupervised means of obtaining opioid medications. Although law enforcement agencies have been aware of these websites since 1999, their availability does not appear to have diminished. Uncontrolled access to prescription opioids introduces a unique development with potential broad implications for law enforcement, health care delivery and drug policy (Forman et al 2006, p.1237).

Representatives of the Kentucky Cabinet for Health and Family Services testified to the problems with such unregulated access. Mr Dave Sallengs of the Drug Enforcement and Professional Practices Branch gave evidence as to how Kentucky teenagers would either access drugs directly from the Internet or alternatively steal them from a family member's medicine cabinet and then find 'recipes' on the Internet for how to combine them to get the best 'buzz'. Often the finished product would be taken to share at 'pharming parties'.<sup>696</sup>

Pharming parties are a big problem with teenagers, they take bags of miscellaneous drugs, they call it trail mix because of the appearance, they get these drugs out of their parents' medicine cabinets at home, they call that pharming where they go into the medicine cabinet, they get the pills out, take them to these parties, throw them in the bowl.

...they'll put anything in there and you can go to these chat rooms on the internet and get recipes and the recipes are by colour, if you take purple pills with a dark stripe around them and put them in the mix and certain colour combinations will give you an up effect, certain colour combinations will give you a downer effect and kids relate to that. The affect of this in 2006, this gentleman died of a drug overdose after a pharm party, he had the equivalent of 67 xanax in his system.<sup>697</sup>

<sup>695</sup> For further discussion of tampering and reformulation efforts to prevent it, see Chapter 5.1.

<sup>696</sup> For a discussion of 'pharming parties' see also Chapter 2.3.

<sup>697</sup> Mr Dave Sallengs, Manager, Drug Enforcement and Professional Practices Branch, Kentucky Cabinet for Health and Family Services, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Frankfort, Kentucky, 31 July 2007.

Certainly, Forman et al's call for more and better research to determine the effect of Internet websites on prescription drug initiation, use, abuse and dependence<sup>698</sup> is worthy of consideration. As the authors of a separate study remarked last year, 'Despite the emergence of the Internet as a potential source of controlled substances, not much is known about this development' (Gordon, Forman & Siatkowski 2006, p.272). This is certainly true of the situation in Australia (see Gijssbers & Whelan 2004).

Notwithstanding these very valid concerns, some commentators have observed that it is not all 'doom and gloom'. For example, Heye et al argue that the Internet can also be used to assist epidemiologists, researchers and law enforcement agencies to identify and report prescription drug abuse and diversion:

There is a better way to identify and report abuse related adverse drug events. More proactive surveillance of electronic media has the potential to detect abuse much earlier than the current systems.

The Internet has revolutionised the way Americans obtain health care information. Nearly 100 million adults use the Internet to find health related information...Importantly, individuals are voluntarily exchanging a huge amount of personal information on the Internet in public forums. In fact because of its anonymous nature, people tend to speak more honestly on the Internet. Further, this information is available in real-time, without months or years of delay. The Internet is a vast underutilized resource for drug manufacturers and regulators (Heye et al 2002, pp.4-5).<sup>699</sup>

The Internet can also be used in other beneficial ways when it comes to addressing prescription drug abuse. In particular, the Committee received evidence from former abusers of benzodiazepines and other prescription drugs that web-based support groups can be of great assistance in supporting people who have current or ongoing problems associated with prescription drug misuse or are former misusers.<sup>700</sup> Such support websites can give information about the medical properties of the drugs, contacts for support networks and information on withdrawal and tapering of benzodiazepines, in addition to general advice.<sup>701</sup>

Further discussion on the use of the Internet to provide useful therapeutic information on prescription drugs is found in Chapter 6.1.

## Internet prescription and Internet pharmacy in Australia

Much of the discussion above pertaining to the use of the Internet to facilitate prescription drug use and abuse in America may possibly be applicable to the growing phenomenon of such use in Australia. However, as there is so little data available in the area it is difficult to

698 One interesting aspect of Internet drug trading that has been little remarked upon is the use of the 'net' to access prescription drugs by people already drug dependent and/or having received, or currently in, treatment. However, a recent study by Gordon et al makes the salutary point that 'treatment providers need to become aware of the new challenges that online drug sales represent' (Gordon, Forman & Siatkowski 2006, p.274). The authors continue:

'Unsolicited e-mails offering drugs of abuse for sale could be a potent relapse trigger for individuals recovering from drug dependence. Clinicians should consider advising patients who use the internet and email to change their email address and use spam blocking software to reduce the likelihood of exposure to drug solicitations. This is particularly true for individuals who have used the internet to make drug purchases prior to entering treatment. Similarly, for these individuals, treatment plans should include the removal of cookies that may have been installed by drug web sites on their computers...Nothing is currently known about the role of the internet in the initiation of drug use, the maintenance of dependence, and the triggering of relapse. Similarly, nothing is known about how prevention specialists and treatment providers might effectively address this problem. More research is required on this emerging issue' (Gordon, Forman & Siatkowski 2006, p.274).

For further discussion of treatment issues relating to prescription drugs, see Section Seven.

699 For a discussion generally of the problems with (American) data collection and surveillance systems as expressed by these authors, see Chapter 2.1.

700 In particular the Committee was pleased to meet with Ms Joan Gadsby, author of the book *Addiction by Prescription*, herself a former prescription drug 'addict', and Ms Janet Currie and Ms. Susanne Murphy of the Psychiatric Medication Awareness Group during its visit to Vancouver, Canada, in July 2007.

701 An example of a comprehensive site of this kind is [www.benzo.org.uk](http://www.benzo.org.uk), a British based site with an international following and subscription list, which is dedicated to addressing benzodiazepine misuse.



know to what extent this is the case. The following short section examines these issues more specifically as they apply to this country.

Online pharmacies are subject to the laws of the country in which they are based. There is no comprehensive international treaty governing the issue. Whilst Australians require a valid Australian prescription before prescription medication will be dispensed, clearly the Internet is one way of getting around such an obstacle. As discussed in Chapter 3.1, the Therapeutic Goods Administration (TGA) controls the importation and manufacture of medications and prohibits the importation of prescription medications without a permit or prescription, which theoretically would cover goods obtained over the Internet without due authorisation. But as St George, Emmanuel and Middleton (2004) state, these regulations are difficult to police. Yet as Gijsbers and Whelan ask: 'What is the size of the cyberpharmacy problem in relation to addictive drugs in Australia?' (2004, p.103). Is the situation as grave as in the United States?

One of the major differences between the United States and Australia, and one of the reasons that explains why the use of the Internet to access prescription drugs is not as pronounced in this country, is that Australian citizens generally have access to low cost prescription medicines through subsidies, most notably the PBS.

Whilst the use of mail order or Internet prescriptions and delivery of medicines may be advantageous for consumers in remote and rural parts of Australia where medical practices and pharmacists are sparsely located, concerns have been expressed, as in the United States, that these methods of supply are deficient. This is because the face-to-face counselling of the doctor or pharmacist is not provided. Such safeguards are a key aspect of addressing the information asymmetry between provider and consumer.

A review by St George, Emmanuel and Middleton outlined some of the ways in which Australian consumers can access drugs online:

In some countries, such as Mexico, many prescription medications can be purchased over the counter, and they can be sold over the Internet without prescription. Of 33 surveyed pharmacy websites in the United States, most (88%) require a prescription before medication will be dispensed and the remaining sites either dispense prescription medication without a prescription, or accept scripts by fax or email. This may mean that one script could be recycled through many of these online pharmacies. Other overseas sites offered to provide consumers with a prescription after an online or phone consultation. Some sites charge a membership fee before medications like morphine and oxycodone can be obtained. There are also sites that provide, for a fee, a directory of online and land-based pharmacies that dispense prescription medications without prescription. Many sites boast of proven methods for getting packages past customs, and some offer to re-ship medication if a seizure notification from customs can be produced (2004, p.118).

Interestingly, despite these concerns consumer groups in submissions to the Galbally Review supported the use of mail order and Internet 'pharmacy' for the cheaper costs they provided. This was also one of the reasons that pharmacy groups were opposed to their proliferation (see Galbally 2000b). Pharmacists are also concerned about the dangers of 'medical misadventure' associated with laypeople buying medicines via the Internet. In a submission to this Inquiry the Pharmacy Board of Victoria expressed their concern that the 'public is not given sufficient awareness of the dangers of buying medicines online'. Whilst the Board considers the TGA website to contain a good alert system with regard to online 'spam' advertising of medicines, few people would be aware of this service.<sup>702</sup>

As far as the use of the Internet to access prescription drugs for recreational purposes is concerned there has been little research undertaken in this area or information available in Australia, although there is little reason to think that the trends in the United States discussed earlier in this chapter won't eventually be replicated in Australia. One study done

<sup>702</sup> See Submission of Pharmacy Board of Victoria to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.



in Australia argued that preventive action with regard to allowing access to prescription drugs via the Internet should be put in place before the problem gets out of hand. The authors argue that whilst:

The use of the Internet as an alternative source of supply of prescription medications for people using illicit drugs is unlikely to overtake the street market or doctor shopping for scripts as a means of obtaining illicit drugs; [and although] the extent of the current use of the Internet as a source of drug supply is unclear...ordering drugs over the Internet is still expensive and entails a 2-week wait for the medications. [The Internet nonetheless] may have the potential to encourage people who would not purchase drugs on the street or 'doctor shop' to purchase drugs over the Internet (St George, Emmanuel & Middleton 2004, p.119).<sup>703</sup>

Some pharmaceutical companies have also expressed concern about what could become a greater trend towards accessing prescription drugs on the Internet. During the Committee's forum for pharmaceutical companies Dr Greg Pearce of Alphapharm said:

I think it is a worry, not only as a supply point but also as an information point, getting inappropriate and biased, unbalanced information. On a scale of 1 to 5, I would say for me, representing Alphapharm, a 4. It is something that we really need to get a much stronger hold of and an understanding of. I do not know how big a problem it is but I am sure it is much bigger than we imagine.<sup>704</sup>

Dr John Whitlam of Mundipharma added that whilst it was clear that many of the products his company produce would appear if one did a 'Google' search, the problem was not having any real idea of how extensive a phenomenon Internet 'shopping' of prescription drugs is in Australia:

We certainly do not know what the size of the problem is. If there was extensive illegal importation of any of our products through illegal internet pharmacies from Mexico or anywhere else, we would be very concerned, and not because of the commercial implications that might have – that is the least of our considerations. It is a concern for the safety of the people who are using it. They are breaking the law, they [products] are being misused – we are not talking about sales and commerce here, we are talking about patients' lives.<sup>705</sup>

On the other hand Australian medical scientists Gijsbers and Whelan, whilst not underestimating the problem, do not believe it should be overstated either. They echo St George et al's point that for some drug abusers the wait to receive drugs via the Internet may be too long:

Cyberdrugs will only take off if there is a significant price advantage over that on the black market. Data are hard to obtain, but we suspect that until it becomes harder for users to obtain benzodiazepines from lax prescribers or on the black market, the purchase of cyberdrugs will be regarded as too slow and too expensive (St George et al 2004, p.103).

Similarly, Mr Peter Muhleisen, pharmacist with the Turning Point Alcohol and Drug Centre, advised caution in overstating the problem when Turning Point gave evidence to the Committee in July 2007. He stated that whilst prescription drugs:

703 Contrary to the general concerns of most American agencies with whom the Committee met in July 2007, the United States Substance Abuse and Mental Health Services Administration (SAMHSA) was relatively sanguine about the phenomenon. One official stated to the Committee that whilst there was certainly a lot of 'spam' about prescription drugs that could be found on the Internet, 'Drugs are generally more expensive on the Internet as it turns out which tends to reduce sales' (Unidentified witness, SAMHSA, comment to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria. Washington, 26 July 2007).

704 Dr Greg Pearce, Medical Advisor, Alphapharm, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Pharmaceutical Industry Forum, Parliament House, Melbourne, 16 July 2007.

705 Dr John Whitlam, Director of Medical Affairs, Mundipharma, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria Pharmaceutical Industry Forum, Parliament House, Melbourne, 16 July 2007.



[a]re certainly widely advertised on the internet. If you go anywhere near any sort of drug site you will get spam about Xanax scripts from Mexico or the Philippines or wherever they are sending them from. I have yet to hear of anyone actually getting them [here in Melbourne], but it certainly sounds like it is an opportunity. These are very cheap drugs.<sup>706</sup>

His colleague, drugs researcher Dr Mark Stoové, added that Turning Point had asked their clients about where they obtained their prescription drugs for illicit use. The result was that the Internet 'does not seem to be a source for the average street injector'.<sup>707</sup>

Notwithstanding these disparate views, the development of e-commerce certainly poses challenges and risks for consumers of pharmaceutical medicines. The Committee is of the view that given the global legal complications involved in addressing Internet pharmacy, this is an area that is primarily the responsibility of the Commonwealth government. Nonetheless, it is also one that requires more consideration at state level.

## Strategies to address prescription drug abuse and the Internet

A variety of strategies have been suggested to address the problem of access to prescription drugs via the Internet and the proliferation and potentially dangerous nature of illegitimate online pharmacies. Most of these are American, reflecting the prominence the issue has in that country compared to Australia. But whilst many of these strategies have their origin in the United States, for the most part – allowing for legal, constitutional and cultural differences between our two countries – they are universally applicable.

The strategies can be broadly divided into legislative and programme interventions.

### *Legislative interventions*

Recognising that an overarching strategy to combat illegitimate Internet pharmacies requires international cooperation and possibly an international treaty or convention, the American state and federal governments have nonetheless acknowledged that some legislative interventions can assist in reducing the amount of illegal pharmaceutical and prescription drugs circulating in the country. The Pharmaceutical Market Access and Drug Safety Bill is currently before the United States House of Representatives seeking to assure the greater safety and efficacy of drugs imported into the USA.<sup>708</sup> It also seeks to strengthen the powers of the Food and Drug Administration to investigate and combat illegal Internet sales and remedy the situation outlined by Dr David Kessler, former FDA Administrator, at U.S. Senate Committee hearings into a former version of the Bill:

The current system is out of control. There is no reliable way to know whether an Internet pharmacy outside the United States is legitimate and sells authentic, safe and effective drugs, although some cities and States have identified legitimate Canadian pharmacies from which consumers can order Canadian drugs.

The existing framework in section 801(a) of the Federal Food, Drug and Cosmetic Act effectively ties the FDA's hands so that it cannot halt packages containing questionable drugs on their way to U.S. consumers. Currently, if an FDA inspector identifies a questionable drug shipment, the agency must conduct a detailed inspection and send a specific notice to the addressee detailing the violations before it can take final action. FDA currently lacks the jurisdiction and resources to verify that legitimate pharmacies in Canada or elsewhere are

706 Mr Peter Muhleisen, Pharmacist, Turning Point Alcohol and Drug Centre, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 9 July 2007.

707 Dr Mark Stoové, Research Fellow, Turning Point Alcohol and Drug Centre, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 9 July 2007.

708 The Pharmaceutical Market Access and Drug Safety bill [HR 380 -2007, 110th Congress] will amend the Federal Food Drug and Cosmetics Act with respect to the importation and safety of prescription drugs. The bill has had a chequered history. Mostly identical versions of the Bill had also been before both houses of the 109th Congress before lapsing. Currently the bill has been referred to the House of Representatives Subcommittee on Commerce, Trade and Consumer Protection and will be debated once the House reconvenes in September 2007. See <http://www.govtrack.us/congress/bill.xpd?bill=h110-380&tab=summary> (accessed Aug 13, 2007).



delivering safe and effective drugs to people here in the United States. The FDA does not have the authority or the resources to inspect pharmacies, wholesalers or manufacturers in Canada or anywhere else outside the United States. The agency's current ability to inspect manufacturing plants producing drugs for the U.S. market does not extend to facilities manufacturing drugs for Canada or anywhere else.<sup>709</sup>

The Pharmaceutical Market Access and Drug Safety Act of 2007 includes provisions that would address these problems. This Bill would allow FDA to implement safeguards to effectively and efficiently stop dangerous imports that currently reach American consumers. The bill would enable the FDA to determine where a drug comes from and whether it truly is the drug that the seller claims. The Bill gives the FDA the authority to assess the manufacturing source of drugs according to the same standards used for domestic drugs and to ban the importation of any drug it finds inadequate. Moreover, the Bill gives the FDA the authority to inspect and verify the 'chain of custody' of the drugs all the way back to the source of manufacture. It also bars imports from countries known to be major sources of counterfeit pharmaceuticals and will impose much more stringent safeguards to the operation of Internet pharmacy sites. It will require all Internet provider sites to require a doctor's prescription before they can dispense drugs and authorises state Attorneys General to go to a federal court to close down pharmacies who fail to comply with such a stipulation.<sup>710</sup> Currently debate on the Bill has been suspended.

At state level, legislative programmes have also been introduced to address illegal Internet supply of prescription drugs. For example, in Kentucky the state Attorney General has recognised that 'traditional law enforcement techniques could not shut down this new pill pipeline'.<sup>711</sup> Legislation was therefore passed in 2005 to create an Attorney General's Internet Pharmacy TaskForce.<sup>712</sup>

The TaskForce draws together law enforcement and pharmacy officials to develop laws combating the sale and shipment of drugs by unlicensed Internet pharmacies and their delivery by pushers to towns across Kentucky. A key element of the TaskForce's operations is to provide training on Internet pharmacy crime and related issues to a wide range of law enforcement, health education and community officials.<sup>713</sup> Representatives of the Kentucky Cabinet on Health and Family Services explained to the Committee some of the problems experienced in Kentucky that led to the TaskForce being established:

[w]e've been trying to combat internet access in Kentucky but it's a national problem in the USA. You can't control it simply at state level because these people are not located in the state...Most of these people that profess to be internet pharmacies are somebody sitting in their basement with a PC with internet access and what they do is they contract for pharmacies and doctors and they pay them a certain amount for their services and then they advertise on the internet or whatever. If you want, for example, Loretabs they can get them for you. So these drug abusers get to the internet and they tell them what they want. About 20 minutes later a doctor from 'who knows where' will call you and say I'm doctor so and so and you contacted this pharmacy site and could you tell me about your problem and they'll say my back hurts, I want some pain pills. So this doctor will call back and tell them

709 Testimony of Dr David Kessler, Former Commissioner of the United States Food and Drug Administration, U.S. Senate Committee on Health, Education, Labor and Pensions Hearings S.334: *An Approach to Drug Importation*, 19 April 2005, accessed at [http://help.senate.gov/Hearings/2005\\_04\\_19/2005\\_04\\_19.html](http://help.senate.gov/Hearings/2005_04_19/2005_04_19.html)

710 This Bill and its provisions were explained to the Committee when it met with Congressman Mark Souder, United States Representative for Indiana during its fact-finding trip to North America in July 2007.

711 Attorney General for the Commonwealth of Kentucky, Greg Stumbo – Office of the Attorney General, accessed at <http://ag.ky.gov/kbi/drug.htm>

712 Internet Pharmacy Law – Senate Bill 63 2005. Currently a bill to strengthen Kentucky's Internet Pharmacy Law (Senate Bill 88) is currently before the state Senate.

713 For further information about such training see comments of Agent Lynne Thompson, Kentucky Bureau of Investigation, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Frankfort, Kentucky, 31 July 2007.



he's going to give this person a prescription, the guy gives him \$20 then he puts him in touch with one of the pharmacies on his list.<sup>714</sup>

To address these types of scams, in February 2007 a Bill was introduced into the Kentucky Senate that included a number of measures that seek to strengthen the original Internet Pharmacy Law of 2005. In particular, Senate Bill 88 holds pharmacies as well as physicians, consumers and 'Internet brokers' accountable for their involvement in illegal drug trafficking. This legislation will also connect Kentucky pharmacies electronically. State Attorney General Greg Stumbo commented on the proposed laws earlier this year:

The new law will build upon what we have learned from our many recent enforcement actions.

The new law will require patients to get a medical exam face-to-face with a physician to eliminate the common practice of fake online examinations. This will preserve and strengthen the doctor-patient relationship that is the heart of responsible medical treatment. The new law will also ensure that rogue pharmacies are brought to justice and end-users are held accountable. Further, it will provide an invaluable tool to prosecute online brokers who act as go-betweens for pharmacies and drug buyers. Anyone who assists in these illegal purchases of narcotics, including online brokers, will now be subject to tough penalties.<sup>715</sup>

His comments were echoed by Commissioner David James of the Kentucky Bureau of Investigation:

Smart and innovative policing can meet the challenges posed by cyber drug pushers. With the efforts of KBI agents, and other law enforcement agencies currently being trained, millions of dollars worth of abused narcotics will be intercepted. Law enforcement now has tools to combat cyber pushers hiding in the shadows of the Internet.<sup>716</sup>

Commissioner James reiterated these concerns when he met with this Committee in Kentucky.<sup>717</sup>

The provisions of the new law and its efforts to strengthen the measures by which access to prescription drugs through illegal Internet sites could be reduced was explained to the Committee by members of a Law Enforcement 'Round Table' during the Committee's visit to Frankfort, Kentucky in August 2007. In particular, Kentucky Bureau of Investigation (KBI) agents were enthusiastic about the sections of the Bill that will require an in-person examination of a patient and precludes physicians who have no relationship with a patient (other than through an Internet questionnaire) from prescribing controlled substances.<sup>718</sup> Agent Lynne Thompson, for example, said that by requiring a personal examination the

714 Certainly the problem of combating Internet access to illegal prescription drugs is not insignificant in Kentucky. In 2006 alone, the Kentucky Bureau of Investigation made 229,181 drug seizures relating to drugs accessed from Internet pharmacies. The street value of the seized drugs was \$1,191,474. (Information sourced from Commonwealth of Kentucky, Cabinet for Health and Family Services and Kentucky Bureau of Investigation. Presentation to the Drugs and Crime Prevention Committee, *Kentucky's Prescription Drug Issues*, 1 August 2007.)

715 Quoted in 'Attorney General Greg Stumbo Announces KBI To Train Other Law Enforcement to Fight Internet Drug Trafficking', Press Release, Office of the Attorney General, Commonwealth of Kentucky, 12 February 2007, accessed 13 August 2007 at <http://www.kentucky.gov/Newsroom/ag/kbi-to-train-law-enforcement.htm>

716 Quoted in 'Attorney General Greg Stumbo Announces KBI To Train Other Law Enforcement to Fight Internet Drug Trafficking', Press Release, Office of the Attorney General, Commonwealth of Kentucky, 12 February 2007.

717 Particularly pertinent provisions of the law are as follows:

'An internet or out of state pharmacy must:

- Have an Out of State Pharmacy issued by the Kentucky Board of Pharmacy
- Have a Pharmacist in Charge who is licensed by the Kentucky Board of Pharmacy
- Must report all Controlled Substances transactions to KASPER [Kentucky All Schedule Prescription Electronic Reporting]
- If it dispenses, more than 25 per cent of their prescriptions via the internet must be VIPPS certified (Kentucky Revised Statutes, Chapter 315.0351).

718 These provisions are now enacted in the 2007 Kentucky Revised Statutes (KRS) Chapter 218A. They now require a 'Good Faith Prior Examination'. A Good Faith prior examination means: 'An in person medical examination of the patient conducted by the prescribing practitioner or other health care professional routinely relied upon in the ordinary course of his or her practice, at which time the patient is physically examined and a medical history of the patient is obtained'.

new laws would prohibit the situation whereby one person may order a batch of pills for five or six people, give them some pills and then keep the rest.<sup>719</sup>

Whilst such interventions are clearly important, of themselves they may have little effect. This is particularly the case at state level, where the ability to police and combat a source of drug supply that has no clear jurisdictional boundaries is even more hampered than at federal level. As Agent Lynne Thompson stated to the Committee:

One of the biggest concerns is the internet drugs being shipped to or from bordering states or people doctor shopping outside the commonwealth and we can't track it and that's still a big thing, they don't know what to do when they stop the car they search the car and find a pill bottle and it's from Ohio or Tennessee and they don't know what to do about it...we had a terrible problem with people getting on the internet and ordering pills and getting them shipped in and the pills were mostly coming out of Florida and there was obviously no doctor patient relationship – you answered a few questions and they charged your credit card for a doctor's consultation and then you got your pills.<sup>720</sup>

As well, unlicensed out-of-state pharmacies are advising patients in Kentucky that they will ship contraband to bordering states such as Ohio, West Virginia and Indiana to avoid seizures by Kentucky law enforcement officers.<sup>721</sup>

On the other side of the country, Judi Nurse, Supervising Inspector for the California Board of Pharmacy, echoed the concerns of Agent Lynne Thompson when the Committee visited Sacramento in August 2007:

Internet pharmacy is a crime of greed so the way we deal with that is [to impose] big fines. We do have an internet code section statute in California but it's very specifically written and the patient must be a California resident [for it to apply]. Internet cases are really hard for the states to deal with. If you talk to the 'feds' they'll tell you it's hard for the feds to deal with also, but for the states, you don't know where they are for the most part. They may say they're in California but they may be in the Philippines so if you're lucky you can find them.<sup>722</sup>

The types of problems outlined above indicate how necessary it is to have a raft of strategies that encompass a wide range of technical and scientific, investigatory, research, education and health approaches, as well as legislative measures.

### ***Programme and other interventions***

A variety of approaches at federal level have been taken in recent years to address the increasing amount of drugs being illegally traded on Internet pharmacies. Many of these have been auspiced by the DEA.

### **Strengthening oversight of legitimate Internet pharmacies**

The DEA and other federal agencies, recognising the utility and benefit of Internet pharmacies, have introduced programmes in conjunction with the private sector to ensure that sufficient safeguards are put in place to guarantee drug safety and reliability. The VIPPS programme discussed above is one such approach. A separate but related issue is developing technical protocols and guidelines for the issuing of electronic prescriptions. This issue is discussed further in Chapter 5.2 of this Report.

719 Agent Lynne Thompson, Kentucky Bureau of Investigation, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Frankfort, Kentucky, 31 July 2007.

720 Agent Lynne Thompson, Kentucky Bureau of Investigation, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Frankfort, Kentucky, 31 July 2007.

721 Information provided to the Committee from Commonwealth of Kentucky, Cabinet for Health and Family Services and Kentucky Bureau of Investigation. Presentation to the Drugs and Crime Prevention Committee, *Kentucky's Prescription Drug Issues*, 1 August 2007.

722 Ms Judi Nurse, Supervising Inspector, California Board of Pharmacy, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Sacramento, 2 August 2007.



## Investigations and surveillance

The Office of Diversion Control has increased its enforcement activity of cyber pharmacy in the past two years, recognising the gravity of both prescription drug abuse and diversion generally and the use of the Internet specifically to facilitate it. Whilst interdicting drugs originating from Internet pharmacies is notoriously difficult, as discussed earlier in this chapter, there have been some notable 'success stories'. As of December 2005 the DEA/ODC had initiated 236 investigations of online sales of controlled substances without a prescription. These operations targeted both offshore pharmacies importing into the United States and domestic outfits supplying prescription drugs directly to American Internet customers. Millions of dollars in cash and assets (such as computers) have been seized, cyber pharmacies closed down and contraband drugs seized as a result of such investigations.<sup>723</sup>

## Inter-agency cooperation

Investigations such as those conducted by the DEA could not have taken place without the cooperation of a wide range of federal, state and local law enforcement, health and other agencies, in addition to the assistance of private sector organisations such as pharmacies and their peak or professional bodies. As the DEA's Mr Joseph Rannazzisi remarked:

Traditional geographic lines of jurisdiction do not exist on the Internet, yet law enforcement must abide by such limits. This means that collaboration is a key component to successfully investigating and arresting those who are nothing more than drug dealers utilizing the anonymity of the Internet to ply their trade.

To better facilitate this interagency cooperation, a federal interagency task force was established in early 2004 with the purpose addressing Internet diversion of drugs and conducting public outreach on pharmaceutical issues in general. Among other groups, DEA, ONDCP, ICE (Immigration and Customs Enforcement), CBP (Customs and Border Protection), and the FDA have been represented at task force meetings past and present. A major focus of this evolving task force has been to reach out to business leaders in key industry sectors that provide services used by Internet pharmaceutical trafficking groups. The purpose of this outreach has been twofold: to raise awareness of the problem; and to elicit voluntary efforts to restrict their services from being used by illicit Internet pharmaceutical traffickers. The task force has also provided support to DEA through ICE and CBP special authorities. ICE and CBP have primary jurisdiction in the enforcement of trans-border smuggling laws and periodically conduct interdiction operations at international mail facilities to identify packages containing illicit pharmaceuticals. The task force meets quarterly and is currently evaluating options for establishing a single reporting point for businesses to report suspicious Internet pharmaceutical sites.<sup>724</sup>

With regard to the private sector, concerted efforts have been made by the DEA to co-opt those organisations that are necessary conduits for providing cyber pharmacy services. As Mr Rannazzisi comments:

To successfully ply their trade, Internet drug traffickers must rely extensively on the commercial services of three principal business sectors: (1) providers of various internet services – including web hosting, domain name registration, and search; (2) express package delivery companies; and (3) financial services companies, including major credit card companies and third party payment service providers. The DEA has reached out to each of these sectors and is working to educate and facilitate their assistance in shutting down Internet drug trafficking operations.

723 These operations were discussed with the Committee when they met with Mr Joseph Rannazzisi of the DEA in July 2007. For further information on these investigations see: <http://www.dea.gov/major/major.htm>. In particular the interested reader is directed to coverage of the two biggest operations conducted with regard to illegal Internet pharmacies by the DEA/ODC and other federal and state agencies – *Operation Cyber Chase* and *Operation Cyberx*.

724 Mr Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Department of Justice. Testimony to the House of Representatives Energy and Commerce Committee, Subcommittee on Oversight and Investigations, 13 December 2005, accessed at <http://www.dea.gov/pubs/cnrgtest/ct121305.html>

Several interagency meetings have been held with senior managers and legal counsel from leading Internet, express parcel carriers, and financial services companies. These meetings provided an opportunity for government and the private sector to reach a better understanding of relevant federal laws and explore areas of potential cooperation and voluntary industry actions to curb the expanding illicit sale of pharmaceuticals over the Internet.

In addition to our investigative efforts aimed to shut down illegal drug sales over the Internet, we are working with the state authorities and representatives of the pharmacy and medical communities to disseminate information regarding activities that can legally be conducted via the Internet.<sup>725</sup>

One important aspect of DEA/private sector collaboration was to increase the awareness of DEA registered pharmacies as to their obligations with regard to Internet pharmacies. Under American law, pharmacies must register with the DEA in order to dispense controlled substances. During one major DEA-led investigation of cyber pharmacy (Operation Cyberx) it was found that the main suppliers of drugs to some domestic Internet concerns were (unwittingly) DEA registrants. An Internet Distributor Initiative was therefore developed to increase the awareness of DEA registrants regarding their obligations and possible role in the illegal distribution of pharmaceuticals via the Internet. As a result:

the distributors voluntarily reviewed their customer base and apprised DEA of the termination of business with over 100 known or suspected illegitimate Internet drug trafficking organizations. An analysis of these pharmacies' buying patterns from January–September 2005 revealed over 60,000,000 dosage units of controlled substances had been purchased.

We believe that because of this initiative, many illegal Internet pharmaceutical sites are now unable to purchase large quantities of controlled substances for illegal sale domestically. While this is an effective approach to go after some of the domestic sources of illegal pharmaceuticals supplying the Internet, this will not affect foreign sources of pharmaceuticals. The global nature of the Internet adds to this challenge, as many substances which are controlled in the United States are not controlled elsewhere, and therefore offering to sell these substances online is not illegal per se.<sup>726</sup>

Private professional organisations have also developed their own unilateral interventions for addressing Internet pharmacy as it pertains to their own areas of expertise or control.

### Professional and private sector initiatives

As discussion throughout this chapter has indicated, Internet 'traffickers' who illegally operate cyber pharmacies often will either not require a valid prescription or at best may offer online 'consultations' consisting of a questionnaire that purports 'yet fails to create a legitimate doctor-patient relationship'.<sup>727</sup> In addressing this issue the American Medical Association has declared that a face-to-face evaluation is necessary to diagnose and confirm a medical need for prescribing. Moreover, the American Medical Association states that it is unethical for a physician to authorise a prescription for someone identified only through electronic means.<sup>728</sup>

725 Mr Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Department of Justice. Testimony to the House of Representatives Energy and Commerce Committee, Subcommittee on Oversight and Investigations, 13 December 2005, accessed at <http://www.dea.gov/pubs/cnrgtest/ct121305.html>

726 Mr Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Department of Justice. Testimony to the House of Representatives Energy and Commerce Committee, Subcommittee on Oversight and Investigations, 13 December 2005, accessed at <http://www.dea.gov/pubs/cnrgtest/ct121305.html>

727 Mr Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Department of Justice. Testimony to the House of Representatives Energy and Commerce Committee, Subcommittee on Oversight and Investigations, 13 December 2005, accessed at <http://www.dea.gov/pubs/cnrgtest/ct121305.html>

728 American Medical Association, *Guidance for Physicians on Internet Prescribing*, Policy H-120.956(2) and H120.949 (AMA Policy Database), accessed at <http://www.ama-assn.org/>



Similarly, the American Federation of State Medical Boards (FSMB) has recently devised a policy on Internet prescribing in which it affirms the principle that no legitimate doctor-patient relationship exists in situations where an Internet purchaser simply fills out a rudimentary online questionnaire. Such a practice simply would not establish an acceptable standard of medical care.<sup>729</sup> At Senate Judiciary Committee Hearings into Drug Trafficking on the Internet in May 2007, the FSMB made the following salient comments:

An appropriate relationship between the patient and the physician must exist before a prescription is written and medication dispensed. Failure to have an appropriate physician-patient relationship poses serious health risks including: (1) adverse drug reactions and/or interactions, (2) misdiagnosis or delay in diagnosis, (3) failure to identify complicating conditions, and (4) misuse, abuse and diversion of prescription medications, including controlled substances...Treatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means will be held to the same standards of appropriate practice as those in traditional (face to face) settings.<sup>730</sup>

As such, in addition to developing guidelines for all members and state organisations the FSMB have been active in establishing a National Clearinghouse on Internet Prescribing (NCIP). The NCIP monitors, collects and disseminates data and information on 'rogue' Internet sites that offer illegal prescribing and dispensing services. Such information is disseminated to its state boards and also to national enforcement and regulatory agencies such as the DEA, FDA, Immigration and Customs Enforcement, in addition to the National Association of Boards of Pharmacies, the pharmaceutical industry and the media.

To date approximately 39 physicians have been disciplined by their licensing board based on Clearinghouse data. The Clearinghouse has supplied information for more than 300 cases on the federal level and more than 600 cases on the state level. Additionally, information regarding Internet prescribing has been shared with [overseas agencies] such as the Medical Council of New Zealand and the Ministry of Health in Germany.<sup>731</sup>

Pharmacy Boards and peak bodies have also taken a key role in addressing the problems arising from 'rogue' Internet pharmacies. For example, the American Association of Pharmacists has recommended that any strategies or proposals to address Internet pharmacies include the following:

*Require identification of the 'pharmacist in charge' on every page of the website to help verify that the site is legitimate.*

*Require and define a 'qualifying medical relationship' to ensure that prescriptions are dispensed with a true prescription not with a questionnaire, the completion of which represents a prescription to the seller. Medications are dangerous. Eliminating health care providers from the physician/pharmacist/patient triad of care eliminates the two 'legs of the stool' who are trained to provide medical diagnoses and to provide pharmaceutical care.*

*Facilitate Broad Enforcement* to assist State Boards of Pharmacy with their enforcement of the Internet drug trade. Even when a Board of Pharmacy has taken action against a rogue Internet drug website that is hosted in their state, the board has limited, if any, jurisdiction over that same website's activities in other states. Allowing States to bring a civil action on behalf of its residents and to enforce compliance, including through a nationwide injunction, would allow one state to shut down activities in all 50 states of a rogue site.

*Recognize Credible Certification Services* that are currently working to ensure a site's legitimacy. A good example of this type of service is the National Association of Boards of Pharmacy's VIPPS program. We support the VIPPS program, which allows for the continuation of state-

729 Model Guidelines for the Appropriate Use of the Internet in Medical Practice 2002 (rev 2007), accessed at [www.fsmb.org/pdf/2002\\_grpol\\_Use\\_of\\_Internet.pdf](http://www.fsmb.org/pdf/2002_grpol_Use_of_Internet.pdf)

730 Testimony of Dr James N Thompson, President, Federation of State Medical Boards, to the Senate Committee on the Judiciary – *Rogue Online Pharmacies: The Growing Problem of Internet Drug Trafficking*, 16 May 2007.

731 Testimony of Dr James N Thompson, President, Federation of State Medical Boards, to the Senate Committee on the Judiciary – *Rogue Online Pharmacies: The Growing Problem of Internet Drug Trafficking*, 16 May 2007.

based pharmacy regulation. A federal program could create jurisdictional confusion and would require the investment of substantial resources to create a new, arguably redundant, registration and inspection process.

#### *Create a National Clearinghouse for Oversight & Reporting*

Health care regulation must carefully balance the needs and authorities of the federal and state regulatory bodies – the state health professions' licensing boards. New regulations should not intrude upon the authority of State Boards of Pharmacy. Rather, Federal authorities should intervene in collaboration with a State Board of Pharmacy, similar to the Food and Drug Administration's activity with the Rx Depot case, and in international cases. A national clearinghouse could identify Internet sites that appear to be in violation of state and federal laws and report those sites to state medical and pharmacy licensing boards.

#### *Address Commerce*

We recommend addressing the source of payments to rogue Internet drug sellers by prohibiting credit card payments to illegitimate Internet-drug sellers. We also recommend prohibiting Internet drug sellers from advertising on Internet search engines unless they meet a credible certification standard, such as VIPPS, and prohibiting advertising that a consumer does not need a prescription to order medications from a website. Finally, we recommend prohibiting shipment companies from accepting packages that do not meet the aforementioned standards. Such standards would enable members of the delivery system to identify products from legitimate pharmacies vs. illegal drug sellers.

#### *Develop a Public Education Campaign*

A public education campaign on the dangers of Internet drug sellers should be a component of regulating rogue sites. Pharmacists already play an important role in educating patients on the dangers of illegitimate Internet drug sellers and that role will only increase as more and more patients seek to use this access point. APhA has taken steps to educate our membership on issues surrounding importation of medications, including counterfeit medications – an issue directly related to the use of the Internet to purchase prescription medications. A continuing education piece was sent in our monthly publication, *Pharmacy Today*, reaching more than 100,000 pharmacists. And our consumer information website, [www.pharmacyandyou.org](http://www.pharmacyandyou.org), includes information on several topics, including information 'About importing medicines and Internet pharmacies'.<sup>732</sup>

In Australia it has been recognised that because of the nature of the Internet, issues pertaining to cyber pharmacy and online access to prescription drugs need to be dealt with at an international and national level (St George, Emmanuel & Middleton 2004). As in the United States there is a move towards inter- and intra-state agency collaborative cooperation.<sup>733</sup> Coalitions of interested parties will also need to work in tandem, including law enforcement and health officials, pharmacists and pharmacy associations and particularly the Customs Department:

Although the Internet may not be the major source of supply for illicit drug users, restricting access to Schedule 4 and 8 drugs through this channel can do no harm. This is where Customs plays an important role. The decrease in the availability of heroin in Australia caused by the 2001 'heroin drought' led to a marked fall in the number of heroin-related deaths, but did not necessarily lead to a decrease in rates of illicit drug use. Many heroin users simply substituted pharmaceutical drugs for heroin. Thus, restricting supply is not the answer to the complex problems posed by drug misuse. Prescription medications are still widely available on the Australian black market and through doctor shopping. However, restricting Internet access to these drugs may help to prevent the creation of new users. Another factor to take

732 American Pharmacists Association, Testimony to the Senate Special Committee on Ageing, Hearings, *Internet Pharmacy and Importation: Exploring Risks and Benefits*, 26 January 2005, accessed at [www.aphanet.org/AM/Template.cfm?Template=/CM/ContentDisplay.cfm&ContentID=7840](http://www.aphanet.org/AM/Template.cfm?Template=/CM/ContentDisplay.cfm&ContentID=7840)

733 For example, the Ministerial Council on Drug Strategy (MCDS) has recently added an investigation of Internet drug sales to its remit and agenda.



into account is that, if drug users are no longer presenting to GPs to acquire scripts, it may be difficult to determine their past drug use histories, as the use of online pharmacies to acquire prescription medication is unrecorded.

Customs plays a vital role at a national level [but] we also suggest that the Australian Government could initiate discussions with the countries where these pharmacies are based, perhaps encouraging them to tighten controls. At a local level, doctors and other professionals working with people who misuse drugs, and especially with young people, should be educated about drug availability on the Internet. All those working with these people should be made aware that the avenues for acquiring drugs are changing, and they should continue to provide support through education and harm-minimisation strategies (St George, Emmanuel & Middleton 2004, p.119).

## Conclusion

Whilst all the strategies discussed in the previous section are valid and useful, from the wider perspective little can be achieved in combating Internet drug crime and/or illegal Internet pharmacies without some form of external international controls. It beholds all levels of government in Australia to work for an international convention in this area to address the jurisdictional issues that a borderless cyberspace poses.

## Section Six: Information, Education and Harm Reduction Strategies

### 6.1 General Information Provision and Education

#### Introduction

One of the most concerning findings of this Inquiry has been the discovery that many people perceive benzodiazepines and opioid analgesics as relatively safe and as not being 'drugs of abuse'. Indeed, one of the most difficult challenges posed by this Inquiry is countering this perception. Challenging the culture of drug use and abuse, and contesting ideas as to what does or does not count as a 'drug', is a very difficult task. Prescription drugs, it would seem, are not viewed with the same gravity as other drugs.

Evidence provided to this Inquiry demonstrates that many people in the broad community including those who use (and misuse) benzodiazepines and opioid analgesics are ignorant of, or underestimate, the risks. Whilst there is some understanding of the appropriate uses for benzodiazepines and opioid analgesics, there appears to be variable knowledge about the risks and harms associated with misuse of these drugs.

#### A lack of understanding?

Experts with whom the Committee has met throughout this Inquiry have expressed concern about the prevailing community attitude and belief that because prescription medications have been provided by a healthcare professional they are essentially safe. Mr Gino Vumbaca, the Executive Officer of the Australian National Council on Drugs (ANCD), the peak drug advisory body to the federal government, observed in this regard:

...it is a lack of awareness people have about the impact of a prescribed pill, because they think if you go to a doctor and get a script... it's safe. The doctor wouldn't give you something that causes grief.<sup>734</sup>

Professor Jason White, Director of Drug and Alcohol Services of South Australia (DASSA) and Head of the Pharmacology Department of the University of Adelaide, made a similar

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<sup>734</sup> Mr Gino Vumbaca, Executive Officer, Australian National Council on Drugs (ANCD), Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, in conversation with the Drugs and Crime Prevention Committee, 17 May 2007.



observation with regard to the misuse of substances such as morphine and oxycodone: 'part of the rationale of people...is the belief it is relatively safe.'<sup>735</sup>

Discussions with representatives from Victoria's culturally and linguistically diverse communities also highlighted this lack of awareness:

It is also not uncommon for some people from an ethnic background, especially elderly people, to keep a wardrobe of medication at home. They store it at home just in case something happens. Some could be off-the-shelf medication, but some could be prescribed drugs that they have left over from some other illness that they used to have, and because of the lack of understanding this means they might start sharing medication. If people have similar symptoms, they start sharing the medication among the community. I know of people who go doctor shopping for sleeping pills just for storage, which can be quite dangerous. It is less serious if the person understands that sleeping pills are not for everyday use, but if, for example, they have children at home, that could lead to serious consequences.<sup>736</sup>

Official data from the most recent National Drug Strategy Household Survey (NDSHS) supports this perception. When respondents were asked to name the drug they thought of when people talked about a drug 'problem', a total of only 0.5 per cent of Australians aged 14 years and older nominated the non-medical use of tranquillisers/sleeping tablets as the drug most associated with a drug 'problem'.<sup>737</sup> The same proportion of respondents nominated the non-medical use of pain-killers/analgesics as the drug they thought of when people talked about a drug problem (Australian Institute of Health and Welfare (AIHW) 2005a). Whilst women were more likely than men to nominate these two classes of drugs as a 'problem', the difference was nominal (0.3% compared with 0.6% for tranquillisers/sleeping pills and 0.4% compared to 0.5% for pain-killers/analgesics) (AIHW 2005a).

As might be expected, the drug that people were most likely to nominate when asked about a drug 'problem' was heroin (39.4%), followed by marijuana/cannabis (29.2%) and alcohol (10%).

When participants were asked to consider the acceptability of regular use of different drugs, non-medical use of pain-killers/analgesics and tranquillisers/sleeping pills rated fourth and fifth respectively (8% and 5%) behind alcohol (77%), tobacco (39.3%) and marijuana/cannabis (23.2%). Whilst women were less likely than men to consider use of tranquillisers/sleeping pills and pain-killers/analgesics acceptable in both 2001 and 2004, there was an increase in the acceptability of regular use of both classes of drugs by both men and women over the period 2001–2004 (AIHW 2005a).

Arguably the perception that prescription medicines such as benzodiazepines and opioid analgesics are relatively safe and the general lack of awareness regarding the associated risks has contributed to the social acceptability of prescription drug use and the normalisation of these medicines. In his discussion with this Committee, Mr Vumbaca of the ANCD concluded:

I think it's just the lack of awareness...There's a lot more acceptance that it's okay to slip a pill in. I think that's added to some concern about benzos being a part of that notion, it's just another pill.<sup>738</sup>

735 Professor White was referring to the misuse of such substances in countries like the United States and other parts of the world 'which have had dramatic increases in use of these drugs.' Professor Jason White, Director of Drug and Alcohol Services South Australia and Head of Department of Pharmacology University of Adelaide, in conversation with the Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Adelaide, 18 May 2007.

736 Ms Wesa Chau, Multicultural Network Coordinator for North-West CALD partnership, Action on Disability within Ethnic Communities, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Forum for Culturally and Linguistically Diverse Communities, Melbourne, 9 July 2007.

737 Respondents to the survey were allowed to nominate up to two drugs (AIHW 2005a).

738 Mr Gino Vumbaca, Executive Officer, ANCD, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, in conversation with the Drugs and Crime Prevention Committee, 17 May 2007.

## The need for information

Clearly there is a need for information and education strategies to improve community understanding about the risks and harms associated with misuse of benzodiazepines and opioid analgesics. There appears to be a shortage of available information for people who do seek assistance or advice, as explained by the Australian Drug Foundation (ADF):

Overall there is not a lot of readily accessible or centrally located information. The information that is available has some issues in terms of its clarity in that we do not find there is a lot of general, clear information available for people, particularly for the prescribed opioids like morphine, pethidine and those sorts of substances. Our experience suggests that there are gaps in community knowledge and understanding about these drugs and where to go for further information and assistance. There is also not a lot of information around for parents and families and perhaps what you might call carers of people who are using or misusing these substances.<sup>739</sup>

The Victorian Alcohol and Drug Association (VAADA), the peak body representing alcohol and other drug services in Victoria, concurred:

In our view there are large information gaps around the misuse of pharmaceuticals amongst a broad range of population groups.<sup>740</sup>

Submissions from local government also commented on the need for information and education programmes to address the low levels of knowledge in the community in general and among particular groups:

Information for the broader community is needed to create awareness that pharmaceutical misuse/abuse can occur and is an issue...information for people at risk needs to focus on identifying misuse/abuse and where [to go to] receive support.<sup>741</sup>

### *What is the community requesting?*

As part of their sphere of activity the ADF operates the DrugInfo Clearinghouse, a state-wide drug information service, incorporating a resource centre (library and infodesk) and website. The DrugInfo Clearinghouse also compiles and produces a range of useful monographs, facts sheets, quarterly prevention publications and research reports pertaining to both alcohol and illicit drug use.<sup>742</sup>

In a submission to this Inquiry, the ADF commented that whilst there may be limited community understanding of benzodiazepines and opioid analgesics and the risks associated with misuse, there is nevertheless some demand for information: 'although the number of direct information enquiries to the Resource Centre is comparatively low [in relation to illicit substances], resource dissemination through the ADF Shop indicates considerable community demand for information on pharmaceutical drugs.'<sup>743</sup>

Mr Mark Durran, Director of Information Services at the ADF, told the Committee that approximately 1 per cent of inquiries to the resource centre are benzodiazepine specific whilst opioid analgesics make up approximately 4 per cent of contacts each year.<sup>744</sup>

739 Mr Mark Durran, Director of Information Services, Australian Drug Foundation (ADF), Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007.

740 Mr Sam Biondo, Executive Officer, Victorian Alcohol and Drug Association (VAADA), Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, June 2007.

741 Submission of Hume City Council to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2007.

742 Submission of the ADF to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

743 Submission of the ADF to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

744 Mr Mark Durran, Director of Information Services, ADF, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007.



A range of people from the general community request information: '...users of these substances...they might be legitimate or illicit users, and parents, families, friends and partners...make up our community inquiries.'<sup>745</sup>

Mr Mark Durran explained that for most drug types approximately 10 per cent of inquiries are from the general community but the pattern changes with regard to benzodiazepines and narcotic analgesics:

In regard to these substances the community enquiries are more over-represented...so they are about double what we would normally see in the resource centre.<sup>746</sup>

Each year the ADF Shop distributes approximately 15,000 copies nationwide of the brochure *How Drugs Affects You: Benzodiazepines*, the majority of which are distributed to professional organisations that then disseminate them to the community. Approximately 150 of those pamphlets were distributed in Victoria between 2005 and 2006 in response to a direct information enquiry. In light of community demand for information, the ADF has developed a brochure *How Drugs Affects You: Analgesics*. Since its publication in October 2006 approximately 130 copies have been distributed.

Inquiries directed to the DrugInfo Clearinghouse with regard to benzodiazepines and other pharmaceutical drugs are varied and include requests for information relating to:

- Effects – long and short term
- Interactions with other drugs – particularly alcohol
- Requests for a specific resource
- Treatment issues and programs
- Detection and screening
- Pregnancy/breastfeeding.<sup>747</sup>

## General sources of information and education

If the requests received by the ADF are indicative, there is a range of information needs within the general community with regard to benzodiazepines and opioid analgesics. In addition to services like the ADF, there are a variety of other sources of information and education programmes available to the community. These sources include health services, needle and syringe programmes, individual medical staff and pharmacies, peak agencies (eg. the Pharmaceutical Society of Australia) and pharmaceutical companies.<sup>748</sup> A number of these sources and their information and education strategies are outlined below.

### *Programmes addressing consumer understanding of medicines generally*

#### **National Prescribing Service**

##### 'Quality use of medicine' programme

Improving community awareness and competence in quality use of medicines is part of the role of the National Prescribing Service (NPS).<sup>749</sup> To this end the NPS has developed a set of national resources to provide medicines information to the community through the NPS Community Quality Use of Medicines (QUM) programme.

<sup>745</sup> Mr Mark Durran, Director of Information Services, ADF, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007.

<sup>746</sup> Mr Mark Durran, Director of Information Services, ADF, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007.

<sup>747</sup> Submission of the ADF to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

<sup>748</sup> For example, see correspondence from Mundipharma, August 2006; and comments of Ms Susan Alexander, Head of Regulatory Affairs and Head of Operations, Roche Products, on behalf of Medicines Australia, in conversation with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

<sup>749</sup> According to the website, the NPS is a member-based organisation providing accurate, balanced, evidence-based information and services to health professionals and the community on the Quality Use of Medicines (QUM). The NPS has over 40 member organisations representing GPs, pharmacists, specialists, nursing, other health professionals, pharmaceutical industry, government and consumers. See <http://www.nps.org.au>

The programme aims to:

build awareness, knowledge and skills in the community that will lead to better use of medicines and ultimately improved health. The NPS Community QUM program provides information and services nationally and to targeted population-based groups: older people, people with chronic conditions, multicultural communities, and Aboriginal and Torres Strait Islander communities (National Prescribing Service 2006, p.14).<sup>750</sup>

The resources available through the programme include:

- ◆ Patient information leaflets – patient information leaflets are produced and distributed by the NPS and cover a range of topics to assist general practitioners, pharmacists and consumers to discuss appropriate use of medicines (NPS 2006).
- ◆ Medimate brochure – a brochure designed to help consumers locate and use information about medicines including advice on safe use of medicines, staying healthy with and without medicines and advice on use of multiple medications. Medimate is intended to encourage discussion about the safe use of medicines between consumers and their health care professional (NPS 2006).
- ◆ Get to Know Your Medicines Kit – this resource is available to community organisations at no cost to assist in the planning and organisation of community events to support the community in appropriate management of medicines (NPS 2006).
- ◆ Medicines List – a resource that enables consumers to carry a list of their medicines at all times (NPS 2006).
- ◆ Medicines Talk – a quarterly newsletter written 'by consumers for consumers giving reliable, accurate information and useful hints on managing medicines' (NPS 2006, p.14).
- ◆ Medicines Line – a toll-free information line where consumers may seek advice on prescription, over-the-counter and complementary medicines, with such advice provided by clinical pharmacists and medicines information specialists (Australian Pharmaceutical Advisory Council; NPS 2006).
- ◆ Consumer Medicine Information (CMI) sheets – over 1,100 CMI sheets are available via the NPS website with over 800 accessed each month (Australian Pharmaceutical Advisory Council 2006; NPS 2006).

#### 'Get to know your medicines' campaign

In August 2007, the NPS launched the 'Get to Know Your Medicines' campaign. This national campaign promoted quality use of medicines generally whilst specifically targeting seniors who may take multiple medications.<sup>751</sup> The campaign aimed to increase consumer awareness and understanding of their medicines and encourage communication between consumers and healthcare professionals about quality use of medicines (NPS 2007a). It also sought to reduce the number of medicine-related problems in the community by promoting consumer awareness of side effects and drug interactions (NPS 2007a). In launching the campaign, Chief Executive Officer Dr Lyn Weekes commented that 'there is a high incidence of preventable adverse medicines events in Australia. It is estimated that more than 140,000 people are hospitalised every year as a result of medication-related problems' (NPS 2007a).

'Get to Know Your Medicines' encouraged consumers to take a more active role and be more informed about medicines and sought to provide consumers with the confidence to seek information from their health professional (NPS 2007a, 2007b). It aimed to increase

<sup>750</sup> The NPS has a two-tiered approach to the delivery of community information and education. Firstly, a range of initiatives have been put in place to enhance knowledge and awareness within the general community (as discussed in this chapter) and secondly, a variety of targeted and local level interventions have also been established (See Chapter 6.2).

<sup>751</sup> As part of the campaign, a range of free medicines information sessions are available in each Australian state and territory to people over 50 years of age.



the number of consumers asking questions and seeking information from their healthcare provider.

The campaign ran from August until October 2007 in two phases. The first phase focused on the quality use of medicines and related issues and the second phase concentrated on generic medicines (NPS 2007a). Both phases of the campaign employed a range of communication methods, including television advertisements, supported by a range of complementary resource materials made available via the NSP website.

Resources included a series of fact sheets which provide advice and instruction to consumers on issues such as 'Talking with your doctor or pharmacist', 'Using the Internet to find reliable health information', 'Read the label. It's important' and 'New medicines – are they always better'. Whilst not specifically focused on drugs such as benzodiazepines and opioid analgesics, the 'Get to Know Your Medicines' campaign is an important step forward in raising community awareness of medicines generally and enhancing opportunities for consumers to seek information and advice from their healthcare professional. The campaign is yet to be evaluated.

### **North American initiatives**

#### *'Be aware & take care – Talk to your pharmacist!' campaign*

The Committee was informed of a number of North American initiatives during its evidence-seeking trip to the United States. The California State Board of Pharmacy has produced a series of leaflets for consumers on a range of topics as part of the 'Be Aware & Take Care – Talk to your Pharmacist!' campaign. Not unlike the NPS campaign, the fact sheets promote safer use and aim to improve consumer understanding of medicines. One such example is a leaflet titled 'Children and their medicines' and provides clear instruction for parents on appropriate administration and storage of medicines for children. The US Council of Family and Health, which has since ceased operation, has produced a medicines guide for older adults.<sup>752</sup>

### **Pharmaceutical Society of Australia**

#### *Pharmacy self care programme*

There have also been numerous voluntary initiatives promoted by healthcare professionals within Australia. For example, the Pharmacy Society of Australia has developed a series of fact cards, through the Pharmacy Self Care programme, that aim to promote safe and effective use of medicines. This health information is intended to support the counselling and advice services that many pharmacies provide (see Pharmaceutical Society of Australia website). The fact cards are reviewed and, where appropriate, updated on an annual basis so currency is maintained. They are made available in pharmacies so that patients can self-select, but may also be provided with advice and counselling from the pharmacist. There are 14 categories of information that include over 80 titles. Of particular relevance to this Inquiry is that they cover subjects such as 'Wise use of medicines', 'Anxiety' and 'Sleeping problems'. No information was provided on the proportion of pharmacies that stock and supply these resources.

### **Pharmacy Board of Victoria**

#### *'Don't go 'til you know' campaign*

At a local level, the Pharmacy Board of Victoria launched the 'Don't Go 'til You Know' campaign in 2003. The community education campaign was initiated to encourage consumers to speak with their pharmacist about medicines, whether prescribed or purchased over-the-counter (Pharmacy Board of Victoria 2003). The campaign ran for an initial period of six months, using a variety of materials to enhance information exchange

<sup>752</sup> For further discussion of targeted information and education initiatives, refer to Chapter 6.2.

between pharmacists and consumers including a consumer information brochure incorporating the following key messages:

- ◆ Role of the pharmacist
- ◆ Getting the best from your medicines
- ◆ Correct use of medicines
- ◆ Appropriate storage of medicines
- ◆ Benefits of using medicines appropriately.

### *Information on benzodiazepines and opioid analgesics*

With the exception of the ADE, the programmes and initiatives discussed above have focused on medicines generally rather than on benzodiazepines and opioid analgesics particularly. However, there are a number of Victorian based programmes and organisations that offer information and education on benzodiazepines and opioid analgesics. The Australian Drug Information Network, Turning Point Alcohol and Drug Centre and Reconnexion are three of these organisations.

The Australian Drug Information Network (ADIN) is managed by the ADF and provides access to information about drug use, drug effects, harm reduction and treatment options and also has links to a range of international websites. Again, like many services, ADIN is not dedicated to prescription drug misuse but allows the user to search for research articles and information on both classes of drugs.

Direct Line is a Victorian service run by Turning Point Alcohol and Drug Centre, running 24-hour, 7-day counselling, advice, information and referral to the community on drug issues and, as noted by Dr McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, this service has now been adopted in other jurisdictions.<sup>753</sup>

Reconnexion (formerly known as TRANX) is a Victorian-based service that provides withdrawal support, a counselling service, education and training, support groups and an information service on benzodiazepines. Ms Gwenda Cannard of Reconnexion informed the Committee of resources they had developed to help improve relaxation and enhance sleep, and the information sheets provided on topics such as safe medication use. Ms Cannard suggested that as well as investing in information and education about pharmaceutical drug misuse, encouraging the use of alternatives to such medications by promoting services such as those that help manage anxiety and sleep disorders was also required. The agency suggested there was a need for:

- Continued community education relating to sleep strategies without drugs and evidence based options for anxiety disorders treatment...
- Continued community education...with reference to people from culturally diverse backgrounds delivered in their first language...
- [Support for] Services providing counselling for anxiety disorders to promote their service more effectively.<sup>754 755</sup>

### *A brief comment on Internet based information*

In undertaking the research for this Inquiry, the Committee located a number of websites that have been specifically designed with benzodiazepine users in mind.<sup>756</sup>

753 Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 20 June 2006.

754 Submission of Ms Gwenda Cannard, Director, TRANX (Tranquilliser Recovery and New Existence) Inc., to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

755 Alternatives to benzodiazepine prescribing for anxiety and sleep disorders are discussed in Chapter 7.2 of this Report.

756 The benefits and dangers of the Internet as a source of information has been canvassed in Chapter 5.3 of this Report, and will not be discussed further in this chapter except to highlight a number of international web-based drug-information services.



The United Kingdom based website (benzo.org), which has been operating for over seven years, provides access to academic and scientific literature on the use and effects of benzodiazepines and dependence and withdrawal for people wishing to access information. When the website was launched in 2000 it contained around a dozen pages and now has over 550 pages of information, academic articles, medical information and personal accounts.<sup>757</sup>

The site plays host to an online support forum for benzodiazepine users, allowing people to discuss personal stories, share insights and access a variety of information. It also provides links to a range of other websites for information on benzodiazepines.

There are also broad-based internet drug information services such as Erowid, Erowid is:

...a member-supported organization providing access to reliable, non-judgmental information about psychoactive plants and chemicals and related issues. We work with academic, medical, and experiential experts to develop and publish new resources, as well as to improve and increase access to already existing resources. We also strive to ensure that these resources are maintained and preserved as a historical record for the future.<sup>758</sup>

The website acts as an online library of information about a range of substances, bringing together information from peer-reviewed research through to media articles, information on drug chemistry, dosage and effects, and a range of other topics.

The Committee found that whilst it proved relatively straightforward to access websites providing quality information about the risks and harms of benzodiazepine misuse (for example the ADIN website), it was much more difficult to access such information about narcotic analgesics via the Internet. Given the level of use and harms associated with narcotic analgesics misuse, especially in illicit drug using populations (see Chapter 2.2), this should be addressed.

## Consumer Medicine Information

It is clear that the community requires information and education on the harms associated with misuse of benzodiazepines and opioid analgesics. However, those people who have been legitimately prescribed these medications also require comprehensive and up-to-date information.

To a certain extent the requirement for such information is mandated by Commonwealth regulation.<sup>759</sup> Since 2003, prescription medicines and pharmacist supplied, or Schedule 3 products, are required to have a Consumer Medicine Information (CMI) document supplied with the medicine.<sup>760</sup>

A CMI provides the consumer with important facts to know before, during and after taking the medication and includes:

- The name of the medicine;
- The active ingredients as well as the inactive ingredients;
- The dosage of the medicine;
- What the medicine is used for and how it works;
- Any warning or precautions, such as when the medicine should not be taken;
- Any interaction the medicine might have with food or other medicines;
- How to use the medicine properly;
- How to store the medicine properly;
- The sponsor's name and address; and

<sup>757</sup> Benzo.org website at: <http://www.benzo.org.uk>

<sup>758</sup> Erowid website at: <http://www.erowid.org/general/about/about.shtml>

<sup>759</sup> See also the discussion in Chapter 3.1 of this Report.

<sup>760</sup> See Section 9A and Schedule 12 of the Therapeutic Goods Regulations 1990.

- The date the CMI was last updated (Therapeutic Goods Administration (TGA) 2007, p.24).

CMI can vary in length but are generally between three and five pages.<sup>761</sup>

### *The evolution of Consumer Medicine Information in Australia*

Hirshorn and Monk state that 'enormous effort has been invested in CMI development in Australia with the aim of producing highly useful and usable information for consumers' (2006, p.667). They continue:

Guidelines called 'Writing about medicines for people' (the usability guidelines) are in their second edition, providing guidance for sponsors on how to prepare CMIs with highly consistent usability. Unlike the European Union, Australian sponsors are not required to provide the CMI as a pack insert but may distribute the documents in a form that enables the CMI to be given to a person to whom a product is administered or dispensed. A system has been developed for electronic distribution of CMIs, so that they may be printed by doctors or pharmacists from their computer software (Hirshorn & Monk 2006, p.667).

Writing in *Australian Pharmacist* in March 2006, Dr Parisa Aslani discusses the changes that have occurred in the past 10 to 15 years with regard to both the development and delivery of CMI. Dr Aslani writes, 'CMI is continuously evolving, being influenced by results of on-going research as well as regular monitoring of CMI documents' (Aslani 2006, p.204).

To a certain extent legislative changes with regard to the supply of CMI have ensured more widespread use in pharmacy practice, however research, education and financial incentives have also contributed to the greater use of CMI by pharmacists when counselling patients on medicines.

A number of incentives, including financial reimbursements, have been made available to pharmacists for providing CMI to their customers. In late 2002 the Medicines Information to Consumers Program was launched and among other things provided pharmacists with incentive payments for providing CMI and promoting quality use of medicines by consumers. Under the scheme an initial payment of \$3000 per pharmacy was made to help meet the establishment costs associated with provision of CMI. From 1 December 2005 incentive payments for providing CMI have been included in the Pharmaceutical Benefits Scheme (PBS) and Repatriation Pharmaceutical Benefits Scheme (RPBS) dispensing fees, at a rate of 10 cents per subsidised paid prescription.<sup>762</sup>

### *How do consumers access Consumer Medicine Information?*

CMI is currently available for prescription as well as 'Pharmacist Only' medications (Aslani 2006) and under the TGA regulations must be made available to consumers as either a package insert or 'in another manner that will enable the information to be given to the person to whom the goods are administered or otherwise dispensed' (TGA 2007, p.24).

### **Access at the pharmacy**

Under the Medicines Information to Consumers Program, CMI should be provided in accordance with professional standards and guidelines developed by the Pharmaceutical Society of Australia (PSA).<sup>763</sup> Pharmacists are also required to promote the availability of CMI in their pharmacy. A CMI is not required to be provided with every script, however should be provided under the following circumstances:

- When a medicine is *first provided* to a consumer;
- On provision of a medicine where:
  - A *significant change* to the CMI has been notified by a sponsor; or
  - The *dosage form* has been changed.

<sup>761</sup> See Appendix 17 for an example of a CMI.

<sup>762</sup> For further information see [www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au)

<sup>763</sup> For a detailed discussion of professional guidelines, please refer to Ch 5.1.



- With each supply of medicine for which there are *valid reasons for regular reinforcement of information*. For example, when:
  - The medication is *teratogenic*;
  - There are *major contraindications* to the use of a medicine; or
  - The patient *has special needs*.
- When the *patient requests* the information;
- At regular intervals for medicines used for *long term therapy* – for example, every six months (Department of Health and Ageing, Pharmacy Guild of Australia & Pharmaceutical Society of Australia 2002, p.1). (Author emphasis).

### Access via the Internet

In recent years, Consumer Medicine Information has been made available to consumers via the Internet in addition to hard copy package inserts and printouts made available at the local pharmacy. Consumers can access CMI via the NPS website and the website of some pharmaceutical companies who produce particular medicines. At a forum hosted by the Drugs and Crime Prevention Committee for representatives of pharmaceutical companies in July 2007, Dr Greg Pearce of Alphapharm told the Committee:

Some recent examples of what Alphapharm has tried to do to support quality use is the provision of consumer medicine information leaflets on our website and encourage them to be distributed through pharmacy dispensing programs.<sup>764</sup>

The use of the Internet as a tool for accessing up-to-date CMI has not been without problems. In a series of discussion papers the TGA has considered the most appropriate means of improving consumer and professional access to web-based copies of up-to-date CMI and product information. In April 2005 it produced and circulated an Initial Discussion Paper proposing five options:

Option 1: Retain the status quo

Option 2: Strengthen existing databases (that currently contain some CMI and patient information [PI])

Option 3: Provide a link on the TGA website to existing databases (this could be implemented in conjunction with Option 2)

Option 4: TGA provides links to sponsors' websites which would be required to include CMI and PI

Option 5: TGA includes all CMI and PI directly on the TGA website (TGA, 2007, p.5).

Consultations with interested parties were held to elicit feedback on each of the proposed options. In early 2007, a second discussion paper was released for further public comment. The paper included the TGA's preferred option:

- The TGA mandates that each sponsor must maintain a web-based version of each CMI and PI and that each sponsor must provide to the TGA the link to each CMI and PI;
- Each sponsor may choose whether to maintain the electronic version of the CMI and PI on their own website or on the website of a third party service provider. In either case, the sponsor must be able to meet the legislated requirements for the CMI and PI to be available on the web (through a link on the TGA website) and for the CMI and PI to be up-to-date. This would ultimately be the sponsor's responsibility even if the actual process of updating was outsourced by the sponsor to a third party provider; and
- In terms of consistent format and presentation, the TGA would still be approving the PI and the onus would continue to be on the sponsor to have appropriate CMI

<sup>764</sup> Dr Greg Pearce, Medical Adviser, Alphapharm, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs, Pharmaceutical Forum, Melbourne, 16 July 2007.

documents. If more details about presentation and specifications were needed, these could be prescribed (TGA 2007, p.18–19)

The paper gives consideration to the benefits and costs of web-based access to CMI and concludes that '...internet access to CMI and PI should not replace the fundamental and significant role of doctors and pharmacists in the provision of CMI and that measures need to be taken to increase the provision of CMI by pharmacists' (TGA 2007, p.14).

### Barriers to use of Consumer Medicine Information

Pharmacists have played a key role in the development of CMI, and the provision of CMI within the pharmacy setting is now recognised as essential to promoting the quality use of medicines among consumers. Whilst clear guidelines on the use of CMI have been developed for pharmacists as part of the broader professional practice standards and patient counselling requirements,<sup>765</sup> ensuring the provision of CMI is accepted as part of the daily professional practice in community pharmacies has not been without its challenges. Australian research has identified barriers to the use of CMI by community pharmacists. Dr Aslani (2006) has reviewed the research and has grouped the barriers into four broad categories as outlined in Table 6.1a below:

**Table 6.1a: Barriers to the use of consumer medicine information**

Category	Barrier
Cognitive	<ul style="list-style-type: none"> <li>Limited awareness and understanding of CMI legislation;</li> <li>Limited skills in using CMI in practice</li> <li>Lack of educational programs on CMI use</li> </ul>
Situational	<ul style="list-style-type: none"> <li>Limited availability of CMIs</li> <li>Limited storage space for loose leaflet CMIs</li> <li>Lack of printers to generate electronic CMIs</li> </ul>
Financial	<ul style="list-style-type: none"> <li>Increased dispensing and counselling times when using CMIs</li> <li>Increased cost (resources and staff) when using CMIs</li> <li>Lack of remuneration for CMI supply and use in counselling practice</li> </ul>
Attitudinal	<ul style="list-style-type: none"> <li>Pharmacists' perceived negative impact of CMIs on consumers' medication taking behaviour</li> <li>Pharmacists' perceived negative impact of CMIs on their relationship with general practitioners if pharmacists were the main providers of CMI</li> <li>dislike of CMI content and format</li> </ul>

Source: Aslani 2006, p.205

The barriers identified by this research have, at least to some degree, been addressed through the development and delivery of a range of education and training programmes on CMI for pharmacists. Through its various state branches the PSA has provided training and support to pharmacists on the use of CMI. In addition to programmes at the pharmacy organisation level, CMI has been introduced into the formal education programme in a number of Bachelor of Pharmacy and Master of Pharmacy Degrees at Australian universities.<sup>766</sup>

### Research on the use of CMIs by consumers

Little was known about the extent to which consumers use CMI and the factors that might affect this use until relatively recently. However, recent research literature suggests a variety of factors influence consumer use of CMIs. These include the way in which information is delivered and the nature of the pharmacist–consumer interaction (Aslani 2006; Koo et al 2003; Koo et al 2005). Other factors identified in the literature and summarised by Aslani (2006) include readability and presentation of written medicine information, health

<sup>765</sup> For a detailed discussion of professional practice guidelines, refer to Chapter 5.1 of this Report.

<sup>766</sup> For an in-depth discussion of education and training initiatives, refer to Chapter 6.2 of this Report.



literacy, health beliefs, timing of information delivery and experience in receiving written information (Aslani 2006).

In their 2005 study, Koo and colleagues uncovered a number of consumer characteristics that influenced understanding of CMI. Consumers for whom English was the main language spoken at home and who had secondary education or higher were more likely to understand the content of CMI. Those with higher levels of health literacy were more likely to use CMI in the future (Koo et al 2005).

Requirements such as CMIs are a valuable, indeed essential, aspect of information provision. However, CMI is but one method of delivering important health information to the broad community. It is not the only way in which consumers can access information on medicines.

## The need for a community education campaign

As this chapter has discussed, there seems to be variable knowledge about *both* the benefits and the risks of benzodiazepines and opioid analgesics by many people in the broad community. Indeed, submissions to this Inquiry expressed concern that there is a high degree of ignorance about the nature and effects of benzodiazepines and narcotic analgesics, and variable knowledge about the risks associated with misuse. Whilst a variety of organisations do provide information and education in the form of hard copy information and advice to individual patients/clients/consumers and via websites, there does not appear to be any systematic approach to identifying what information and education is needed at a broad community level. Nor was there evidence of coordinated effort in the development and delivery of strategies.

There is a vast body of literature examining the role of information and education in preventing drug misuse in the first instance, and reducing the harms associated with misuse in the second. Certainly prevention based approaches aimed at informing the general public about drugs are a common educational strategy. The evidence suggests, however, that public and community education campaigns which aim to raise awareness of alcohol and other drug abuse, particularly those run through the media, have a mixed response. In a major review of responses to drug problems in general, Loxley, Toumbourou, Stockwell, Haines et al (2004) noted a lack of compelling evidence that can inform the development and implementation of quality community information and education initiatives. Rehm, Babor & Room (2006) reached a similar conclusion about education and persuasion initiatives that were aimed at reducing alcohol-related harm. More directly relevant to preventing pharmaceutical misuse, a review of various information and education strategies in the United States concluded that unfortunately:

No formal independent evaluations of the effectiveness of these programs in preventing prescription drug abuse are available (National Center on Addiction and Substance Abuse (CASA) 2005, p.95).

Many people who made submissions to this Inquiry argued that there was a need for more investment in providing quality information and education.<sup>767</sup> A similar conclusion was reached in the United States, where it was recommended that:

- Government-sponsored public awareness campaigns that focus on alcohol, marijuana and other illicit drugs should include the abuse of controlled prescription drugs as well as the dangers of poly-substance abuse.
- Government-sponsored public awareness campaigns should inform parents to safeguard their prescription drugs from their children, and advise individuals and families to dispose properly of unused and controlled medications.

<sup>767</sup> See for example, submission of Western Region Health Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

- Schools and communities should incorporate prescription drug abuse...into evidence-based substance use prevention programs (CASA, 2005, pp.102–103).

In light of these issues, the Committee believes that there should be a state-wide comprehensive public education campaign on benzodiazepines and opioid analgesics, along the lines of the QUIT, TAC or WorkCover campaigns that is based on best practice. This campaign should include information on the:

- ♦ Risks and harms associated with misuse
- ♦ Questions to ask your doctor and pharmacists
- ♦ Negative effects of sharing medication
- ♦ Appropriate storage of medicines; use-by dates and appropriate disposal
- ♦ Treatment options and support services
- ♦ The harms associated with poly drug use.

However, in developing and implementing information and education campaigns the limitations of educational strategies should be realised.

There is always a balance to be struck between providing relevant and evidence-based information and encouraging experimentation. This issue is of particular relevance with educational strategies aimed at young people.<sup>768</sup> Australian researchers have recently reviewed the international literature and make the following cautionary note with regard to educational interventions:

The more successful approaches to drug education have a grounding in what is known about the cases of adolescent drug use, adolescent developmental pathways in relation to drug use, and the psychological theoretical frameworks of social learning and problem behaviour. Because this body of evidence has been well established over several decades of research, the authors sensibly caution those considering developing drug education programs to base them on what is known rather than what seems intuitive or ideologically sound. Poorly conceptualised programs have historically been ineffective or at worst, actually harmful, for example, by increasing drug use (Loxley, Toumbourou, Stockwell, Haines et al 2004, p.118).

## Conclusion

Information and education are important components of efforts to address misuse and abuse of benzodiazepines and opioid analgesics. At present, however, the community is not well informed of the dangers and harms associated with misuse and abuse of these drugs. To date, there have been very few information or education initiatives undertaken in Australia which specifically focus on benzodiazepines or opioid analgesics. There is a clear need for information and education initiatives to be implemented which inform the broad community of both the risks and harms associated with misuse. There is also a need for more targeted information and education which addresses the specific needs of a number of groups as will be discussed in Chapter 6.2.

<sup>768</sup> The problems and pitfalls of educational interventions including school based drug education have been discussed in detail in the Drugs and Crime Prevention Committee 2006, *Inquiry into Strategies to Reduce Harmful Alcohol Consumption – Final Report*, Drugs and Crime Prevention Committee, Parliament of Victoria, 2006.





## 6.2 The Need for Targeted Information, Education and Training

### Introduction

As discussed in the previous chapter, most people associate 'drug problems' with illicit drugs, alcohol and tobacco and not with prescription drugs, despite the significant dangers their misuse and abuse pose. Evidence received during this Inquiry revealed a need for further education and information among a number of specific populations and groups, including health professionals.

This chapter examines existing education, information and training programmes, the inadequacies of these and the type of education and skills training required. The first part of the chapter pertains to education and training for general practitioners (GPs), and the second part looks at the education and information needs of other professions that provide services for users of prescription drugs, as well as examining the role of the pharmaceutical industry in supplying comprehensive information and education. The final section examines the information and education needs of specific populations and discusses the relevancy of targeted information and education to meet the needs of discrete groups of benzodiazepine and opioid analgesic users.

### Information, education and training for health professionals

#### *Identifying inadequacies*

The following quotes from two people affected by the consequences of prescription drug dependency illustrate the lack of knowledge and understanding a number of healthcare professionals have about appropriate prescribing and treatment in relation to this issue:

I walked into the GPs office with some personal troubles when I was a 29-year-old woman. I had no idea I would be prescribed a very potent medication at that very first visit. I naively thought that the prescription and the GPs were there to help. That was 11 years ago...I now have experienced withdrawal many times during my patienthood. I had no idea that the withdrawal symptoms would precipitate additions to my medication regime, visits to emergency, blood tests, MRI scans, ECGs, feeling sick, extreme anxiety, depression, severe headaches, reflux, stomach problems, heart palpitations, dizziness, vertigo, panic attacks and hypertension, just to name a few...

I'm not a drug abuser. I took medication as prescribed by my doctors, in whom I had placed my trust, or in this case my life.<sup>769</sup>

It is so important that doctors are trained on how to help addicted people, not just cover up their problems with more drugs. Helping addicts was not on the agenda 10, 20 years ago but it is now, and doctors must have extra training to know when to seek psychological help for their patients. Because of a doctor who sought extra training in order to help addicts, my child has recovered and is now a professional and a different person.

<sup>769</sup> Submission of Mr Ange Vassallo and Ms Susan Evans to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.



I felt betrayed and disillusioned by the first doctor I took my child to because of his lack of training to help addicts withdraw from illicit drugs. I thank God for the second doctor, his training, his support and the knowledge to refer my child on to a psychiatrist when he felt he was out of his depth.<sup>770</sup>

During this Inquiry the Committee found a wide variation in the knowledge, skill level and willingness of health professionals to effectively address misuse and abuse of benzodiazepines and opioid analgesics, despite many professional boards and bodies having developed clinical and practice guidelines in this area, as described in Chapter 5.1. Ms Penny Buykx, Research Officer, Faculty of Health Sciences at Latrobe University Bendigo,<sup>771</sup> expressed concern about this issue:

The prescription guidelines for benzodiazepines have been around for a long time. You would think that it would be common knowledge amongst medical practitioners that benzos are a short-term use medication. So my question out of the whole thing is, what is happening? I am not wanting to be overly critical of doctors because I think, as others have said, that sometimes they are in a difficult situation with a patient that they do not know what to do with or who is quite insistent or whatever it is, but do the doctors not understand the risks of dependence? Are they under pressure from their patients to prescribe? Are they not aware of treatment alternatives? What is driving this ongoing inappropriate prescription of this group of medications?<sup>772</sup>

As this Inquiry has progressed, the Committee has sought answers to such questions from a range of organisations and institutions and has endeavoured to assess the adequacy of existing education, training and workforce development for health professionals. It appears that while a range of programmes have been developed and implemented by a variety of organisations, there is little evidence of coordinated effort, and to some extent the rather voluntary nature of much of the education may go some way to explaining why some doctors continue to prescribe these medicines inappropriately to their patients.

It has been argued that a significant proportion of health care staff in Australia does not provide optimal care to people who are drug dependent, and also has little understanding of drug and alcohol issues and addiction medicine (Allsop & Helfgott 2002; Jansen et al 2005). Poor engagement and reluctance to intervene might occur due to a variety of reasons, as suggested by Allsop and Helfgott:

Responses may not be consistent with the practitioners' beliefs and values. Organisations may not have relevant policies, funding contracts or performance indicators, or the available resources...[This can include]...lack of knowledge and skills, limited opportunities to develop skills, lack of incentives and overstretched staff lacking time and enthusiasm to adopt new ways of working...Personal factors can include attitudes about drug use and the all too common marginalisation of people affected by drugs...Subjective experience and opinion may compromise objective and compassionate consideration of the individual client's needs (Allsop & Helfgott 2002, p.217).

Research also suggests that some GPs are reluctant to treat drug and alcohol problems, including addiction to prescribed drugs, due to perceived lack of knowledge and confidence (Jacka et al 1999; Jansen et al 2005). Turning Point Alcohol and Drug Centre, for example, commented that:

770 Submission of 'Concerned Mother' to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006. The name of the person making this submission has been changed to protect her privacy and confidentiality.

771 Ms Buykx undertook a study of medication-related overdoses that presented to Melbourne's St Vincent's Hospital Emergency Department in 2004. Her research showed that participants had little understanding of dependence issues or that their benzodiazepine medication may be exacerbating their anxiety and panic symptoms. (Ms Penny Buykx, Research Officer, Faculty of Health Sciences, Latrobe University Bendigo, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Bendigo, 30 May 2007).

772 Ms Penny Buykx, Research Officer, Faculty of Health Sciences, Latrobe University Bendigo, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Bendigo, 30 May 2007.

A major concern in the community setting is that some unskilled (in the sense of drug and alcohol treatment) General Practitioners inappropriately prescribe benzodiazepines to alcohol and drug treatment seeking clients by 'rubber-stamping' requests. Possibly the best response to these clients is that practitioners uniformly offer to engage them in a treatment program where they receive safe daily amounts of the drug they are dependent on and where this is tied to them attending for regular appointments. This referral process, however, often does not occur because practitioners are not equipped with the information skills to handle such clients. An additional problem is that treatment-presenting clients are sometimes not actually interested in treatment and become antagonistic when practitioners do not give them what they want the way they want it (i.e. prescription drugs). In this context there is an ongoing need for alcohol and drug treatment modalities to be entrenched in medical curricula, alcohol and drug information materials to be readily available to community prescribers (and pharmacies), and for referral information to be available in community treatment settings (e.g. general practices).<sup>773</sup>

In the absence of appropriately trained medical practitioners, the sad reality for individual drug users, their families and loved ones is brought to light:

We do not blame all doctors nor do we blame the chemists. They, like us, are not equipped to recognise, understand or solve drug addiction. In our experience, many of the so-called experts are also useless with their goody-goody approach to such a serious problem. Those equipped are few and far between and because they excel in this field they are often too busy, or totally inaccessible to help.

There is a serious lack of trained doctors and nurses who are aware of the consequences of over-prescribing, and of staff in hospitals trained to deal with the effects of drug use.<sup>774</sup>

#### *Drug education and training: Gaps in the medical curricula*

Until recently, education and training of Australian health professionals has been distinguished by the near absence of 'drug education' from mainstream health curricula (for example, see Allsop & Helfgott 2002; Roche 1997, 1998). This has been almost a universal comment made with regard to every inquiry conducted by the Drugs and Crime Prevention Committee and this Inquiry has been no exception.

According to a United States study, inadequate education in addiction medicine seems to be the case also in that country. The National Center on Addiction and Substance Abuse (CASA) at Columbia University stated that few medical practitioners and pharmacists receive instruction in identifying addiction, especially to prescription drugs, and that even when they do receive such training it is usually only for a few hours. They were apparently ill-equipped to understand the laws governing prescription drug controls and were unsure what to do to conform to these:

Less than a third of physicians believe that federal (31.0 percent) and state (30.3 percent) laws were "very or somewhat" clear and six in 10 pharmacists believe that federal (59.0 percent) and state (62.4 percent) laws are "very or somewhat" clear on what actions they should take if they believe a patient is diverting or abusing controlled prescription drugs (CASA 2005, p.91).

Physicians were also not particularly skilled at identifying pharmaceutical dependence. Describing an earlier investigation, CASA observed that:

...physicians were presented with a hypothetical case of a 68-year-old female patient with symptoms consistent with alcohol or prescription drug abuse and asked to offer five possible diagnoses. In this case, only one percent of the physicians surveyed offered substance abuse as a possible diagnosis (CASA 2005, p.92).

<sup>773</sup> Submission of Turning Point Alcohol and Drug Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

<sup>774</sup> 'Mr and Mrs Brown', Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Bendigo, 29 May 2007. The names of the witnesses have been changed to protect their anonymity.



This American study reported that physicians also found it difficult to discuss pharmaceutical misuse with their patients, which led to poor prescribing practices.

When asked about the delivery of general drug and alcohol education received in Australia by medical students through undergraduate medical curricula, Professor Jason White, the Director of Drug and Alcohol Services South Australia and Head of the Pharmacology Department at Adelaide University, offered this summation:

It is a bit variable here in Adelaide. We do that at Adelaide [University]; all our medical students have a core component of drug and alcohol. It is not huge. They have several lectures in their first three years. They have lectures on the nature of drug dependence, on alcohol, on tobacco, and then a general one on illicit drugs. When they start to get into their clinical years they learn a bit about the biology of dependence. They also visit our treatment clinics and learn a bit more from those, and they actually get to interact with some of the patients and so find out a bit more about that side of things...They get some sessions on the sorts of presentations that they will see in public hospitals, and on managing alcohol problems, which are common in their practice.<sup>775</sup>

One specific area of concern to Professor White was the current level of training on drug pharmacology:

There has been a bit of a change in fashion in medical schools of problem based learning and so forth, and the students do not get as strong a core body of lectures. It is learning by case examples and so forth as opposed to more structured blocks. I think our universities are probably moving back a bit towards the older way, but not as much, and I would say that as a department we are concerned that they do not have as much pharmacology as they used to, and I think the students have also expressed concern about that.<sup>776</sup>

Dr Tedeschi, Senior Lecturer, Canberra Hospital, however, believed that improvements in understanding of drug and alcohol issues would be seen as a new generation of GPs emerged from medical school with greater training on these issues. He believed that this new knowledge may have a positive impact on prescribing methods and contribute to a change in the culture of prescribing.<sup>777</sup>

### *What currently exists?*

General practitioners undergo basic training and are then provided with a range of education and training options to enhance and build on their medical expertise throughout their career.

### **Basic process of GP education and training**

The first step in pursuing a vocation in medicine in Victoria requires students to enrol in an undergraduate bachelor of medicine, which is generally a six-year course, although only five years at Monash University.

The Committee sought information from both the University of Melbourne and Monash University on education and clinical training offered to medical undergraduates in the area of drug use and dependency, addiction medicine and details of any specific education and training related to benzodiazepine and opioid analgesics.

While Monash University noted that addiction medicine is not currently a specific component of the medical curriculum, topics relevant to the subject are taught and

775 Professor Jason White, Director of Drug and Alcohol Services South Australia and Head of Department of Pharmacology, University of Adelaide, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Adelaide, 18 May 2007.

776 Professor Jason White, Director of Drug and Alcohol Services South Australia and Head of Department of Pharmacology, University of Adelaide, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Adelaide, 18 May 2007.

777 Dr Mike Tedeschi, Senior Lecturer, Australian National University Medical School, Canberra Hospital, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 16 May 2007.

students have the opportunity to learn about dependency issues from an addiction medicine specialist during their general practice rotation. Students may also encounter patients with problems related to benzodiazepine and opioid analgesic misuse during their general practice rotation.

Through tutorials, lectures and patient-centred learning examples, students are taught about the pharmacology of both classes of drug and the behavioural aspect of drug use, including stress and mind-body interactions, as well as stress management and non-pharmacological interventions for anxiety and insomnia.

A review of addiction medicine content within the curricula of the Faculty of Medicine, Nursing and Health Sciences is currently underway.<sup>778</sup>

With regard to addiction medicine training and education, the University of Melbourne informed the Committee that teaching on dependence and addiction occurs throughout the undergraduate medical course, including four lectures in the Semester 4 Body Systems subject on 'Pain', 'Analgesics', 'Drug dependence and Drugs of Abuse' and 'Hypnotics and Anxiolytics'. Details of the learning objectives of the latter course are as follows:

- To appreciate the mechanisms of action, therapeutic uses and adverse effects of drugs used to treat anxiety (anxiolytics)
- To be able to describe the mechanism of action and adverse effects of hypnotic agents
- To understand general principles of psychopharmacology.<sup>779</sup>

Pain management and anxiety management skills are developed through problem-based learning sessions including non-pharmacological approaches to management. An anxiety management skills programme in Semesters 10/11 includes training on:

- Basic cognitive behavioural assessment
- Motivational interviewing
- Cognitive reappraisal
- Relaxation exercise
- Problem solving
- Activity scheduling.<sup>780</sup>

Graduates then must undertake pre-vocational training as junior doctors in a hospital for two years, following which they are eligible for registration with the Medical Practitioners Board of Victoria and can practise as a non-vocationally registered GP.

An additional three-years training is necessary to become a vocational GP (and a fellow of the Royal Australian College of General Practitioners (RACGP)). This entails hospital training, placements in the field and placement as a general practice registrar.

To maintain status as a vocational GP, continuing professional development is required consisting of accumulating a total of 130 points of training over a three-year period. Providers who deliver the training undergo an accreditation process with the RACGP and have their training allocated a point value. GPs are encouraged to undertake this training in the five areas (or domains) of general practice the RACGP recommends. These are: communication skills and patient-doctor relationship; applied professional knowledge and skills; population health and the context of general practice; the professional and ethical role of GPs; and organisational and legal dimensions (for example, information technology, confidentiality and record keeping). In practice, however, the individual needs of the GP determine whether or not training in all these areas is undertaken. If the required 130 points are not obtained in the three-year period, registration as a vocational GP and a fellow of the RACGP will not be maintained.

778 Correspondence from Acting Dean Leon Piterman, Faculty of Medicine, Monash University, to the Drugs and Crime Prevention Committee, 3 October 2007.

779 Correspondence from Mr Albert Frauman, Professor of Pharmacology & Therapeutics, University of Melbourne, to the Drugs and Crime Prevention Committee, 8 October 2007.

780 Correspondence from Mr Albert Frauman, Professor of Pharmacology & Therapeutics, University of Melbourne, to the Drugs and Crime Prevention Committee, 8 October 2007.



A major incentive to maintain vocational GP registration is financial, as Medicare Australia provides a higher rebate to both the GP and the patient for consultations if the GP is a fellow of the RACGP with vocational registration. Table 6.2a below shows the differing scales of Medicare benefits, depending on the aforementioned criterion.

**Table 6.2a: Differences in Medicare Benefit Scheme refunds**

Consultation Type	Group A1*		Group A2#	
	Code	Benefit	Code	Benefit
Standard Consultant	23	\$32.10	53	\$21.00
Long Consultant	36	\$60.95	54	\$38.00

Notes: \* Group A1 = vocationally registered GP. # Group A2 = non-vocationally registered GP.

Source: Medicare Benefit Scheme online, at <http://www.health.gov.au/mbsonline>

*RACGP review of undergraduate and professional development curriculum*

The RACGP has recently reviewed its education curriculum across all levels of experience including undergraduate medical student, pre-vocational doctor, vocational GP registrar and continuing professional development. The new curriculum was released in October 2007.

A number of areas neglected in the previous curriculum have been considered in the review, which has resulted in the inclusion of curriculum statements on pain management and drug and alcohol issues. Each statement includes a definition of the subject, a rationale, discussion of the five domains of general practice, and learning objectives 'across the GP learning life' from medical student, prevocational doctor, vocational registrar to continuing professional development. The rationale for inclusion of a statement on pain management, for example, is stated thus:

Pain is associated with many general practice conditions, and diagnosis and management is often poorly understood and under-treated... (RACGP 2007a, p.3).

The traditional reluctance of GPs to become involved with the management of patients' drug and alcohol problems is acknowledged by the RACGP in their curriculum statement on Drug and Alcohol:

General practitioners are being increasingly asked by government and public health authorities to become more involved in the diagnosis and management of drug and alcohol problems among their patients.

Many general practitioners resist taking on this role. This may stem from a lack of confidence and skills in the area, and a belief that intervention is doomed to failure. Other perceived barriers are lack of time, difficulties in raising the topic during the consultation, and having negative attitudes towards individuals with alcohol and other drug problems. Yet the results of interventions by general practitioners can be very significant. Brief interventions for alcohol abuse and opiate pharmacotherapies for heroin addiction are two common examples of effective general practitioner initiated treatments proven by multiple studies in Australia and overseas (RACGP 2007b, p.3).

The statement also notes that GPs are well placed to manage these issues, but adds the following caveat:

...the degree to which a particular general practitioner will manage these conditions will depend upon the level of skills they possess. General practitioners need to know where and when to refer patients, and clinicians working in communities with a high rate of substance use disorders may consider incorporating more specialised skill into their everyday work and this may involve further training in drug and alcohol medicine as required (RACGP 2007b, p.4).

As with pain management, the curriculum statement for drug and alcohol discusses the requirements of a GP across the RACGP's five domains of general practice. In domain two

'Applied professional knowledge and skill', for example, it is stated that GPs need to take a non-judgemental medical history and perform an examination relevant to the presenting problem; be familiar with the management of the main drugs of abuse; be able to manage adolescent drug problems; safely prescribe medications for dealing with withdrawal from various drugs and alcohol; assess and advise on co-morbidities; and manage common coexisting psychiatric conditions (RACGP 2007b).

Whilst it is encouraging that pain management and drug and alcohol curriculum statements have been included in the RACGP curriculum, it is not clear to what extent universities will be required to develop their undergraduate curricula in accordance with this. Neither is it apparent that GPs who are not vocationally registered will be required to undertake ongoing professional development in these fields of medical practice.

### **Other education and training programmes for medical professionals**

Unfortunately the Committee received limited evidence on the education programmes that currently exist but did hear of a number of innovative projects that focused on improving understanding of appropriate prescribing and addiction medicine.

#### *'Reducing the use of benzodiazepines in Insomnia Management' – a South Australian project*

One such example was a project run in South Australia which provided education and training to various health practitioners including GPs, pharmacists and nursing home staff. The project was designed to:

reduce the inappropriate use of benzodiazepines by – encouraging the use of evidence-based non-drug strategies as a first line management of insomnia, encouraging patients to approach their general practitioner about reducing their long-term use of benzodiazepines, and by providing information and resources to assist patients in the withdrawal from long-term use of benzodiazepines (Stevens 2000, p. 4).

An extension of an earlier project, the 'Reducing the use of benzodiazepines in Insomnia Management' project was run in the Southern Fleurieu Peninsula with general practitioners and pharmacists in the region invited to participate in two consultation sessions. The project provided information about benzodiazepines, including the risks and benefits and how to manage withdrawal. It focused on providing education in non-pharmacological interventions for sleep management.

The training was accompanied by 'Insomnia Management Kits', which provided information on non-pharmacological interventions for sleep patterns and management. The kits were publicised through a media campaign and were distributed by GPs and pharmacists (Stevens 2000).

One month after the training there was evidence of a decline in the dispensing of benzodiazepines in the region. Within a year, a 20.5% reduction had been achieved (Stevens 2000).

#### *Victorian Metropolitan Alliance programme*

Another example of a 'one-off' education programme was a 2004 pilot addiction medicine workshop that was delivered to all advanced GP registrars through the Victorian Metropolitan Alliance (VMA).<sup>781</sup> A total of 46 GP registrars attended a one-day workshop that delivered information on the abuse of and dependency on a range of substances including benzodiazepines, heroin and cannabis. The workshop aimed to increase knowledge and confidence in this field of medicine and used a mixture of interactive

<sup>781</sup> The Victorian Metropolitan Alliance's (VMA) mission is to 'to develop integrated and innovative models of General Practice education and training. The purpose of these models is to continually improve the educational outcomes for GP Registrars and ultimately, their patients and the community. This is not to suggest that past practice has been inadequate but rather a process of continuous improvement maintaining those elements that are considered good practice and gradually incorporating new approaches that will deliver increased flexibility and improved outcomes'. The VMA is the regional training provider that delivers the AGPT program. For further information on the VMA and GP education and training see [www.vma.com.au](http://www.vma.com.au) and [www.gpet.gov.au](http://www.gpet.gov.au)



presentations, role-plays, case discussion and information on the legal issues surrounding prescribing (Jansen et al 2005). A post-workshop evaluation was undertaken and the results written up as a research article and printed in *Australian Family Physician*. The results of the study were promising:

More than 95% of registrars either agreed or strongly agreed that they felt more confident in dealing with addiction issues in practice and believed they had a better understanding of the issues pertinent to patients who have an addiction. Registrars also felt more confident in talking to patients about benzodiazepines, cannabis and treatment options for heroin dependency (Jansen et al 2005).

A series of implications for general practice emerged from the findings. These included:

- Addiction medicine is an important area of general practice training
- General practitioners feel a reluctance to treat addiction problems, due to a preconceived lack of knowledge and confidence
- Training in addiction medicine for general practice registrars is relevant to their work, has been well received and can increase knowledge and confidence
- Further research is needed to assess whether the knowledge and confidence gained from training workshops is sustained over time (Jansen et al 2005, p.36).

In a submission to this Inquiry, Dr Benny Monheit spoke of his role in various education programmes, including VMA workshops:

I have been involved in some of the education programs for medical students and GP Registrars on benzodiazepine prescribing. In these education sessions I discuss the legal issues regarding benzodiazepine prescribing (which are really quite complex and confusing to young doctors). For the GP Registrars groups in the VMA training consortium we run a full day drug and alcohol workshop, which includes a role-play of a new patient seeking a script for alprazolam. We discuss with them different ways of managing this request and how to weigh up the potential benefits and risks for the individual patient and for the community when prescribing benzodiazepines. It is always a lively educationally stimulating session for all involved.<sup>782</sup>

#### Education and Quality Assurance Program

The Education and Quality Assurance Program is run by the National Prescribing Service (NPS) primarily targeting GPs and pharmacists. The Program is designed to improve clinical practice in prescribing and use of medicines and covers six therapeutic models. The information is delivered using a wide range of interventions including clinical audits, written information, feedback on personal prescribing, educational visits, case studies and peer group discussions (NPS 2006). However, it is not clear to what extent benzodiazepines and opioid analgesics have been a focus of the Program.

#### **Other sources of information and education**

Despite the possibility of generational change, it appears that at present, in the absence of structured and coordinated education and training, GPs currently receive their information and education on drug-related issues and addiction medicine from a variety of sources.

For example, organisations such as the RACGP provide information and education to GPs including access to clinical resources, a library, ongoing GP education sessions and publications such as the *Australian Family Physician*, a peer reviewed journal 'dedicated to meeting the ongoing educational needs of general practitioners.'<sup>783</sup> Mental health was the theme for a recent edition published in March 2007 and included articles on management of anxious patients, pharmacological treatments for anxiety and depression and clinical notes on issues such as benzodiazepine dependence. For example, the article by Ellen et al

782 Submission of Dr Benny Monheit, Southcity Clinic, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

783 To access copies of the *Australian Family Physician* see <http://www.racgp.org.au/>

(2007) provided advice for GPs on when to prescribe benzodiazepines, their period of efficacy, avoiding withdrawal syndrome and including psychosocial interventions in the treatment plan for anxiety disorder. Specific information on benzodiazepine dependence and the role of the GP in management of this dependence was discussed in an article published in a 2004 edition of the journal (Khong, Sim & Hulse 2004).<sup>784</sup>

The NPS also provides a number of publications to GPs, pharmacists and other health professionals including the *NPS Prescribing Practice Review* (PPR), a quarterly publication provided primarily to GPs, GP trainees/registrars and pharmacists (NPS 2006).<sup>785</sup>

In addition, there are resources such as *Australian Prescriber*, an independent resource providing information on drugs to doctors, pharmacists, dentists and students.<sup>786</sup> According to the NPS, *Australian Prescriber* is circulated to over 50,000 health professionals and students within Australia and is accessed online by local and overseas readers (NPS 2006).

Despite the usefulness of these publications and resources, it was not possible to assess the proportion of GPs and pharmacists who frequently access and utilise this information in their daily practice. Notwithstanding these issues, publication of resources such as these is encouraging.

Government departments may also be a source of information, education and training for health professionals. The Victorian Department of Human Services, for example, provides educational material on the Drugs, Poisons and Controlled Substances legislation. Information on the misuse of medication including the management of drug seekers is also provided to medical practitioners undergoing vocational training, nursing graduates, pharmacy pre-registrants and the Divisions of General Practice.<sup>787</sup>

In many ways, despite the breadth of education and training available to GPs at the various stages of their medical careers, the delivery and availability of ongoing education and training appears uncoordinated and somewhat inconsistent. In evidence given to the Committee, Dr Greg Pearce, Medical Advisor, Alphapharm, commented that the fragmented nature of much GP education makes it difficult to provide uniform messages:

We do as a company run a lot of education meetings with respect to managing chronic persistent pain. Those meetings are well attended by GPs, but as I think I said in the submission, a lot of education the GPs receive is fractured because it comes from many different sources. But we do our best because there is no body coordinating this information. We also do education meetings on addiction for GPs as well, how to ensure they can recognise when a patient is starting to go off the rails; they may have made a bad selection, and what to do about it – refer them to D and A, refer them to a pain clinic where they can better managed. Education for medical students is important; they get very little as I understand it in medical school about the treatment of pain. Every doctor, no matter what their specialty is, will be treating pain patients at some stage. They will be treating pain patients. Yet the curriculum as I understand it in most medical schools is a little bit short on pain treatment education and in particular use of opioids.<sup>788</sup>

### *Suggestions to address education and training inadequacies*

In order to provide practitioners with the necessary skills to support people who are drug dependent, medical curricula from an undergraduate level should provide addiction medicine education and training, with specific sections of the courses focusing on drug

<sup>784</sup> See Section Seven of this Report for discussion of treatment issues.

<sup>785</sup> To access copies of the *NPS Prescribing Practice Review* see <http://www.nps.org.au/>

<sup>786</sup> To access copies of *Australian Prescriber* see <http://www.australianprescriber.com>

<sup>787</sup> Correspondence from the Mental Health Division, Department of Human Services (Victoria) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and other Pharmaceutical Drugs in Victoria, 13 November 2007.

<sup>788</sup> Dr Greg Pearce, Medical Advisor, Alphapharm, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Pharmaceutical Industry Forum, Melbourne, 16 July 2007.



dependence and treatment.<sup>789</sup> It is also clear that medical practitioners require further education and training to improve their understanding of the benefits and the risks of prescribing benzodiazepines and opioid analgesics and of alternatives to these pharmacological interventions, particularly in the area of pain management and management of anxiety and sleep disorders.

Many submissions have raised these issues, including the RACGP who recommended:

Making addiction medicine a more significant component of the undergraduate curriculum and perhaps more significantly of the GP Registrar program and psychiatric registrar training program.<sup>790</sup>

Moreover, the importance of continuing education and training for practising GPs should be recognised. This issue has also been highlighted in a number of submissions to the Inquiry such as that of the Latrobe Community Health Service (LCHS), which stated:

Ongoing education of GPs and other primary health care providers in regard to long-term prescription of narcotic analgesics and benzodiazepine medications is also of high importance, in particular when working with people who are substance dependent.<sup>791</sup>

The Victorian Alcohol and Drug Association (VAADA) provided a comprehensive list of the areas it believed should be covered in education and training materials given to prescribers and dispensers:

- How to reduce levels of dispensing commonly misused pharmaceutical drugs
- Alternative pharmaceutical remedies, or non-pharmaceutical alternatives, for conditions treated with commonly misused pharmaceutical drugs
- Information on referral pathways to counselling services and other non-pharmaceutical remedies for patients
- How to manage the prescription of commonly misused drugs to polydrug users
- Prescribing within a residential aged care setting
- Upskill prescribers/dispensers to deliver information about misuse of pharmaceutical drugs
- How to manage withdrawal of patients who misuse pharmaceutical drugs
- How to diagnose misuse of pharmaceutical drugs in patients
- Techniques to deal with patients diagnosed as misusing pharmaceutical drugs in a sensitive and appropriate manner
- Training on how to avoid stigmatising patients generally who seek treatment by benzodiazepines and other commonly misused pharmaceutical drugs
- Referral pathways to AOD (alcohol and other drugs) treatment services that specialise in treating misuse of benzodiazepines and other pharmaceutical drugs
- Information about referral pathways to harm reduction services that assist people who misuse pharmaceutical drugs.<sup>792</sup>

<sup>789</sup> The United States Drug Enforcement Administration (DEA) has published an excellent Guide for Drug Addiction in Health Care Professionals which assists healthcare professionals, friends and families to recognise the signs that may indicate a colleague, co-worker or treating healthcare professional may be diverting controlled substances to support a substance abuse problem. This guide is accessible on [http://www.deadiversion.doj.gov/pubs/brochures/drug\\_hc.htm](http://www.deadiversion.doj.gov/pubs/brochures/drug_hc.htm) (see Appendix 18).

<sup>790</sup> Submission of the Royal Australian College of General Practitioners (RACGP) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, September 2007.

<sup>791</sup> Submission of Latrobe Community Health Services to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, August 2007.

<sup>792</sup> Submission of VAADA to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

### A sample of areas requiring specific training

This section exemplifies the need for specific education and training for GPs and other healthcare professionals through highlighting two such areas: 'doctor shopping'/drug-seeking behaviour and pain management.

#### *'Doctor shopping' and drug-seeking behaviour*

Evidence provided to this Committee has suggested that many GPs and pharmacists lack skill in the identification of drug-seeking behaviour, particularly new and inexperienced GPs.<sup>793</sup> Dr Moynihan, President of the Victorian Rural Doctors' Association, makes the point that most, if not all, doctors will be targeted at some point:

As a solo doctor I was frequently visited by drug seekers. In Swan Hill I became involved in drug and alcohol work. I see a great deal of this. I have always had to kind of wage a campaign here to help other doctors not prescribe unnecessarily to people who are in fact drug seekers and drug peddlers or addicts or in other sorts of ways, diverting their medications for intravenous use...very often when people come to us they have already tried elsewhere and the first thing we do is to try and get an address off them and ring the other doctor and get the low-down, and we often find they have had the same problems with them where they came from. In terms of the locality, we found that drug seekers will try it from over quite a radius and try every doctor in the district. They will virtually go to everyone in their efforts to get things. From time to time I have resorted to mailing every single doctor and pharmacist within about 100 kilometres over certain individuals to try to limit their activities.<sup>794</sup>

Dr Moynihan believes that inadequate education and training contributes to the problem and should be addressed:

It is quite surprising the number of letters I get back or other communications saying, 'We've seen this person and they seemed very genuine and we gave them medications'. It is quite a generalised problem. We also get people coming interstate quite a great deal. They will work all the way down – they will work Queensland, New South Wales, Victoria, all the way down to Adelaide. They will basically go from Brisbane to Adelaide trying out every single surgery on the way. You have to be very wise to these people. They are often very convincing the way they present. They often present with pictures of back pain and that sort of thing. There are the ones who do not know how to act but there are ones who know how to act very well. They often confuse you. They are the ones who know how to play on your sensitivities in terms of, 'This person might make a complaint about me to the medical board or health commissioner, so to get rid of them I will give them something'. Yes, it is a very general problem. I find when I give tutorials to other doctors, if I go elsewhere, this is a subject which always has a very instant and major interest from other doctors. 'How do you get by? How do you recognise? How do you avert? How do you not prescribe without creating a scene?' etcetera. It is a very generalised problem.<sup>795</sup>

Dr Moynihan stressed the importance of developing an approach and a strategy to deal with people who are seeking drugs but noted how difficult this can be for inexperienced

793 See for example submissions to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, from Dr Nick Carr (July 2006); Mr John Galloway, Chief Pharmacist, and Ms Mary Sharpe, Deputy Chief Pharmacist, Pharmaceutical Services Branch, Department of Health and Human Services Tasmania (June 2007); and 'Mary' and 'Anne' (April 2006) whose names have been changed to protect privacy and confidentiality. See also Dr Mike Moynihan, President, Rural Doctors Association of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Teleconference, 18 June 2007.

794 Dr Mike Moynihan, President, Rural Doctors Association of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Teleconference, 18 June 2007.

795 Dr Mike Moynihan, President, Rural Doctors Association of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Teleconference, 18 June 2007.



doctors, and especially for overseas trained doctors 'who generally have a pretty hard time of it anyway and will do anything to avoid a confrontational situation'.<sup>796</sup>

Dr Nick Carr, a GP and medical educator/trainer, expressed the view that a coordinated approach was needed for instructing GPs on managing this problem:

It has long been my view that GPs are not given clear enough advice and instruction about how to deal with doctor shoppers. This is partly because "experts" have not always agreed on the appropriate approach. I would like to see a state/national programme of workshops for GPs on how to manage this problem, but only if the content of such workshops was clearly agreed on in advance and did not just reiterate the somewhat woolly advice that has often circulated previously.<sup>797</sup>

The development of such skills to manage drug-seeking behaviour requires specific education and training. Notwithstanding the need to enhance education and training in the area of addiction medicine, education and training in the field of pain management has also been reported as an area requiring further consideration.

#### Pain management issues

In 2006 hearings were held in the United States to address the growing problem of prescription drug abuse. One of the people who testified at these hearings was Ms Barbara van Rooyan<sup>798</sup> whose son died from ingesting OxyContin® in 2004. The following text is an extract from part of her testimony focusing on the shortcomings of GPs' training with regard to prescription drugs and pain management:

The July 2005 report from [CASA] states that 4 in 10 doctors surveyed say they received no training in medical school on prescribing controlled substances; more than half received no training in medical school on drug abuse or drug addiction and three fourths said they had no training in medical school identifying diversion of prescription drugs for illicit purposes. Yet in 2002 Oxycontin was, by far, one of the most widely prescribed opioid medications in the U.S. with an increase of 380% between 1992 and 2002...

...In addition, the Waismann 2005 Opiate Dependency Survey indicates that 71% of patients with opiate dependency were originally prescribed opioid medications by their doctors.

The question becomes, "How can so many prescriptions for opioids be written by so many doctors with so little training?"

Consider that:

- The majority of physicians do not know that the long term safety and effectiveness of opioids for management of non-malignant pain have NOT been substantiated
- The majority of physicians do not know that patients seeking pain relief for chronic, non-malignant pain often have underlying psychosocial problems and need psychological or rehabilitation services or would respond better to other non-drug interventions
- In busy medical practices, particularly primary care and family practice office settings, a thorough diagnosis of the cause and type of pain and a balanced, multifaceted pain treatment program are intuition or hearsay, and ends up aggravating rather than ameliorating prescription pain medication abuse or addiction
- Many good physicians relied upon false marketing information regarding Oxycontin from an aggressive Purdue Pharma sales force that was prompted by greed. The result

796 Dr Mike Moynihan, President, Rural Doctors Association of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Teleconference, 18 June 2007

797 Submission of Dr Nick Carr to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

798 In her testimony Ms Van Rooyan states that she is 'a California Community College Faculty member and counsellor, the wife and daughter of physicians, the mother of two sons. My first born son, Patrick Stewart died on July 9, 2004 at 24 years of age after ingesting one Oxycontin.'

was an expansion of opioid therapy for patients who might benefit from non-drug interventions or alternate drugs, without the accompanying risks of opioids...

...Comprehensive pain management education with a balanced, multi-faceted approach is needed for all physicians.<sup>799</sup>

Dr Malcolm Hogg, respected pain specialist clinician and Head of pain services at Melbourne Health, commented on the lack of consistent education on pain issues across Victoria:

We need the guidelines which are in development, and I think we then need further GP education. We need some unified processes across the state boundaries and possibly across Victoria. There is great inconsistency about access and management.<sup>800</sup>

Representatives of the Pharmaceutical Services Branch at the Department of Health and Human Services in Tasmania recognise the need for further education and training on the use of prescription opioids, and made the following recommendation in a detailed submission to the Inquiry:

That the Committee consider supporting the establishment of a multidisciplinary group to investigate and review the national picture in regard to the strengths and weaknesses relating to current practices regarding medical use of drugs of dependence, and to initiate strategies and improvements in education, clinical practices and regulatory arrangements with a view to maximising benefits and minimising harms associated with these substances.<sup>801</sup>

A number of pharmaceutical companies made reference to the deficiencies in current medical training with regard to pain management. In a submission to the Inquiry Mundipharma noted that despite limited education in this area, '...all doctors, irrespective of their speciality, will be required in their daily practices to treat patients presenting with pain.'<sup>802</sup> Representatives of Mundipharma, like many of the organisations with whom the Committee met, were of the view that new medical graduates were likely to have received little training in pain management issues, particularly in the assessment of pain and how this relates to appropriate prescription of opioids.

Commenting on the knowledge and expertise of overseas trained doctors, Mundipharma stated:

it is critical that these issues be addressed so that inadvertent diversion of prescribed medicines, including opioids, is avoided. At the very least, overseas trained doctors should be made familiar with both State and Federal regulations pertaining to the prescription of opioids before being permitted to practice in this country.<sup>803</sup>

Clearly specific education and training on pain management and addiction medicine, particularly the prescribing of benzodiazepines and opioid analgesics, is required for GPs and other healthcare professionals.

799 Ms Barbara van Rooyan, testimony to United States House of Representatives Committee on Government Reform Subcommittee on Criminal Justice, Drug Policy, and Human Resources, 26 July 2006.

800 Dr Malcolm Hogg, Australian Pain Society, Australian and New Zealand College of Anaesthetists, Melbourne Health, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007.

801 Submission of Mr John Galloway, Chief Pharmacist and Ms Mary Sharpe, Deputy Chief Pharmacist, Pharmaceutical Services Branch, Department of Health and Human Services Tasmania, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

802 Submission of Mundipharma to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other forms of Pharmaceutical Drugs in Victoria, June 2007.

803 Submission of Mundipharma to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.



## Information, education and training for other professional groups

Whilst the discussion so far in this chapter has concentrated on the education and training needs of GPs, there are also other professional groups that have a similar requirement. The education and training 'gaps' in these professions will be discussed in this section.

### Pharmacists

As with GPs, pharmacists require specific education and training in identifying drug-seeking behaviour and working with drug dependent people. A number of education, training and information programmes targeting pharmacists have already been discussed. Unfortunately, as with GP education, it was difficult to locate information on the number of education and training programmes available to pharmacists. However, there have been a variety of specific programmes designed to enhance pharmacists' skills in this area.

In addition to professional standards and guidelines, pharmacy organisations such as the Pharmacy Guild and the Pharmaceutical Society of Australia have worked closely with their member pharmacists over the years to develop and deliver a broad range of education and training programmes (and accompanying resources) to improve the quality of care received by patients. One such example is the Quality Care Pharmacy Program, an initiative of the Pharmacy Guild of Australia.

### Quality Care Pharmacy Program

The Quality Care Pharmacy Program (QCPP) is a quality assurance programme now in its second edition. Any pharmacy in Australia can register, with over 86 per cent of pharmacies currently accredited under the QCPP.<sup>804</sup> The Program establishes professional standards, procedures and policies for community pharmacies to ensure they are delivering the highest level of customer care.

Pharmacies are required to undergo an external audit every two years to ensure that they are meeting the required Standard in all areas of their pharmacy business. Financial incentives are available from Medicare Australia for accredited pharmacies. There are 18 QCPP Standards including specific standards on: customer service (Standard 11), ongoing staff training (Standard 15), and delivery of health programmes and services (Standard 3).

With regard to strategies to ensure appropriate dispensing of drugs and appropriate consultation with clients who may be misusing drugs, Ms Bergin of the Pharmacy Guild of Australia noted:

...the Quality Care Pharmacy Program would require the pharmacy to use established protocols. The protocols would need to be complemented with other strategies like staff training programs or the private counselling area...so if you put a few of those things together and you might have an environment that is more conducive to dealing with these issues.<sup>805</sup>

### Pharmacy Self Care Program

The Pharmacy Self Care Program, developed by the Pharmaceutical Society of Australia (PSA) over 20 years ago, has been discussed in Chapter 6.1 with regard to consumer information and education. However, the Program also aims to better equip pharmacists to deliver quality health information to consumers, as outlined in its goals:

- ♦ To use and promote pharmacy's unique position to improve community access to quality health information, increase health awareness and encourage consumer involvement in their own health care
- ♦ To establish pharmacies as primary centres for health information and advice

<sup>804</sup> See <http://www.guild.org.au/qcpp/>

<sup>805</sup> Ms Jenny Bergin, Director, Community Pharmacy Practice, Pharmacy Guild of Australia, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Canberra, 16 May 2007.

- ◆ To ensure pharmacies, viability through facilitating and promoting the professional aspects of pharmacy practice
- ◆ To work with governments, the pharmaceutical industry and interested bodies to have pharmacy products and services used optimally.<sup>806</sup>

A number of education modules have been developed for pharmacists and pharmacy staff. Pharmacists receive education and training on how to use the Self Care resources through *inPHARMation*, an education and health promotion publication for pharmacists and their support staff. The resource is published monthly and incorporates core materials, news and updates on the Program. Pharmacy support staff are provided with specific education through the 'Counter Connection' education module.

In addition to programmes such as the Quality Care Pharmacy Program and the Pharmacy Self Care Program, a number of educational opportunities are offered through bodies such as the Australian College of Pharmacy Practice and Management (ACPPM). The College offers education and training at a postgraduate level through the Continuing Pharmacy Education (CPE) program. Pharmacists may enrol in graduate diplomas and certificates with the College or may wish to enrol in individual education modules (known as Individual CPE modules) or undertake CPE short courses to update their knowledge and skills on specific topics.

Individual CPE modules are offered in Drug Abuse and Misuse (offered in 2 units). Through these modules, pharmacists enhance their knowledge of drug use and misuse including understanding of the factors which lead to drug misuse, the identification of drug misuse among clients, tolerance and dependence issues, including the physiological and psychological components of dependence. These courses also provide information on withdrawal and drug treatment issues, such as the role of the pharmacist in drug treatment and medication management.

The College also offers an Individual CPE module on pain management. This course includes information and instruction on pharmacological and non-pharmacological treatment modalities for alleviation of pain.<sup>807</sup>

Pharmacists also receive information on benzodiazepines and other pharmaceutical drugs from a variety of other sources. These include specialist journals such as the *Australian Prescriber*<sup>808</sup> and pharmaceutical companies.

Notwithstanding the valuable work of pharmacy organisations and other bodies in providing a range of education and training programmes to pharmacists, the Committee has received evidence that pharmacists would benefit from further ongoing education and training opportunities and access to additional information sources.<sup>809</sup>

In particular, it has been suggested that pharmacists may require specific education and training on best practice benzodiazepine and opioid analgesics dispensing and further training on the identification and management of people with drug dependency issues. The Australian Drug Foundation, for example, highlighted the need for further training of pharmacists to ensure that patients receive relevant and appropriate information about their medications including possible interactions and potential problems.<sup>810 811</sup> Further, it

806 For further information see: <http://www.psa.org.au>

807 For further information see: <http://www.acpp.edu.au>

808 For further information see <http://www.psa.org.au/>

809 For example, the Pharmaceutical Society of Australia and the Pharmacy Board of Victoria have suggested that pharmacists would benefit from access to the Clinicians Health Channel. The Clinicians Health Channel is part of the Victorian Government Health Information website and is available to clinicians working in the Victorian public health sector. The service provides clinicians with access to a variety of publications and other health resources (See <http://www.health.vic.gov.au/clinicians/>).

810 Submission of the Australian Drug Foundation (ADF) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

811 Moreover, the peak agency for alcohol and drug services in Victoria, VAADA, also recommended that specific education and training materials be developed for pharmacists, GPs and a variety of other health professionals.



has been proposed that pharmacists would benefit from further education and training in the areas of pain management and the management of sleep and anxiety disorders including education on the alternatives to pharmacological interventions.

The Pharmacy Board of Victoria supported the need for further education of health practitioners regarding the circumstances of pharmaceutical drug misuse and abuse.<sup>812</sup> A similar observation was made by the Essendon Community Legal Centre who noted that resources, particularly in relation to pain management and appropriate prescribing of analgesics, be made available to various health practitioners including pharmacists, doctors and nurses.<sup>813</sup>

The Pharmaceutical Industry has also made calls for additional education and training of pharmacists. In a submission to the Inquiry, Mundipharma detailed the need for ongoing education of pharmacists that covers areas such as identification of drug-seeking behaviour and doctor shoppers, identification of forged prescriptions (and the action to be taken when forged prescriptions are identified) and recognition of inappropriate prescribing.<sup>814</sup>

The evidence suggests that pharmacists, as with doctors, would benefit from further education and training in relation to best practice benzodiazepine and opioid analgesic dispensing, pain management, sleep disorder and anxiety management and education on alternatives to pharmacological interventions. The Committee has also found that pharmacists' ability to provide quality information and education on these issues would be enhanced by the provision of private counselling rooms or a private space for detailed consultation.

### Nurses

Nurses are employed in a range of settings where they are required to treat people suffering from chronic non-malignant pain and sleep and anxiety disorders. These settings include primary health care, acute hospital settings and drug treatment agencies and are often the first point of contact for patients. As such, the nurses' role demands a sound understanding of the pharmacology of drugs, an ability to identify and manage drug-seeking behaviour and an understanding of the healthcare needs of drug-dependent patients.

Traditionally nursing in drug and alcohol services has not been viewed as an attractive specialisation with the profession. The Committee has received some evidence that nurses are often not adequately trained in drug and alcohol issues and would benefit from enhanced education and training in the area. Formal training that is available for nurses to improve knowledge of drug and alcohol issues is often generalist and does not focus on specific substances such as benzodiazepines and/or opioid analgesics.<sup>815</sup>

It has also been suggested that recruitment of trained and suitably qualified nurses remains difficult, particularly in rural and regional Victoria. Ms Cheryl Sobczyk, Clinical Nurse Manager at Bendigo Community Health Services, explained that there were many challenges in training an 'inexperienced and naïve workforce'.<sup>816</sup>

812 Submission of Mr Steve Marty, Registrar, Pharmacy Board of Australia, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

813 Submission of Essendon Community Legal Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2007.

814 Submission of Mundipharma to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

815 Ms Cheryl Sobczyk, Clinical Nurse Manager, Bendigo Community Health Services, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Bendigo, 30 May 2007.

816 Ms Cheryl Sobczyk, Clinical Nurse Manager, Bendigo Community Health Services, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Bendigo, 30 May 2007.

Ms Kate Harrington O'Brien concurred with this view, Operations Manager, Alcohol and Drug Services at Bendigo Community Health Services, agreed with this assessment, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Bendigo, 30 May 2007.

Ms Sobczyk noted that formal training available to nursing staff in drug and alcohol issues is often generalist and deals with all substances rather than focusing on particular drugs such as benzodiazepines or opioid analgesics.<sup>817</sup>

Whilst this discussion has demonstrated the need for further education and training of health practitioners such as nursing staff, GPs and pharmacists, there are other groups for whom further education and training is necessary including alcohol and drug workers.

### *Drug and Alcohol workers*

It is sometimes assumed that people who work in the drug and alcohol sector are automatically equipped with the knowledge to advise on specific drugs. Whilst this may be true of some or even most drugs that alcohol and drug workers focus on, evidence to this Committee suggests that this will not always be the case with regard to prescription drugs. For example, Mr John Ryan of Anex gave evidence to the Committee that in relation to benzodiazepines:

One of the most obvious areas of lack of knowledge is around benzodiazepine half-lives. People assume that, if they pop a pill today [there will be no lasting effects tomorrow], whereas in fact the half-lives of a lot of benzodiazepines are much more significant and, in fact, can go up to several days, in which case people are at significant risk of overdose a long time after they think that their benzo use is no longer relevant. That sort of information is not well understood by people who use drugs. It is also not well understood by people who are providing services to people who use drugs, and I think that would especially include the Needle and Syringe Program sector.<sup>818</sup>

In its submission to the Inquiry, Anex noted there was a need for improved 'training and other workforce development initiatives for NSP [needle and syringe program] staff to increase knowledge of the harms and contexts associated with the use of benzodiazepines and other pharmaceutical drugs'.<sup>819</sup>

VAADA made the suggestion that educational materials should be developed for alcohol and drug treatment staff and coupled with training on the following issues:

- General information about the misuse of pharmaceutical drugs
- The role misuse of pharmaceutical drugs may play in polydrug use
- How to identify misuse of pharmaceutical drugs in clients
- Referral pathways to AOD [alcohol and other drugs] treatment services that specialise in treating the misuse of pharmaceutical drugs
- Referral pathways to harm reduction services that assist people who misuse pharmaceutical drugs.<sup>820</sup>

VAADA recognised the need for education and training materials for a number of health and welfare professionals including mental health workers, generalist alcohol and drug treatment workers, dispensers of pharmaceutical drugs (GPs and pharmacists) and generalist health workers.<sup>821</sup> With regard to mental health workers and generalist health workers, VAADA suggested that education and training should involve:

- General information about the misuse of pharmaceutical drugs

817 Ms Cheryl Sobczyk, Clinical Nurse Manager, Bendigo Community Health Services, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Bendigo, 30 May 2007.

818 Mr John Ryan, Chief Executive Officer, Anex (Association for Prevention and Harm Reduction Programs Australia Inc), Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 20 June 2006.

819 Submission of Anex to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2007.

820 Submission of VAADA to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

821 Submission of VAADA to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.



- Information about conditions that may be associated with misuse of prescription drugs, eg. conditions involving chronic pain, anxiety disorders
- How to identify misuse of pharmaceutical drugs in clients
- Referral pathways to AOD treatment services that specialise in treating misuse of benzodiazepines and other pharmaceutical drugs
- Referral pathways to harm reduction services that assist people who misuse pharmaceutical drugs.<sup>822</sup>

### *Local government service providers*

One final point with regard to the education and training needs of those who come into contact with misusers/abusers of benzodiazepines and opioid analgesics concerns the role of local government. Although local governments provide services to individuals who misuse these drugs, little is known about the training of their staff who deliver such services. For example: What education and training needs might such groups have? Do prescription drugs create particular training needs for staff who come into contact with such clients? Unfortunately, there was little evidence in the literature to answer such questions and little input from local government to this Inquiry. However, submissions from those municipalities who did respond provide some insight. The City of Melbourne, for example, noted that there is a limited understanding of these issues among local service providers and expressed the need for collaboration at a local level:

Council supports the need for education and training for health professionals and police on the affects of poly-drug use (often illicit and licit drug use combined). A thorough and systematic understanding of the nature and effect of poly-drug misuse and of strategies to address this issue is vital so that these sectors may work together more effectively to address pharmaceutical drug misuse.<sup>823</sup>

## **Education and training – What is the pharmaceutical industry’s role?**

This Inquiry has identified a broad range of sources of information and education on benzodiazepines and opioid analgesics. Medical associations and colleges, state health bodies and individual clinicians all play a role in the delivery of information and education to health professionals. However, the role of the pharmaceutical industry in delivery of information and education has yet to be considered. Concerns have been expressed throughout this Inquiry that some pharmaceutical companies may not always provide the most exhaustive, frank or useful information with regard to the products their sales representatives are promoting to medical professionals. To what extent pharmaceutical industry representatives should be ‘educators’ and to what extent they should be trained is unclear.

### *Continuing education programmes*

It would seem that efforts have been made to improve standards in recent years, particularly through the use of continuing education programmes (CEPs) run through Medicines Australia in collaboration with the University of Queensland.<sup>824</sup> The course is run through the Faculty of Health Sciences and uses a mixture of online and distance learning unit modalities.

Medicines Australia’s CEP is compulsory for all representatives of member companies of Medicines Australia and is designed to educate medical representatives to a recognised

822 Submission of VAADA to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and other Pharmaceutical Drugs in Victoria, June 2007.

823 Submission of City of Melbourne to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and other Pharmaceutical Drugs in Victoria, June 2007.

824 This programme was formerly run by Deakin University Victoria and known as the Medical Representative Education Program (medREP).

industry standard and to ensure such representatives are fully familiar with the Industry's Code of Conduct.

The course is designed for flexibility and students can fast track through each of the programs to complete.

CEP is primarily directed at medical representatives working within the prescription medicines industry, and recommended to those who may not be currently employed within the industry but would like to pursue a career as a medical representative. It is also available to personnel working for organisations interacting with the pharmaceutical industry.<sup>825</sup>

Under the Medicines Australia Code of Conduct, discussed in Chapter 5.1, pharmaceutical companies are responsible for ensuring representatives are fully cognisant of the Code and Australian privacy legislation. Representatives should also:

[p]ossess sufficient medical and technical knowledge to present information on the company's products in a current, accurate and balanced manner and should be cognisant of all provisions of the Code (Medicines Australia Code of Conduct 2006, Section 4.3).

The CEP endorsed through Medicines Australia is noted in the Code as providing sufficient information and training to uphold this section of the Code.

Courses currently being provided through CEP include:

- ♦ The Medicines Australia Code of Conduct – familiarises current and potential representatives with ethical practice, the importance of the Code, and its relevance to everyday practice
- ♦ The Pharmaceutical and Health Care Industry – examines the development of the industry, its role in the Australian healthcare system and government regulatory processes
- ♦ An Introduction to Pharmacology and Understanding Clinical Evidence – these courses look at the technical, clinical and scientific information a company representative needs to know to appropriately disseminate product information to doctors and other medical professionals
- ♦ Understanding Product Information – gives students an overview of the scientific, medical and therapeutic information contained in Product Information and how this information is structured to comply with Therapeutic Goods Administration requirements.<sup>826</sup>

Whilst the content and structure of these courses seem comprehensive, it does beg the question whether they should be mandatory for *all* representatives in the field. It is nonetheless reassuring that the course is compulsory for all representatives of member companies of Medicines Australia. Moreover, CEP provides a series of refresher courses for students who have already completed the core courses, enabling them to keep up with changes to the Code of Conduct and other important developments in pharmaceutical practice.

### ***Other education and training industry initiatives***

In addition to education and training packages mandated under the Medicines Australia Code of Conduct, pharmaceutical companies also provide a number of educational, scientific and community awareness programmes aimed at ensuring better knowledge of the hazards associated with pharmaceutical drug use and abuse.

In a submission to this Inquiry, Mundipharma outlined a number of education and information initiatives developed and distributed by the company. As well as conducting regular educational sessions for doctors and pharmacists on issues including safe

825 See Continuing Education Program website at <http://ma.healthinsitu.uq.edu.au/portal/programs/index.cfm>

826 For further information as to the conduct of these courses, see <http://ma.healthinsitu.uq.edu.au/portal/programs/index.cfm>



prescribing of opioids and sessions on 'doctor shopping', materials have been developed to encourage appropriate use of opioid products for chronic pain by doctors, pharmacists and patients.

Among the materials developed by Mundipharma is a leaflet providing advice on preventing diversion and identifying drug seekers.<sup>827</sup> The leaflet offers a long list of 'pointers' to help doctors identify a potential drug diverter. Among these are: the patient wants a late or after-hours appointment; insists on being seen immediately; is unable or unwilling to give the name of his or her regular doctor; claims to have lost current prescription; or will not give permission to obtain past records. This leaflet also provides advice on ensuring adherence to professional standards and protecting prescription pads.

Other resources produced by Mundipharma include an information brochure for patients who require opioids for pain management.<sup>828</sup> The Committee notes, however, that there is limited discussion of the risks of dependence, although the brochure does state that the patient should be told about known and expected side effects and their management, and suggests that a practitioner:

Explain, in simple lay-terms, the difference between tolerance, physical dependence and psychological dependence. Avoid the use of the terms addict or addiction. Reassure the patient that the use of opioid medication is supported by the Australian Pain Society, and the Faculty of Medicine, provided the guidelines are met and the patient takes the medication as prescribed.<sup>829</sup>

Janssen-Cilag detailed their education programme 'FOCUS' in a submission to the Committee. The programme, accredited by the RACGP and the Australian College of Rural and Remote Medicine, seeks to create better outcomes in chronic pain through education of GPs in the areas of chronic pain diagnosis and appropriate treatments, including the safe and responsible prescription of opioids to manage moderate to severe chronic non-cancer pain.<sup>830</sup>

### *Reservations about the industry's information and education provision*

Notwithstanding the valuable work that some pharmaceutical companies have undertaken to minimise the risks associated with use of their products, they have received criticism from various sectors of the health and medical communities. A particular criticism expressed by several individuals and agencies is that pharmaceutical companies on occasion tend to minimise the side effects of the drugs they are promoting.<sup>831</sup> Professor White told the Committee that:

Sometimes, undoubtedly, the side effects are underplayed in the marketing from the pharmaceutical companies. I will give you an example. In Australia, the drug tramadol is used for pain relief and is purported to be either non-opiate or to have very weak opiate effects. It was said that the main mechanism of action was different from other medication's action. I cannot recall exactly what the wording was, but it was more or less implied that you did not have to worry about opiate issues with tramadol. The reality is very different from that. While it is probably not as strong as a morphine or a methadone or an oxycodone,

827 For a copy of Mundipharma's leaflet, see Appendix 19.

828 For a copy of Mundipharma's brochures, see Appendix 19.

829 For a copy of Mundipharma's brochures, see Appendix 19.

830 Submission of Janssen-Cilag to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs, August 2007.

831 Concerns with regard to the way in which some pharmaceutical companies may underplay, mislead or over-promote their products were expressed by inter alia, Mr John Galloway, Chief Pharmacist and Ms Mary Sharpe, Deputy Chief Pharmacist of the Pharmaceutical Services Branch, Tasmanian Department of Health (Transcript 18 June 2007); Dr Mike Tedeschi, ANU Medical School, Canberra Hospital (Transcript 16 May 2007).

The most serious case of over-promoting or misleading the public with regard to the effects of a pharmaceutical drug in recent years was that of the American company Purdue Pharma in their marketing of the opioid OxyContin®. A discussion of this incident and the court case that followed is found in Chapter 4.1 of this Report.

it nevertheless does have a quite clear opiate effect. People can become addicted to it in the same way they can to opiate drugs, and they experience withdrawal when they cease taking it, and so I think it was marketed as a considerably safer drug than it has turned out to be. That is an instance where they get educated in a certain way, which is not really correct.<sup>832</sup>

Other doctors agreed with the sentiments expressed by Professor White.<sup>833</sup>

Addiction medicine specialist Dr David Richards added that a sales representative will not always inform you of the negative sides or the downsides of overuse or misuse of prescription drugs.

I can remember sitting for the first time when I was a brand-new, wet-behind-the-ears GP, when I had been working in the hospital system for 12 years in Britain, and a rep came and sat down at my desk and said, 'We've got this wonderful new drug. It's absolutely great. It won't cause dependence in the way that Librium does. It's absolutely great. It's called Valium. It's wonderful.' As each new drug comes onto the market, the job of the sales rep is to market their drug, so they tell you about all the good sides of it.<sup>834</sup>

Nonetheless, many witnesses did not believe all the responsibility for the dissemination of pharmaceutical knowledge can rest with the pharmaceutical companies or their representatives. Doctors too have a responsibility to keep abreast of developments in pharmacology and product information.<sup>835</sup>

Dr Harry Hemley, Vice President of the Victorian Chapter of the Australian Medical Association, expressed a similar view:

I have drug reps coming in to my practice every day. I have a routine of seeing one a week. I make an appointment and I see one a week. You know, they have got to earn a quid just like everybody else in the world, so I do not begrudge them that. They provide valuable information, which is information I would never have known. They tell me about the new drugs on the market and that is all very good.<sup>836</sup>

Whilst Dr Alex Wodak agrees that many GPs do obtain information from pharmaceutical representatives primarily because of time restraints, this information is not necessarily comprehensive or the most objective:

Doctors do get a lot of their information from pharmaceutical companies. Some doctors are more willing to listen to the pharmaceutical companies than others. Doctors are very often pressed for time. Listening to a representative from a pharmaceutical company means that in a few minutes you can fairly painlessly get a lot of information and a few pens and mirrors and beads in the process. Some doctors are more willing to do that than others, but I think it is fairly clear that most of the information doctors get from pharmaceutical companies is

<sup>832</sup> Professor Jason White, Director, Drug and Alcohol Services of South Australia, and Head of Department, Pharmacology, University of Adelaide, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Adelaide, 18 May 2007.

<sup>833</sup> See for example, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria by Dr David Richards, Addiction Medicine Physician, Western Region Alcohol and Drug Centre (Prescription Drug Forum, Warrnambool, 29 May 2007); Dr Alex Wodak, Director, Alcohol and Drug Service, St Vincent's Hospital (Public Hearing, Melbourne, 25 June 2007); Dr Con Constantinou, Health Manager, Practitioners Board of Victoria (Public Hearing, Melbourne, 9 July 2007).

<sup>834</sup> Dr David Richards, Addiction Medicine Physician, Western Region Alcohol and Drug Centre, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Warrnambool, 29 May 2007.

<sup>835</sup> See for example Dr David Richards, Addiction Medicine Physician, Western Region Alcohol and Drug Centre, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Warrnambool, 29 May 2007.

<sup>836</sup> Dr Harry Hemley, Vice President, Australian Medical Association (Vic), Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 26 June 2007.



very loaded. The benefits are exaggerated and the harmful side-effects of the drugs are downplayed or ignored altogether.<sup>837</sup>

Despite concerns expressed in this section about the information pharmaceutical companies provide (or don't provide) when promoting their products, the Committee acknowledges that many pharmaceutical representatives do feel a responsibility to ensure their products are used correctly. And in conjunction with organisations such as the NPS, the Pharmaceutical Society of Australia and the various pharmacy guilds they do 'have a sense of stewardship to make sure [their] products are used correctly as far as [they] can'.<sup>838</sup> The Committee is mindful of the comments of Dr Greg Pearce, Alphapharm, that in many ways pharmaceutical companies are 'damned if they do and damned if they don't' when it comes to providing educational materials to doctors and other medical professionals. Dr Pearce also expressed the following views about the industry's social responsibility:

The industry has to have a key role because whether society likes it or not, industry has the wherewithal to provide education to health professionals. We get criticised for doing it, but there has to be more incentive for industry to be encouraged to do this. I firmly believe in that. I think this gets drowned in the argument about whether industry should promote drugs to consumers. What we should be doing is saying industry has a role to educate about drugs, and education is not just talking about the good things about drugs, it is talking about the whole thing and it is talking about the whole package. Our drugs are good, but there are other things you can use too and you should use those first maybe. We have a social responsibility, every industry does. Our social responsibility is to get the balance right.<sup>839</sup>

## Information and education for specific populations

The provision of appropriately tailored information and education is essential to the success of prevention and harm reduction strategies.<sup>840</sup> Whilst the information, education and training needs of a number of professionals including medical practitioners have been canvassed, there are specific populations of users who also require tailored information and education. These include rural and regional Victorians, Aboriginal communities, culturally and linguistically diverse communities (CALD), injecting drug users,<sup>841</sup> young people, families, women, drivers, those suffering from chronic and acute pain,<sup>842</sup> and people with a mental illness. The third and final section of this chapter discusses the need for targeted information for these groups.

### *One size does not fit all*

Information and education needs will vary for different groups within the community according to the different contexts of use, different populations of users and varying harms associated with misuse. It is essential in developing strategies to address any problem associated with drug misuse, be it licit or illicit drugs, that it is placed in the often-shifting context of that use. As the Youth Substance Abuse Service (YSAS) stated in a submission to

837 Dr Alex Wodak, Director, Alcohol and Drug Service, St Vincent's Hospital, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 25 June 2007.

838 Dr John Whitlam, Director of Medical Affairs, Mundipharma, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Pharmaceutical Industry Forum, Parliament House, Melbourne, 16 July 2007.

839 Dr Greg Pearce, Medical Advisor, Alphapharm, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Pharmaceutical Industry Forum, Parliament House, Melbourne, 16 July 2007.

840 Prevention, information and education has also been discussed in Chapter 6.1 of this Report. For a detailed discussion of harm reduction strategies see Chapter 6.3 of this Report.

841 The specific needs of injecting drug users are canvassed in Chapter 6.3 of this Report.

842 The specific needs of people suffering from chronic and acute pain are canvassed in Section Seven of this Report.

this Inquiry, 'Context is an important precursor to understanding and assessing possible harms associated with problematic drug use'<sup>843</sup>

This is particularly the case with regard to prescription drugs, as the nature of the drug, the reason the drug is taken and the culture surrounding the use of that drug can be markedly different between various groups of drug misusers. Moreover, understanding of the risks and harms associated with misuse may vary between and within groups. Such differences are important not only in themselves but also in terms of the strategies employed to address prescription drug misuse, including information and education strategies. Dr Alex Wodak and Ms Mary Osborn from the Drug and Alcohol Service at St Vincent's Hospital, Sydney stated that:

It is important to separate out the very different problems arising in different age groups and populations in terms of developing effective interventions. Very different problems arise in quite different settings [such as] young poly drug users; middle-aged people with severe chronic illnesses; and the elderly...Most of the problems with benzodiazepines in particular are seen in the first and third groups.<sup>844</sup>

These remarks are supported by a well established research literature which argues that substance use needs to be understood in the context of 'drug, set, setting' (Zinberg 1984). Zinberg's theory requires an exploration of the interconnectedness of the drug (in this case benzodiazepines and/or opioid analgesics), the set (the attributes, desires, beliefs, expectations or personality of the user) and the setting (using alone, with friends, at a party) – in short, the physical, social and emotional environment in which drug using takes place.<sup>845</sup>

Various organisations and bodies have supported the need for information and education interventions that utilise such an approach. As Mr Sam Biondo from VAADA explained:

Education initiatives should be targeted, distinct. It is different in CALD communities, indigenous communities, women etcetera. These approaches need to be conducted in collaboration with communities. By communities it might be, you know, community of drug users, community of people who are in nursing homes, people who have some experience in the environment in which the abuse is occurring because you have greater likelihood of the message getting through.<sup>846</sup>

### **Differentiation within target groups**

However, there is also a need to differentiate within groups. Some approaches to drug education do not take this into account. Even when discussing a specific population such as young people, interventions are often based on the assumption of homogeneity:

One of the reasons that drug education has been so ineffective may be that only a small population of those targeted are likely to progress beyond experimentation with drugs or low levels of recreational misuse. On the other hand, problematic drug users (those with physical, psychological or legal problems arising from their drug use) are likely to be beyond the limited potential of most drug education interventions aimed at adolescents. There appears to be a need to develop variable and targeted interventions which account for the needs of different groups. The educational needs of most young people who may or may not pass through a phase of 'normative' use will differ from the needs of those who have the

843 Submission of Youth Substance Abuse Service (YSAS) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2007.

844 Submission of Dr Alex Wodak, Director, and Ms Mary Osborn, Senior Policy Officer, Drug and Alcohol Service, St Vincent's Hospital Sydney, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

845 For further discussion of Zinberg's theory, see d'Abbs and MacLean (2000); Drugs and Crime Prevention Committee (2006); Zinberg (1984).

846 Mr Sam Biondo, Executive Officer, VAADA, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 25 June 2007.



potential to develop drug use and problems. On a continuum of drug use from no use, through experimental and recreational use to problematic use, it is possible to view normative users as those whose experimental or recreational misuse does not result in perceived physical, psychological, economic or legal problems. It is important to note there is often a significant disparity of views between young people and adults (health/social care professionals, legal authorities and policy makers) as to what constitutes misuse. The difficulty here is to have any degrees of confidence in being able to distinguish, at an early enough age for proactive interventions, between those likely to be non-users and normative users, on the one hand, and problematic users, on the other (Health Education Board for Scotland (HEBS) 2002, p.10).

Mr Jacob Lee of the South Eastern Migrant Resource Centre explained that the practice of treating all CALD groups as being homogenous often shapes interventions for these groups:

...little research has been done in this area, and even though there is some research it is not broken down into separate communities. As we all know, the CALD community is not one homogeneous group.<sup>847</sup>

This issue is not restricted to CALD communities; a similar phenomenon has also been found with regard to research on, and interventions aimed at, Indigenous populations and rural and regional communities. Dr Rodger Brough of South West Healthcare in Victoria, for example, argues that interventions are limited when differences between and within rural communities are ignored:

Rural communities are very different and strategic responses need to be tailored to the nature of rural communities...it is not sufficient to tailor a rural response as opposed to a metropolitan response because in fact the cultural and even epidemiological differences between particular rural communities are different, and the tailoring of the responses needs to be done at a local level or you get inappropriate responses or you get inappropriate complications or unforeseen difficulties etcetera. Until as a community we look at policies and their applications in rural communities, we are disadvantaging between a quarter and a third of our constituents in terms of making effective responses. We really do need not only a body like an Alcohol and Education Rehabilitation Fund (AERF) or a VicHealth body looking at alcohol and drug policies but we need a body that really consults and gets to understand what rural issues are all about.<sup>848</sup>

Dr Brough explained further the need to take into account specific issues pertinent to rural communities:

There are some particular issues that are more relevant and applicable to rural communities, and particularly smaller rural communities, and we are not looking at responses that could be put together to take account of those sorts of things. You read a lot of reports where they acknowledge in about three lines isolation, anonymity, and the half a dozen issues.<sup>849</sup>

It is clear that different user profiles, varying patterns of use and different harms associated with misuse require tailored responses.

<sup>847</sup> Mr Jacob Lee, Manager, Aged Care and Disability, South Eastern Region Migrant Resource Centre, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Forum for Culturally and Linguistically Diverse Communities, Melbourne, 9 July 2007.

<sup>848</sup> Dr Rodger Brough, Drug and Alcohol Physician, South West Healthcare, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Warrnambool, 29 May 2007.

<sup>849</sup> Dr Rodger Brough, Drug and Alcohol Physician, South West Healthcare, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Warrnambool, 29 May 2007.

### ***What strategies currently exist? Recent international, national and local information programmes***

However, despite these calls, the Committee found very few examples of education and/or information programmes specifically addressing benzodiazepines or opioid analgesics. Those programmes that do exist have tended to provide general information about prescription drugs.

#### **United States programmes**

##### *The buzz takes your breath away. Permanently*

One of the more well-known consumer education campaigns to prevent misuse of prescription pain relievers was developed in the United States using the tagline *'The buzz takes your breath away...Permanently'* (U.S. Department of Health and Human Services n.d.).<sup>850</sup> Campaign materials such as posters, brochures and radio advertisements were used to specifically target young people.<sup>851</sup> The campaign uses stark imagery and slogans to deliver the message that these drugs are potentially fatal if misused:

It starts with "just this once", and it can end there. Misuse of prescription pain relievers can kill you. If someone offers you oxy, percs, vics or some other party drug, *think twice – because you only die once*. For information or help, call 1.800.622.HELP (U.S. Department of Health and Human Services) (emphasis in original).

Similarly, the Food and Drug Administration, in conjunction with other federal agencies and non-federal organisations, produced an open letter titled *'Is this where your teenager goes to get high?'* to educate parents about the risks of medication misuse and abuse:

...teens often don't recognise the dangers of prescription drug and over-the-counter drug abuse; they don't see it being as harmful as illicit drug use. After all, these drugs are approved for medical use. But when taken without medical supervision, intentionally abused or mixed with other drugs or alcohol, prescription medicines can be dangerous. Teens who decide to abuse prescription drugs run the risk of addiction, strokes, seizures, comas and even death. (Food and Drug Administration, U.S. Department of Health n.d.).

Such campaigns, however, may be limited in their capacity to reach young people and engage in a meaningful way. Ms Kate Harrington-O'Brien from Bendigo Community Health Services told the Committee that:

...education only reaches a certain audience and sometimes you are only preaching to the converted or to the people that are willing or able to be reached. ...it is often the issues that underpin why people are using: it is the poverty, it is the lack of education, it is the social isolation, it is the social poverty; it is because you do not know how to accept being told 'no'...You do not have the same resources; maybe it is a different level of intellect, but just your socialisation in general. As much as I agree that we have got to have education – I absolutely agree with that – it is how you market that to all audiences or potential audiences, or those audiences that maybe are at most risk because of problematic use or misuse of substances. I do not think we necessarily, in mainstream, do that well.<sup>852</sup>

<sup>850</sup> The Campaign materials including several posters and brochures, radio advertisements, information for parents were developed jointly by Divisions within the U.S. Department of Health and Human Services – US Food and Drug Administration (FDA), Substance Abuse and Mental Health Services Administration (SAMSHA) and the National Institute on Drug Abuse.

<sup>851</sup> In particular, one of the brochures provides information on the risks associated with misuse and abuse, signs and symptoms of overdose, what to do if a friend has overdosed and service listings for further information and support. Written in plain English, the brochure tells young people that non-medical use of pain relief medication 'to get high' is not safe and lists a range of prescription pain relievers that are considered particularly dangerous, including OxyContin® and opioid and morphine based pain relievers.

<sup>852</sup> Ms Kate Harrington-O'Brien, Operations Manager, Alcohol and Drug Services, Bendigo Community Health Services, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Bendigo, 30 May 2007.



It has also been suggested that, particularly when targeting young people, written materials in the form of brochures and posters may not be the most appropriate method of delivering information. Increasingly, a range of 'youth-friendly' technologies such as SMS, the Internet and podcasts are being used to deliver messages, as discussed later in this chapter.

### **Australian programmes**

A range of tailored projects have been developed in Australia to meet the information and education needs of different communities; most notably a number of initiatives developed and delivered by the NPS in collaboration with community agencies and services.

#### *Initiatives of the National Prescribing Service*

The NPS has driven a variety of schemes at both a national and local level to improve consumer use of medicines. Adopting a 'multi-strategic approach' to behaviour change, the NPS:

...develop[s] and deliver[s] a comprehensive range of interventions including websites, newsletters on topical information, unsolicited direct mail with prescriber feedback combined with specific educational messages, educational visiting (academic detailing), clinical audit with feedback, peer group meetings, hypothetical case scenarios that facilitate problem-based learning (PBL) for individuals or groups, curriculum and training, information on new drugs and research, patient information leaflets, community information sessions, and community capacity building. Opinion leaders and community peers are also used to deliver and endorse key messages where appropriate (NPS 2006, p.4).

Whilst many of the projects discussed below do not specifically address benzodiazepines and opioid analgesics, they demonstrate the importance of tailoring information and education to fit the identified needs of a community. What follows is a brief overview of the information and education components of various projects.

The NPS provides information and services to the whole of the community (as discussed in Chapter 6.1) as well as providing information and services to targeted populations. These include older people, multicultural communities, Aboriginal and Torres Strait Islander communities and people with chronic conditions.

#### *'Families get to know their medicines'*

The 'Families get to know their medicines' is an initiative of the Federation of Ethnic Communities' Councils of Australia and the NPS in partnership with Community Languages Australia, Queensland LOTE Centre and Ethnic Schools Association of Queensland.

The project aims to educate young people about medicines through a curriculum package tailored to the specific beliefs and practices of different communities and delivered in after-hours ethnic schools (or community language schools). By improving students' understanding of information about medicines and enhancing students' competency in their family language, it is envisaged that students will take part in family discussions about safe use of medicines:

By respectfully engaging with traditional family interactions, it is anticipated the program will place the information within a two-way family learning context, which has been shown to be an effective way of increasing awareness of health issues in multicultural populations. Key messages will be reinforced by homework activities which will require participation of older family members as well as informal discussions between family members (NPS 2006, pp.17–18).

The curriculum materials were trialled in Term 3, 2007, in Chinese, Greek and Vietnamese after-hours ethnic schools throughout Queensland. The specific objectives of the curriculum package are to develop students' knowledge of medicines and safe practices in their use, and encourage students to discuss managing medicines safely with their families.

The package is designed for students aged 10–16 years and, by extension, their families. Through seven tailored sessions, the package is designed to address ‘common sense’ issues related to the safe use of medicines. In particular, key messages outlined in the education curriculum are:

- Knowing about medicines – it is important to know about the medicines you take to improve your health, to get better results from medicines and to avoid medicine mix-ups;
- Knowing the different types of medicines – medicines include those prescribed or bought over the counter, as well as many natural, herbal and traditional remedies;
- Knowing what questions to ask your doctor and pharmacist when you get a new medicine – understanding that doctors and pharmacists are there to help answer any of your questions (‘Families get to know their medicines’ curriculum package, Rationale section, 2007, p.2).

At the time of writing this Report, the project was in the trial phase.

#### *Rural project schemes 2004–2005*

In recognition of the particular difficulties facing people living in rural and remote Australia in accessing health professionals, medicines and medicines information, the NPS supported a range of community Quality Use of Medicines (QUM) projects across rural and regional Australia. The projects each incorporated information on QUM in various formats with each project tailored to the needs of a specific community.

Whilst it was encouraging that a number of education and information projects had been developed to address pharmaceutical drug issues more generally, it was disappointing to find so few that address benzodiazepines and opioid analgesics in a meaningful way.

#### *Barriers to accessing information for specific populations*

There is a range of barriers preventing specific populations accessing current drug information and education. These include denial, shame and fear about drug use and the associated stigmas, ignorance or confusion about drug issues, and language and communication difficulties, all of which need to be taken into account if particular groups of misusers are to be reached. Among CALD communities, social pressure to be discreet about drug use has been mentioned as one of the major barriers limiting access to information and services (for example, see Department of Human Services (DHS) 2000).

#### **Attitudes and knowledge about medicines and drugs**

General attitudes to health and wellbeing and to medicines in particular may act as a barrier to gaining information and education on benzodiazepines, narcotic analgesics and other prescription medications. It may also be that some people, particularly newer arrivals to Australia, do not know how the Australian medical system is structured:

Victoria is home to a significant number of humanitarian arrivals from the Horn of Africa, Sudan, Myanmar, Iraq and Afghanistan. Many community members have never dealt with a systematic medical structure, which creates difficulties when accessing the correct pharmaceutical drug.<sup>853</sup>

Comments made by a range of service providers suggest that specific groups also hold the general community’s belief that drugs prescribed by a medical practitioner are essentially safe. Attitudes and expectations towards doctors compound this problem. As Ms Wesa Chau explained:

Many Chinese people actually believe drugs can cure everything, that medication is always good if it is prescribed by doctors and that if doctors do not prescribe medication – this is

853 Submission of the Ethnic Communities Council of Victoria to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2007.



actually very true – they are not fulfilling their duty. That is in the Chinese cultural mentality, and so in some parts of Asia some overseas doctors prescribe drugs just to keep their patients happy.<sup>854</sup>

She also explained how basic knowledge of medicines including use-by-dates and the dangers of sharing medication is not necessarily well understood in her community:

It is also not uncommon for some people from an ethnic background, especially elderly people, to keep a wardrobe of medication at home. They store it at home just in case something happens. Some could be off-the-shelf medication, but some could be prescribed drugs that they have left over from some other illness that they used to have, and because of the lack of understanding this means they might start sharing medication. If people have similar symptoms, they start sharing the medication among the community. I know of people who go doctor shopping for sleeping pills just for storage, which can be quite dangerous. It is less serious if the person understands that sleeping pills are not for everyday use, but if, for example, they have children at home, that could lead to serious consequences.<sup>855</sup>

### **It's more than language: Communicating with different populations**

A further barrier to gaining information is language. The inability to effectively communicate health issues and comprehend medical instruction can lead to unintentional misuse:

...there are many instances where practitioners prescribe the wrong drugs due to the communication barrier. They tend to rely on family members who have a slightly better English proficiency to help with interpreting. Despite that, professional practitioners may not use professional interpreters to assist with the consultation. I suppose practitioners use highly technical terms, which I probably do not understand, let alone migrants with a low level of English proficiency. One example that I will draw on is that some cultures do not actually have a word for stress or mild depression. They use the words 'crazy' or 'mental illness' – things that sound very serious. If they go to a doctor saying, 'My husband is crazy', the doctor will probably think they have a mental illness rather than just stress or depression and will consequently give them the wrong drug for the wrong reason. I suppose I am not saying that ethnic communities are at a higher risk of misuse, but because of the language barrier they may misuse drugs without knowing rather than making a decision that they want to take the drug. But having said that, the misuse of drugs happens across all cultures.<sup>856</sup>

In these circumstances, relatives including children may be relied on to act as 'pseudo-interpreters' translating information between doctors and patients. It has been suggested that the wider use of interpreters within the healthcare system generally and within the drug and alcohol field specifically would go some way to addressing this problem:

Some recommendations that I can talk about are to promote and emphasise the importance of interpreters in doctor consultations. That is very important to assist with communication and education in the community as well as, as you mentioned before, in nursing homes, workers about culture. So there is two-way education, not just the community but also the workers who are working with the communities and talking to ethno-specific agencies who deal with clients every day, ethno-specific broadcasting to educate the communities, and

854 Ms Wesa Chau, Multicultural Network Coordinator for north-west CALD partnership, Action on Disability within Ethnic Communities, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Forum for Culturally and Linguistically Diverse Communities, Melbourne, 9 July 2007.

855 Ms Wesa Chau, Multicultural Network Coordinator for north-west CALD partnership, Action on Disability within Ethnic Communities, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Forum for Culturally and Linguistically Diverse Communities, Melbourne, 9 July 2007.

856 Ms Wesa Chau, Multicultural Network Coordinator for north-west CALD partnership, Action on Disability within Ethnic Communities, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Forum for Culturally and Linguistically Diverse Communities, Melbourne, 9 July 2007.

community partnership programs among the funded ethno-specific agencies to provide cultural training to nursing homes and residential homes. The translation of important instructions on tablet packages is very important as well.<sup>857</sup>

However, the role of interpreters in the healthcare setting is not necessarily without its limitations. Without a sound understanding of medical terminology, interpreters can unwittingly provide incorrect medical information to patients.<sup>858</sup>

Whilst not acting directly as interpreters for medical professionals, bilingual staff employed by various agencies play an important role in communicating with people who are not proficient in the English language:

Bilingual workers can be useful for communicating with users with low English language proficiency. Bilingual staff have proven to be extremely effective in a number of organisations.<sup>859</sup>

Although interpreters and bilingual workers provide an important resource for conveying information about benzodiazepines and opioid analgesics, new resources providing drug information in a range of community languages need to be developed. Mr Lee of the South Eastern Migrant Resource Centre noted that relatively straightforward changes to package labelling or instructions which simplify messages may be useful:

Or very simply they could have instructions which say, 'Before meals' or 'After meals' or 'With meals', or maybe how many times a day and so on in a table so they can check off the information.<sup>860</sup>

It has also been suggested that information and education for particular populations such as CALD and Aboriginal communities should be expanded to include advice on using traditional medicines in combination with prescription medicines.

As outlined in Chapter 5.1, the Committee believes a review of the current presentation and marketing of prescription drugs is required with a view to strengthen and improve the way information is provided to consumers. Such a review should give consideration to providing information in community languages.

### *Issues for consideration in the development of information and education for specific populations*

The evidence provided in this chapter demonstrates how drug education and information materials produced for a general audience may not be appropriate for specific populations of users. Yet, there is clearly not enough good quality culturally relevant information being produced in the area of benzodiazepines and opioid analgesics. A number of communities require tailored information and education specifically about these drugs, their effects, and potential problems associated with misuse. They also require information about the risks associated with sharing medications; information on use-by-dates; reading labels and appropriate storage of medicines.

857 Ms Wesa Chau, Multicultural Network Coordinator for north-west CALD partnership, Action on Disability within Ethnic Communities, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Forum for Culturally and Linguistically Diverse Communities, Melbourne, 9 July 2007.

858 Mr Tut Pal Ding & Mr Bullant Agau of the Sudanese Lost Boys' Association, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Melbourne, Forum for Culturally and Linguistically Diverse Communities, Melbourne, 9 July 2007.

859 Submission of Ethnic Communities Council of Victoria to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2007.

860 Mr Jacob Lee, Manager, Aged Care and Disability, South Eastern Region Migrant Resource Centre, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Forum for Culturally and Linguistically Diverse Communities, Melbourne, 9 July 2007.



### Utilising appropriate technologies and mediums in the delivery of information and education

There is a range of ways such information can be provided to specific populations. For example, school based drug education only reaches a certain proportion of young people. It is equally important that young people who are not in formal education as well as those over 18 years have access to adequate information regarding benzodiazepines and opioid analgesics and the associated risks and harms.

The Internet can be one means of providing factual and accurate information about drugs and drug-related harms to a variety of audiences but particularly to young people.<sup>861</sup> As Mr Mark Durran of the Australian Drug Foundation noted:

Our experience suggests that there is a need for information that is targeted at particular groups and particular issues as well as your general whole-of-community information. I have picked out young people in particular, because young people tend to use these substances in a number of different ways, and they are an often difficult-to-reach target group as well, and we need to be wary about how we do go about reaching them. A pamphlet might not do it these days; it is more about using the appropriate technology, like websites and SMSs and pod casts and those sorts of youth friendly technologies.<sup>862</sup>

One such example is the Australian Drug Foundation (ADF) project Somazone ([www.somazone.com.au](http://www.somazone.com.au)), a youth health information website developed by young people for young people. The site is aimed at young people aged between 14 and 18 and is accessed worldwide, receiving over 87,000 monthly visits from young people.<sup>863</sup> A key component of the site is an anonymous question and answer service where young people can post questions and have them answered by volunteer health professionals (for example, doctors, sexual health nurses, psychologists and other relevant professionals). The site also publishes personal stories and information and links to youth services and resources.

ADF expanded upon the importance of information services such as Somazone: '...information needs to be made available in a regulated and anonymous forum so that young people, and the general population, can reduce their risk of misadventure when using prescribed medications in conjunction with illicit substances'.<sup>864</sup>

The service provides young people with clear, accurate and unbiased answers to their questions about health-related topics, such as mental health, sexual health and drugs. Approximately 10 per cent of drug-related questions submitted to Somazone are related to benzodiazepines.

As technology progresses, new mediums are being used to provide people with information on a whole range of issues including drugs. Young people are recognised as one of the highest users of mobile phone technology such as SMS and so this medium is increasingly used to promote services and provide information to this group. The New Zealand Drug Foundation launched the 'Get the Msg' campaign in August 2006. 'Get the Msg' is a free text information service where young people text the name of a drug, including common street names, to DRUG (3784) and receive harm minimisation information and links to further information and help.<sup>865</sup> According to the New Zealand Drug Foundation, this type of information provision has only been used in Ireland and

861 However, as noted in Chapter 5.3, the Internet can also act as a source of misinformation.

862 Mr Mark Durran, Director, Information Services, Australian Drug Foundation, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 26 June 2007.

863 <http://somazone.com.au>

864 Submission of the Australian Drug Foundation (ADF) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

865 For further information see <http://www.nzdf.org.nz/media-drug-txt-service-launch-aug06>

New Zealand. Youth friendly technologies such as SMS and the Internet should be considered when developing education and information programmes for this audience.

### **Use of peer educator and peer networks**

Despite there having been much debate over the definition and appropriate uses for peer education, the concept is now used in the areas of sexual health and HIV prevention, sex education for young people, and drug and alcohol education (ADF 2006).

The use of peer educators is well established as a means of providing 'hard-to-reach' groups in Australia and overseas with education and information (ADF 2006). Peer education can be an important means of providing non-judgemental health information to particular drug using populations who may have limited access to other forms of education and information provision. Peer education can provide the following benefits.

- Adolescence is a time when peer group influences are particularly significant to a young person's development and peers can appear more credible than an adult
- Peer education is relatively cost effective
- It is empowering for those involved
- It allows access to hard-to-reach populations (for example, young gay or lesbian populations or drug users)
- Peers can reinforce learning through ongoing contact
- Peer educators act as good role models (ADF 2006, p.1).

Peer education has been used widely in a variety of different contexts among particular age groups, social demographics, types of drug users and people of different cultural backgrounds. Mr Jacob Lee believes that peer education has an important role in working with people from refugee and migrant backgrounds:

Language is an issue, as is information in an appropriate language – not just the language itself but pitched at the right level so that they can understand it. Peer educators is another thing that may help. We also need to educate them that talking about the issue is okay.<sup>866</sup>

Drug user organisations such as VIVAIDS and the Western Australian Drug User Organisation (WASUA) have used peer education models in recognition that the knowledge and experience of someone with a drug using background can prove invaluable in providing credible health and drug information. Peer educators can be integral components of outreach services, sometimes known as 'peer outreach' (DHS 2000):

Peer outreach workers often function as peer educators undertaking outreach with other members of their peer group or social network so as to provide health education services. In addition to working as peer educators themselves, they may also encourage their peer contacts to educate their own peers (DHS 2000, p.10).

### **Outreach services<sup>867</sup>**

Outreach plays a pivotal role in contacting groups that might otherwise not have access to health services including drug and alcohol services. While outreach is often considered in the context of drug treatment, it is one tool through which to provide information and education to particular groups, especially in the early stages of an intervention.

In practice the term 'outreach service' is vague. There is a lack of clarity in terms that probably overlap with outreach work, such as 'satellite work', 'detached work', 'mobile

<sup>866</sup> Mr Jacob Lee, Manager, Aged Care and Disability, South Eastern Region Migrant Resource Centre, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Forum for Culturally and Linguistically Diverse Communities, Melbourne, 9 July 2007.

<sup>867</sup> Peer support and outreach can be both a means of providing information and education and can be an important source of treatment and support. The discussion in this chapter, however, is limited to the role of peer educators and outreach in providing information and education. Section 7 of the Report discusses peer support as it pertains to treatment and management.



work', 'streetwork', 'peer outreach', 'community care', 'assertive community outreach' and 'case finding'. Leviton (1991) defines outreach as including three elements:

- Establishing contact with the target population.
- Maintaining contact until clients are motivated to take advantage of services being made available to them.
- Following up with later contacts, maintaining communication with clients until they have successfully completed their use of services (DHS 2000, p.11).

In their recent submission to the House of Representatives Standing Committee on Family and Human Services Inquiry into the impact of drug use on families, WASUA emphasised the importance of both peer educators and outreach services in reducing the harms associated with drug use for individuals and their families:

Often the fear of discrimination by some health providers and agencies makes many illicit drug users reluctant to access such services. WASUA's peer based philosophy and user friendly service enhance our engagement with drug users who subsequently feel more comfortable and 'safer' in disclosing issues concerning their drug use. In turn this enables us to respond with meaningful and appropriate support and guidance. It is by the dissemination of reliable information through peer networks that many of the harms associated with illicit drug use can be dramatically reduced.

For example it is critical that young people are aware that if something goes seriously wrong with a friend who has consumed illicit drugs that emergency services should be immediately contacted; call an ambulance or contact someone to transport the person to hospital. Many younger drug users think that calling an ambulance in an overdose situation will result in police attending and lives have been lost because of this false belief.<sup>868</sup>

It is important that services and agencies have sufficient resources to utilise broader information and education techniques such as outreach, peer education and support.

#### **Consulting with communities in the development of information and education**

For information and education to resonate with the community, it is important that the community is involved in the development and delivery through collaboration, as acknowledged by VAADA in a submission to the Inquiry.<sup>869</sup> Moreover, attendees at a multicultural forum hosted by the Committee cautioned against developing interventions before having a clear picture of the needs of different communities:

I think what we need to do is to know the community before we actually look at what to do because each community would have some [sub-communities], for example; they have different educational levels, different English proficiency levels and a different level of integrating into the Australian society. We have to also look at a different range of format, for example video, audio and cartoons. DVDs are very popular nowadays, but for some communities they may not know what a DVD is. An audiotape may be a better option. Also different kinds of mass media, for example radio, video, Channel 31 – it depends on which community, so we need to know the community before we know what will be more effective.<sup>870</sup>

The importance of consulting with a community to build support for interventions was also emphasised:

<sup>868</sup> Submission of Western Australian Drug User Organisation (WASUA) to the House of Representatives Standing Committee on Family and Human Services, Inquiry into the impact of illicit drug use on families, May 2007.

<sup>869</sup> Submission of Victorian Alcohol and other Drug Association to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

<sup>870</sup> Mr Jacob Lee, Manager, Aged Care and Disability, South Eastern Migrant Resource Centre, Evidence to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Forum for Culturally and Linguistically Diverse Communities, Melbourne, 9 July 2007.

How should the educational material and information be delivered? What we suggest is to let the community tell you, and so we need to do consultation...It may not be once, maybe we have to go back a few times. We need to build a trusting relationship with them. We can talk to the community through religious leaders. We can look at bilingual community educators. The Cancer Council actually did something very good over the past 10 years. They have bilingual community educators, and that is good. We may also work with ethnic-specific providers. Because they know the community it will be much more effective if you actually work with them rather than setting up something different.<sup>871</sup>

Moreover, the need to incorporate existing community expertise, experience and knowledge in programme development and delivery was stressed by Koori Drug and Alcohol Service Providers:<sup>872</sup>

Unless something changes nothing is going to change, simple. We are going to come here in another 20 years time and talk about the same stuff. We as workers have the knowledge and stuff like that. We know what is going on out there...You can only do it through us people, if you know what I mean.<sup>873</sup>

### **Delivering information through community resources**

One way to deliver information and education about benzodiazepines and opioid analgesics is through existing community resources such as local newspapers, local community figures and community groups.

This may be particularly important for communities where English is not a first language, as pointed out by the Ethnic Communities' Council of Victoria:

Many users that come from CALD backgrounds may have difficulties expressing themselves in English. They still consider ethnic newspapers and media to be a more important source of information than mainstream media service providers.<sup>874</sup>

Latrobe Community Health Service suggested that information and education on benzodiazepines and opioid analgesics could be delivered to the local Indigenous community through their community groups:

Education in schools and in community groups like Koori Men's and Women's groups is of high importance. Investment in this type of program is crucial to encourage service providers to step out into the community to talk about the drugs of concern but also the social impacts on the community.<sup>875</sup>

While traditional drug education programmes target the individual, Aboriginal people have stressed the importance of including the whole family in the education and treatment process.<sup>876</sup> Importantly, the need for interventions to be based on community knowledge and understanding was also raised.

### **Enhancing information sharing between agencies**

Another means of facilitating appropriate provision of information and education is through strengthening links between mainstream drug and alcohol services and specialist agencies and communities, be they youth services, Aboriginal organisations or ethno-

871 Mr Jacob Lee, Manager, Aged Care and Disability, South Eastern Region Migrant Resource Centre, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Forum for Culturally and Linguistically Diverse Communities, Melbourne, 9 July 2007.

872 For a detailed discussion of this issue see Drugs and Crime Prevention Committee 2006, 2003, 2001.

873 Mr David Dryden, Koori Drug and Alcohol Worker, South Eastern Alcohol and Drug Service, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Aboriginal Forum, Melbourne, 20 August 2007.

874 Submission of Ethnic Communities' Council of Victoria to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and other Pharmaceutical Drugs in Victoria, July 2007.

875 Submission of Latrobe Community Health Service to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, August 2007.

876 For further discussion of this issue see Section Seven of this Report.



specific agencies. The importance of enhancing professional collaboration and cooperation is discussed in detail in Chapter 7.2 of this Report.

### ***Education for drivers: An area of growing importance***

Whilst the available, albeit limited, research evidence suggests that 'within the general Australian population, drink driving and illicit drug driving are considered dangerous unacceptable behaviours' (Mallick et al 2007, p.47), the views of the general community with regard to pharmaceutical drug use and driving are more ambivalent. The findings of a recent study into driving and drug use (including licit prescription drugs) suggest that there is a great need for targeted education with regard to the use, abuse and effects of prescription drugs on driving ability (Mallick et al 2007). This brief section drawing from this recent research examines the issue of risk perception among drivers with regard to prescription drug use. It also discusses the need for an education campaign with regard to prescription drugs and driving that addresses the finding of this research that for many drivers the use of prescription drugs prior to or whilst driving is unproblematic.

### **Risk perceptions and knowledge of drug driving**

The study *Drug Driving in Australia: A survey of community attitudes, experience and understanding* (Mallick et al 2007) was conducted jointly by the Australian Drug Foundation and Turning Point Alcohol and Drug Centre. Its methodology was threefold, consisting of a literature review of current research in the area; interviews with key stakeholders in the areas of both driving and road safety and drug education and treatment services; and an internet survey with respondents randomly selected from members of the public who are over sixteen years of age.

The study acknowledged that very few studies have been conducted with regard to attitudes and perceptions to drug driving, although as stated above with regard to illicit drug use, there was a general consensus amongst the community that driving with illicit drugs in the system was unacceptable (Sweeney Research 2005). Notwithstanding this lack of research, the authors of the Report stated that:

Understanding perceptions of risk that drivers attach to drug driving, as well as their knowledge and understanding of how drugs affect driving, should be central to efforts to develop effective drug driving countermeasures (Mallick et al, p.46).

### **Attitudes to pharmaceutical drug use and driving**

Very little is known when it comes to attitudes and risk perceptions towards the use of prescription drugs and other pharmaceuticals (including over the counter drugs) when driving. Drawing from earlier research by McLeod (1998) the Mallick study reported that many members of the general community perceived driving whilst using painkillers for example unproblematic, although only a small percentage of the McLeod sample (10 percent) found the use of sedatives whilst driving unproblematic (McLeod 1998 cited in Mallick et al 2007, p.46).

The results from the expert interviews and public surveys conducted by the Mallick study nine years later suggest little has changed:

It was suggested that everyone underestimates the dangers associated with the driving while affected by medicines...Some of the experts discussed that some sectors of society are hypocritical in their opinions of 'drug driving'. For example, those critical of illicit drug users driving may themselves drive whilst affected by prescription drugs or over the counter medications which could be as impairing as some illicit drugs...It was suggested that people conceive 'drug driving' as meaning driving under the influence of illicit drugs (Mallick et al 2007, p.50. Committee emphasis).

In short, the views of the expert stakeholders consulted in addition to the limited literature undertaken in this area suggest that for the most part 'People are ignorant of the fact that medications can significantly impair driving ability' (Mallick et al 2007, p.50). As such the

Report strongly recommends that 'there needs to be a concerted effort to inform the public about [pharmaceutical] drugs and driving' (Mallick et al 2007, p.49).<sup>877</sup>

### **A targeted education campaign for drug drivers?**

Whilst, as the above discussion suggests, there is widespread ignorance about the dangers associated with drug driving, particularly with regard to prescription drugs: 'there have not been any information or education campaigns to inform the public about drug driving' (Mallick et al 2007, p.49). This is despite the fact that in the area of alcohol and driving there is evidence to suggest that information and education campaigns, particularly in association with strategies such as random breath testing, have been highly effective in reducing the incidence of drink driving and associated death and injury (Mallick et al 2007, p.83).

The Mallick Report asks whether similar mass media and social marketing campaigns can be targeted at drivers who use pharmaceutical drugs. The Report suggests that whilst there is little published literature available either here or overseas in this area, the answer is probably a qualified yes with some important caveats.

First, any media or other education campaign directed at drug users should not be a 'stand alone' intervention. In other words it should be implemented in conjunction with other initiatives that are already in existence, particularly law enforcement initiatives such as police testing of drivers for the presence of drugs in the system.<sup>878</sup>

Second, a media or education program/campaign needs to incorporate materials and information already available in the community such as Consumers Medicines Information, labelling information and advice delivered by doctors and pharmacists.<sup>879</sup>

Third, it is also imperative, as discussed in Chapter 2.2, that any education strategies directed at people using prescription medicines do not lead to patients stopping using their medications as this can result in equally deleterious consequences to their health (Mallick et al 2007, p.83). Experts consulted in the 2007 study have argued that ultimately 'new ways of disseminating information regarding the impairing effects of pharmaceutical drugs need to be developed [particularly] targeted at older members of the community' (Mallick et al 2007, p.84).

The key message from the Mallick Report and the evidence upon which it relies is that information and education strategies with regard to drug driving generally and the use of prescription drugs specifically cannot be developed and implemented in isolation:

[s]ustained and integrated information and education initiatives are essential components in influencing attitudinal and behavioural change, and that such campaigns should commence alongside (or ideally prior to) the implementation of road side testing initiatives. Despite this, all of the key experts noted that in Australia, to date, very little has been done in the way of drug driving related information and education campaigns. In addition, while there is evidence that information and education campaigns have been very effective components of countermeasure strategies to reduce [drink driving], particularly in conjunction with random breath testing, no evaluations of the effectiveness of such strategies for drug driving have been undertaken (Mallick et al 2007, pp.82-83).

The question remains, however, as to whether campaigns and strategies that address drink driving are necessarily transferable to drugs other than alcohol, particularly prescription drugs that are being used legitimately and according to directions. As the Mallick Report itself recognises, clearly a lot more work needs to be done in this area.

877 This was also a recommendation of the Standing Committee on Family and Community Affairs in its Inquiry into Substance Abuse in Australian Communities (see Commonwealth of Australia 2003)

878 See Chapter 3.2 for a discussion of testing for the presence of prescription drugs in drivers by Victoria Police pursuant to amendments to the Road Safety Act 1985 incorporated in 2000.

879 See discussion earlier in this chapter.



## Conclusion

The Committee understands that benzodiazepines and other pharmaceuticals have a legitimate and important role in the treatment of a range of medical and psychological conditions. The problem remains, however, that despite community perceptions that benzodiazepines and other pharmaceutical drugs are relatively innocuous, all of these medications have varied side effects and the potential to produce a range of harms, not least of which is dependence. The Committee believes there are special groups that require targeted information and education on these drugs. Health professionals also require targeted information and education to ensure they are equipped to provide quality advice to patients on the risks and harms associated with long-term use and to prescribe these medications in an appropriate manner. Moreover, health professionals require education and training on alternatives to pharmacological treatments for patients suffering from pain, anxiety and sleep disorders and on the appropriate management of clients with drug dependence issues.

In 1998 Roche argued 'Until there is adequate and appropriate education and training of all relevant personnel, efforts with respect to treatment, prevention and policy development will remain hampered' (Roche 1998, p.95). Almost 10 years later, these comments remain valid.

## 6.3 Harm Reduction Strategies

### Introduction

Throughout the course of this Inquiry it has become clear that harm reduction strategies have an important role to play alongside treatment, information and education responses in addressing the harms associated with the misuse of benzodiazepines and opioid analgesics. Evidence received from a number of organisations clearly demonstrates that harm reduction strategies are a necessary component of integrated strategies to reduce these risks and harms.

### What is harm reduction?

The concept of 'harm reduction', in its current form, emerged in the early 1980s, substantively driven by the observation that sharing injecting equipment played a major role in the transmission of HIV and the subsequent AIDS epidemic. Whilst closely associated with needle and syringe programs (NSPs), harm reduction is not restricted to such activities. As Loxley and her colleagues explained:

Harm reduction is often thought of only as needle and syringe programs, but many more strategies are used and, in many cases, have been shown to be effective (Loxley, Toumbourou, Stockwell, Haines et al 2004, p.236).

In a review of international harm reduction perspectives, Inciardi and Harrison (1999) outlines the range of policies and programmes that could be considered within a broad definition of harm reduction:

1. Advocacy for changes in drug policies – legalisation, decriminalisation, changes in drug paraphernalia laws, reduction of penalties for drug-related crimes, and treatment alternatives to incarceration
2. HIV/AIDS-related interventions – needle/syringe programs, HIV prevention/intervention programs, bleach distribution, referrals to HIV testing and HIV medical care, and referrals for HIV/AIDS-related psychosocial care and case management
3. Broader drug treatment options – methadone maintenance by primary care physicians, changes in methadone regulations, heroin substitution programs, and new experimental treatments
4. Drug abuse management for those who wish to continue using drugs – counseling and clinical case management programs that promote safer and more responsible drug use
5. Ancillary interventions – housing and other entitlements, healing centres and support and advocacy groups (Inciardi & Harrison 1999, viii).

Effective harm reduction strategies are generally designed to focus on the broad context of drug use, such as the mode of use, context of use and preventing harm to others (for example, members of an individual's family or the broad community). Whilst there has been much debate about what is and what is not harm reduction, some useful and practical



definitions are available.<sup>880</sup> The International Harm Reduction Association has defined harm reduction as:

Policies and programs which attempt primarily to reduce the adverse health, social and economic consequences of mood altering substances to individual drug users, their families and their communities (International Harm Reduction Association n.d.).

Lenton and Single (1998) critiqued some of the definitions of harm reduction and offered their own definition:

A policy, program or intervention is one of harm reduction if and only if (a) the primary goal is the reduction of drug-related harm rather than drug use *per se*; (b) where abstinence oriented strategies are included, strategies are also included to reduce the harm for those who continue to use; and (c) strategies are included which aim to demonstrate that, on the balance of probabilities, it is likely to result in the net reduction of drug-related harm (Lenton & Single 1998, p.216).

In this regard, harm reduction consists of those actions that have reducing harm as the principle objective; thus strategies are directed primarily at the reduction of harm rather than primarily at the reduction of drug consumption. Reducing use or abstinence can be appropriate strategies within harm reduction policies, as long as the policies meet the criterion of focusing on the reduction of harm as the primary goal.

## The context for harm reduction interventions

Prescription drug use and misuse by injecting drug users has increased in recent years, due at least in part to the decline in availability of heroin from late 2000. The latest data from the Illicit Drug Reporting System (IDRS), which includes surveys with injecting drug users in each Australian state and territory, indicates that a significant proportion had used prescription drugs illicitly over the previous six months (O'Brien et al 2007).

Dr Wodak, Director of Drug and Alcohol Services at St Vincents Hospital, Sydney, and one of the key figures in the establishment of NSPs in Australia, commented on the increasing consumption of prescription opioids:

...[the] consumption of [prescription opioids] has increased considerably in Australia since the beginning of the heroin shortage in 2000–2001, and they are now the third most commonly injected drugs in Australia. Their consumption is rising, whereas consumption of heroin now seems to be falling. Amphetamine has overtaken heroin as the most commonly injected drug in Australia, and these drugs are now third.<sup>881</sup>

Chapter 2.2 provided an example of harm reduction in relation to temazepam capsules, which was effected through the combined strategies of providing information about the risks of injecting temazepam, reducing access through limiting their availability on the Pharmaceutical Benefits Scheme (PBS), and finally, with the cooperation of the pharmaceutical industry, removing them from the market. Importantly, a key feature of the initiative was the focus on implementation across several organisations, engaging the support of professionals, those responsible for the regulatory system and consumer groups. Mr John Ryan from Anex (the Association for Prevention and Harm Reduction Programs Australia Inc) observed:

The reduction in temazepam gel caps is a great success, both with supply control at the prescribing end, combined with a collaborative approach with pharmacists and with health services dealing with drug users on a day-to-day basis, and with the Victorian Drug User Organisation. It was a very good example of a linked up approach, combining all of the

<sup>880</sup> For further discussion as to how harm reduction is conceptualised and defined, see Drugs and Crime Prevention Committee 2002, 2004 and 2006.

<sup>881</sup> Dr Alex Wodak, Director Drug and Alcohol Services, St Vincents Hospital, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 25 June 2007.

elements of the harm minimisation framework, based on the understanding from experience that a supply control methodology only is unlikely to be successful.<sup>882</sup>

Notwithstanding reduction in harms resulting from the withdrawal of temazepam gel caps, there can be unintended consequences as Dr Mark Stooze, Research fellow at Turning Point Alcohol and Drug Centre, explained:

...on the illicit side of the market, you play around with supply restrictions of one type of drug and it generally has a knock-on effect with other types of drugs.<sup>883</sup>

Dr Wodak offered the following cautionary note:

I suppose the underlying theme of what we are saying in terms of both sets of prescription drugs is that people, especially young people, will use mood-altering drugs whatever the community does to try to stop them, and if we stop them using one drug they will often replace that with another drug, and often the replacement drug is even more dangerous than the first drug. That should always be a strong caution to action in this area.<sup>884</sup>

It is within this context that harm reduction interventions play a particularly important role in addressing drug-related harm and ensuring drug users are not pushed into more harmful drug use patterns through drug substitution.

### Specific harms to be targeted

There is a range of harms related to pharmaceutical drug misuse that can be addressed through harm reduction interventions. In a submission to the Inquiry, Anex identified a number of these issues, in particular in relation to the injection of benzodiazepines and other pharmaceuticals that have not been developed for that purpose. This could result in injection site damage, vascular damage and more serious health consequences.<sup>885</sup>

Whilst there are a number of harms associated with injecting any substance including scarring around repeat injection sites, infection from non-sterile injecting practices and the risk of 'dirty hits' among others, the variety and severity of injection-related health problems increases markedly when benzodiazepines and other pills intended for oral use are administered intravenously.

Such harms include scarring and bruising of veins, difficulty finding veins to inject into, infection, abscesses, 'dirty hits', damage to the heart, lungs and capillaries, swelling of hands, arms, legs, blood clots and thrombosis, gangrene and in severe cases – amputation (Breen et al 2004; Dobbin et al 2003).

Injection-related health problems can be associated with the chosen injection-site. For example, there are specific harms associated with injecting into the femoral vein (or groin injection). Anecdotal evidence suggests that this may be a preferred site for particular cultural groups to avoid detection of their drug use.<sup>886</sup>

### Equipment and tools for harm reduction

With regard to vascular and other health problems in particular, Mr Ryan, Anex, outlined how such damage could be prevented through the provision of a better and wider range of harm reduction equipment:

882 Mr John Ryan, Chief Executive Officer, Anex (Association for Prevention and Harm Reduction Programs Australia), Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 20 June 2006.

883 Dr Mark Stooze, Research Fellow, Turning Point Alcohol and Drug Centre, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 9 July 2007.

884 Dr Alex Wodak, Director Drug and Alcohol Services, St Vincents Hospital, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 25 June 2007.

885 See also Chapter 2.2 of this Report.

886 Submission of Anex to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.



There is a limited range [of equipment] and I am sure that, as the role of the Needle and Syringe Program and our understanding of injecting drug use has expanded, the actual range of equipment has not expanded to keep pace with our understanding. For example, there are people using unsterile water for injection because needle and syringe programs do not distribute water free of charge. There are people sharing spoons and other mixing devices because needle and syringe programs are not able to distribute that equipment. There are no filters available, even cotton wool filters, but certainly in relation to the pill injecting there is no pill filter distribution throughout the Victorian Needle and Syringe Program.<sup>887</sup>

Anex stressed to the Committee the importance of providing a range of equipment that could help prevent the harms that can arise from (inappropriately) injecting pharmaceutical drugs. Of particular importance, in Anex's view, is the provision of what are known as 'wheel filters':

Wheel filters (sometimes called pill filters), are the best way to filter any solution. Filtering pills and tablets is a practical way to reduce the number of particles being injected and the associated vascular damage.<sup>888</sup>

Submissions to the Inquiry emphasised that the risks associated with pharmaceutical misuse, particularly the risks associated with injecting drugs such as benzodiazepines and opioid analgesics, provided a strong case to invest in such equipment.<sup>889</sup> However, it was also pointed out that the cost of equipment was sometimes a disincentive for their use and clients need to be educated in the effective use of such equipment.

The Western Region Health Service<sup>890</sup> in a submission to the Inquiry recommended that pill filters be made available to injecting drug users to reduce the well-documented harms of injecting benzodiazepines, narcotic analgesics and other pharmaceutical drugs not intended for intravenous administration.<sup>891</sup>

The Yarra Drug and Health Forum, a broad network of locally based health and welfare agencies, council, local residents, parliamentarians, businesses and traders, police and representatives from education and relevant government departments, recognises that a range of interventions is required to effect a reduction in benzodiazepines and other prescription drug-related harm. In a submission to the Inquiry, the Forum outlined a number of recommendations to address the harms associated with benzodiazepine and

887 Mr John Ryan, Chief Executive Officer, Anex, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 20 June 2006.

888 Submission of Anex to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

889 See Submission of Anex to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006; Submission of Western Region Health Service to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006; Submission of the Yarra Drug and Health Forum to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2007.

890 The Western Region Health Service is an organisation providing a range of health services to the general community in the City of Maribyrnong including a Health Works programme that provides an integrated, multifaceted primary health service for people who inject drugs. 'Community development, harm reduction and a social model of health are the 3 principles which underpin the activities of Health Works. Health Works provides a range of services including:

- safer injecting and vein care education;
- blood borne virus and sexually transmitted infection screening;
- hepatitis C and HIV monitoring and management;
- generalist health care including wound care;
- needle and syringe program;
- education workshops on relevant issues ie blood borne viruses, dental health;
- supported referrals to drug treatment programs;
- assistance with a range of related issues ie legal, housing;
- responding and referring to psycho/social needs' (Submission of Western Region Health Service to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006).

891 Submission of Western Region Health Service to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

narcotic analgesic misuse. The Forum supported the funding of pill filters and also recommended appropriate training for workers in needle and syringe programmes and drug and alcohol services to ensure that these workers are equipped to educate drug users about the adverse effects of benzodiazepine and opioid analgesic misuse/abuse.

### **Harm reduction – enhancing quality of life**

Harm reduction can also address quality of life issues, such as primary healthcare, accommodation, social support and safety. The first submission from Anex indicated that some work is progressing to address the needs of injecting drug users in a holistic manner:

Five primary health services [PHSs] with co-located NSPs have been established as a result of the initial strategy and offer a variety of health services to people who inject drugs. Services such as Living Room in central Melbourne operate from a social model of health to 'promote optimal health and well-being to diverse and marginalised communities in the central business district of Melbourne by incorporating the principles of harm reduction and primary health' (Living Room 2003).<sup>892</sup>

[These services] provide a holistic model of health care and through a range of medical and welfare staff assist in meeting the immediate needs of clients, as well as facilitating access to mainstream services. Through information sharing and involvement in shared care plans with service providers from specialists and generalist services, PHSs also provide continuity of care for clients.<sup>893</sup>

### **Information as harm reduction**

It has become clear throughout the course of the Inquiry that in order to reduce the harms associated with misuse and abuse of benzodiazepines and opioid analgesics a range of harm reduction strategies are required including the development and delivery of targeted information and education.

Calls have been made for the provision of specific information and health education that addresses the risks and harms associated with injecting prescription drugs.<sup>894</sup> NSPs, which record approximately 200,000 contacts with injecting drug users each year, provide a unique opportunity to reach a population with limited access to other health and welfare services and mainstream organisations.<sup>895</sup>

One of the main concerns with regard to benzodiazepines has been users' limited knowledge of overdose risks and in particular the 'half life' of drugs:

Workers have expressed concern that some adverse effects experienced by some drug users relate to the user's lack of knowledge about the length of the 'half life' of some benzodiazepines. Providing workforce development for a range of alcohol and other drug workers would increase the ability of the sector to be responsive to changing drug use patterns and the information needs of the service users.<sup>896</sup>

In response to these issues, some services have developed their own health promotion and education campaigns. The Western Region Health Centre provides information and education to people who misuse these drugs. They identified that a lack of awareness about benzodiazepines was of concern. Issues they specifically identified were:

<sup>892</sup> Submission of Anex to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

<sup>893</sup> Submission of Anex to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2007.

<sup>894</sup> Organisations such as Anex called for specific information to be provided to injecting drug users (IDUs) as part of ongoing health information and education provided through services like Needle and Syringe Programmes.

<sup>895</sup> Submission of Anex to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2007.

<sup>896</sup> Submission of the Yarra Drug and Health Forum to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2007.



- lack of awareness about risk associated with 'benzos' and dependency
- lack of awareness about effects of 'benzos'
- lack of awareness about interactions between 'benzos' and opiates.<sup>897</sup>

The organisation developed a benzodiazepine health promotion campaign to increase users' awareness of the effects of benzodiazepines and ways to reduce the risks and harms.

As part of the campaign, users were engaged in our needle and syringe program for one-on-one education and peer education workshops were held. Health Works recognised the importance of developing and providing this new education workshop to its service users and found within current systems the capacity to employ a worker to write and deliver the workshop. Due to budgetary limitations, Health Works was restricted to the delivery of only 12 workshops throughout the month of March. During this period, 71 Health Works' service users were educated on the harms associated with benzodiazepine use. The following feedback from a participant in one of the workshops highlights the importance of resourcing organisations to provide responsive and quality information sessions to drug users:

*This is the first time I've been in a workshop (in a long time) regarding Benzos which helped me understand it more. And I do feel so much more positive, I'm working towards stopping, say slowing down as much as I can and only use them when I really need them (the prescribed amount).*<sup>898</sup>

Education initiatives undertaken by individual health services have made some progress with regard to users' knowledge of the risks and harms associated with benzodiazepines. It could also be argued that education and information initiatives such as the Temazepam Injection Prevention Initiative<sup>899</sup> may have contributed to improvements in users' knowledge of the risks associated with injecting prescription drugs, in particular benzodiazepines. However, it is difficult to evaluate the effectiveness of these programmes among injecting drug users and many, particularly inexperienced injectors, may remain unaware of the risks associated with prescription drug use. Submissions from several organisations with knowledge of this user group have commented on the need for further education and information that provides clear harm reduction messages.<sup>900</sup>

The evidence provided to the Committee suggests firstly that information and education for intravenous drug users should be framed by a harm reduction approach which aims to reduce the particular harms associated with prescription drug use by injecting drug users.

Clearly there is a need for targeted information and education to be delivered to injecting drug users. Given the particular educational needs of this group, such information and education should be delivered through Victorian NSPs and associated services to ensure that the experience and knowledge of these services informs the development of education. These services should be adequately resourced to deliver such education.

However, developing targeted information and education to users will require service providers to be equipped with the appropriate knowledge and skills. Submissions to this Inquiry recognise that whilst many harm reduction staff are highly skilled in drug and alcohol, there is also a considerable number of staff who may not have the expertise to

897 Submission of Western Region Health Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

898 Submission of the Western Regional Health Service to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs, July 2006.

899 See Chapter 2.2 for detailed discussion of this initiative.

900 See Submission of Anex to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006; Submission of Western Region Health Service to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006; Submission of the Yarra Drug and Health Forum to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2007.

deliver tailored harm reduction services and interventions that address benzodiazepine and pharmaceutical drug misuse.<sup>901</sup>

Organisations that give evidence to this Inquiry have called for improved training and workforce development opportunities for Drug and Alcohol workers including Needle and Syringe Program Staff. Such training would aim to improve knowledge of the harms and contexts of benzodiazepine and other pharmaceutical drug use.<sup>902</sup>

## **Harm reduction: Issues requiring further consideration**

### *A role for industry in harm reduction?*

Much of the discussion in this chapter has necessarily focused on interventions directed towards reducing harms associated with injection of benzodiazepines and opioid analgesics. Drug reformulation also can be seen as a harm reduction measure. For example, in Chapters 4.1 and 5.3 there was discussion of how drug reformulations could reduce the potential for diversion and misuse (although sometimes unintended increases in harms can also arise from such reformulations).

Another example of what could be called harm reduction is the practice of dispensing or administering benzodiazepines and/or other prescription drugs in limited quantities. Such an initiative has been suggested to the Committee from a number of sources including the Turning Point Alcohol and Drug Centre:

An appropriate modality for dispensing benzodiazepines to drug dependent clients is through daily dispensing, which is occurring in increasing numbers. This practice, however, raises a number of concerns related to costs of providing the service. Currently there is no PBS or other government funding source to provide for dispensing costs.

The PBS payment for the prescription is generally for a month's supply, therefore, for pharmacies to dispense in this way they will only receive one dispensing payment for dispensing 30 times on the prescription. Given the social and economic disadvantage of many opiate dependent clients, they are usually unable or unwilling to pay for this service. In addition, PBS regulations preclude surcharging. Many pharmacists dispensing alcohol and drug dependence treatment have advocated for daily dispensing charges to be a PBS-funded service – a model that is also advocated by many with regards to methadone (Muhleisen, 2002).<sup>903</sup>

## **Conclusion**

There are a variety of harm reduction strategies, services and programmes that aim to reduce the harms associated with benzodiazepine and opioid analgesic use, particularly in the context of injecting drug use. Harm reduction strategies should be directed to reduce a variety of risks and harms associated with prescription drug misuse such as overdose risk, vascular damage and other health problems. Targeted education programmes for injecting drug users are required which deliver ongoing health information and education on benzodiazepines and opioid analgesics. Victorian Needle and Syringe Programs should be appropriately resourced to develop and deliver this education.

901 The submission from Anex drew attention to this issue and argued that the limited knowledge of some Needle and Syringe Program workers with regard to benzodiazepines and other prescription drugs was at least in part the result of current resource constraints and the limited opportunities to access workforce development and training.

902 Organisations that have put forward this suggestion include Anex and the Yarra Drug and Health Forum. For further discussion of workforce development and training issues refer to Chapter 6.2.

903 Submission of Turning Point Alcohol and Drug Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006. For further discussion of dispensing options including daily dispensing see Chapter 5.1 of this Report.



The Commission has received a number of reports of misuse/abuse of benzodiazepines and other forms of pharmaceutical drugs in Victoria. These reports have been received from a variety of sources, including health professionals, law enforcement agencies, and the public. The Commission has conducted a thorough investigation into these reports and has identified a number of key issues that need to be addressed.

One of the main issues identified is the over-prescription of benzodiazepines and other forms of pharmaceutical drugs. This is often due to a lack of understanding of the risks associated with these drugs, or a failure to consider alternative treatments. The Commission has found that many health professionals are not adequately trained in the safe use of these drugs, and that there is a need for better education and training.

Another key issue is the misuse/abuse of these drugs by individuals. This can take a number of forms, including taking the drugs in higher doses than prescribed, taking them for longer than intended, or using them in combination with other substances. The Commission has found that this misuse/abuse is often driven by a number of factors, including pain, anxiety, and a desire for a "high".

The Commission has also identified a number of other issues, including the need for better monitoring and surveillance of the use of these drugs, and the need for better support and treatment for individuals who are misusing/abusing these drugs. The Commission has made a number of recommendations to address these issues, including the need for better education and training for health professionals, the need for better monitoring and surveillance, and the need for better support and treatment for individuals.

The Commission believes that these recommendations are essential for addressing the misuse/abuse of benzodiazepines and other forms of pharmaceutical drugs in Victoria. It is the Commission's hope that these recommendations will be implemented, and that the misuse/abuse of these drugs will be reduced.

## Section Seven: Treatment and Management Responses

### 7.1 Treatment Responses to Benzodiazepines and Opioid Analgesic Misuse and Abuse

#### Introduction

Treatment has a complementary and important role in responding to pharmaceutical misuse and dependence.

It is important that treatment approaches are based on sound evidenced based principles to be effective. In Australia the Principles of Effective Treatment developed by the National Institute on Drug Abuse (2000) are widely recognised as being a best practice basis guide for developing optimal treatment interventions. Based on these principles:

- ◆ Treatment must be cost-effective
- ◆ No single treatment will be effective for all individuals. It is important to have a range of modalities with demonstrable effectiveness to facilitate informed client choice of the most effective intervention.
- ◆ Treatment needs to be available and accessible. The more barriers there are to entering treatment, the less likely an individual will be to enter, adhere to, and be retained in treatment.
- ◆ Treatment needs to attend to the multiple needs of the individual. Effective interventions are often those that enhance, or are associated with improvements in, quality of life subsequent to any change in drug taking behaviour.
- ◆ Combined interventions are often the most effective. For example, combining pharmacotherapy with psychosocial counselling strategies and lifestyle supports is often more effective than any single strategy on its own. Treatment needs should be continually monitored and adapted to changing needs
- ◆ Treatment is appropriately matched to the stage of change
- ◆ Co-existing mental health and drug-related problems should be treated in an integrated way. The treatment systems should be designed to respond to the co-



occurring needs of clients who present for either condition<sup>904</sup>

- ◆ Coercion into treatment may help engage in treatment but is not sufficient to ensure good outcomes<sup>905</sup>. Coercion is not a treatment but a means of helping some people get treatment.
- ◆ Relapse is a frequent occurrence in the change process. Treatment strategies need to include recognising relapse risk and integrating responses to prevent and manage relapse.
- ◆ Treatment outcome should be determined along several dimensions. Treatment outcome should not be simplistically determined, for example as failed/successful or using/abstinent.
- ◆ Treatment might need to respond to the needs of 'significant others'<sup>906</sup>

For further discussion of these principles of effective drug treatment and how they may apply to addressing benzodiazepine and opioid dependence, see Drugs and Crime Prevention Committee (2006).

### **What kinds of interventions are appropriate for benzodiazepine and opioid analgesic misuse and abuse?**

According to Dr Benny Monheit, only 194 out of 8,323 people accessing treatment in Victorian Department of Human Services (DHS) funded services in 2006/2007 presented for benzodiazepine treatment.<sup>907</sup> These are a number of general reasons for pharmaceutical misusers not presenting for treatment, such as a lack of specialist services and other geographic and cost barriers. These are explored more fully in Chapter 7.2. However, at an individual level, patients may not consider doctor-prescribed benzodiazepines to be dependence inducing drugs, and therefore do not seek help.

There is little specific evidence about effective interventions for people who misuse and/or are dependent on pharmaceutical medicines. This is particularly the case for benzodiazepine misuse (National Center on Addiction and Substance Abuse (CASA) 2005). In the absence of quality evidence about the treatment of pharmaceutical misuse and dependence, the recommended treatment approach is broadly similar to that of dependence on other drugs (CASA 2005). However, the specific effects of benzodiazepines and the individual needs and circumstances of the misuser need to be taken into consideration for interventions to be appropriately targeted.

904 The issue of 'cross over' between drug dependence and psychiatric illness is an extremely vexed issue that has major implications for effective treatment modalities. In general terms this issue is discussed at length in a number of Drugs and Crime Prevention Committee reports (see in particular Drugs and Crime Prevention Committee 2004, 2006).

In the context of this Inquiry local clinicians have commented upon the failure of both diagnostic and treatment services to adequately address co-morbidity issues. For example, Dr Matthew Frei of the Inter-hospital Liaison Group stated to the Committee at a Public Hearing:

'I think we are recognising that a lot of people are using prescription drugs prescribed inappropriately and in large amounts to treat their own mental illness because they have not had it diagnosed or reined in properly. It is difficult, when people are using drugs in an uncontrolled way and withdrawing a lot when they cannot get them and getting back on them and taking too many, to try to decide if they have a mental illness. It is very hard because they might be in withdrawal and when people are in withdrawal they get agitated and sometimes they can get psychotic. Certainly the so-called personality disorders which are arguably a mental illness – the personality disorder type mental illness – seem to be quite common in a lot of this group; people with very difficult personality types, challenging personality types. But it is very hard with the so-called high-prevalence disorders like anxiety and depression to tease them out from the effects of the drugs. The drugs might be causing depression or withdrawal might be causing anxiety, so it is really difficult. It really clouds the diagnosis for people with two morbidities – with mental illness and drug dependence' (Dr Matthew Frei, Addiction Medicine Physician, Interhospital Liaison Group, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 19 June 2006).

905 The evidence indicates that coercion into treatment may help engage some people in the treatment system (for example, see Wild 2006). Coercion alone, however, is insufficient to ensure therapeutic engagement, adherence and good treatment outcomes. For a discussion of coercion in treatment see Drugs and Crime Prevention Committee 2006.

906 For a discussion of the needs of family members in this context, see later in this chapter.

907 Submission of Dr Benny Monheit to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 2 June 2007.

### *The need for a variety of treatment interventions*

Effective responses are likely to involve a range of interventions, depending on the various needs of the individual. This is illustrated in the following case study provided to the Inquiry by the Interhospital Group.

#### **A case study**

A 59-year-old lady presented to hospital for management of anaemia. She was living alone, at home, having separated from her husband and was estranged from her children. She was unemployed. Over the previous 3 months she had become increasingly short of breath, had reduced exercise tolerance and had multiple episodes of hyperventilation, anxiety and tremulousness. She was found to have a low haemoglobin but when she presented for further investigations, she was found to be too intoxicated with alcohol for a gastroscopy to be performed safely. She had a past history of:

- falls resulting in fractures to her left arm
- suicide attempts by overdose
- social isolation.

She had developed a significant alcohol dependence, which she described as a response to receiving inadequate benzodiazepine dosage. A history of chronic benzodiazepine dependence emerged. She had first been prescribed barbiturates when 14 years of age, in response to symptoms of agoraphobia. Subsequently, she had used benzodiazepines continually, escalating in doses up to 24mg of alprazolam per day (equivalent to 240mg diazepam per day).

When her doses were reduced, she described increasing social dysfunction and limitation of daily activities due to anxiety. She had developed a significant pattern of helpless and hopeless psychological themes and fitted into the diagnostic criteria for borderline personality disorder. There had been multiple instances where clinicians had refused to prescribe her high doses and she had experienced prolonged withdrawals. She described frequenting up to 7 General Practitioners concurrently to gain a supply of benzodiazepines. Her dissatisfaction with treatment and ongoing poor response to medications resulted in her drinking heavily for 4 years. She attended a residential detoxification unit for alcohol dependence but started drinking soon after leaving there.

Her treatment is ongoing but difficult. She was given 3 units of blood and the cause of her anaemia continues to be investigated, with gastroscopy being normal and colonoscopy yet to be performed. There has been a focus on developing an integrated care plan that addresses drug dependence and psycho-social issues concurrently. Limits have been set upon her access to benzodiazepines and dosing is within strict limits (currently 35mg diazepam daily). The first step in reducing benzodiazepine dependence was to change short acting medications like alprazolam to diazepam, so that the actions of the medication do not fluctuate over the day. There is a need to address coping strategies for insomnia and anxiety accompanying benzodiazepine and alcohol withdrawal. Most difficult is the adjustment to a different world view, one which is not continually cushioned by the sedative effects of alcohol or high dose alprazolam.

Outpatient management is complicated by the issue of how best to supply benzodiazepines in a long-term reduction dosing regimen. In her case, supply is by twice-weekly dispensing. However, it is difficult to manage the issue of her returning to accessing medications from multiple prescribers. The current regulatory framework and lack of real-time monitoring of prescriptions contribute to this problem.

...Patients often misreport their consumption of these drugs, and given the variety of sources of benzodiazepines in the community, it can be difficult to assess extent of usage. Benzodiazepine use in conjunction with other substances such as alcohol can make the management of withdrawal difficult. These drugs carry a risk of overdose, particularly when combined with other sedatives. Management of benzodiazepine dependence usually requires long-term and close follow up (often over months) as patients gradually withdraw.<sup>908</sup>

908 Submission of the Interhospital Liaison Group to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.



As this case study illustrates, treatment involves a range of strategies, including case identification and diagnosis, assessment and treatment planning, possibly withdrawal management and counselling, and management of other health problems that are caused by, or are coincidental to, the pharmaceutical drug problems. Sometimes treatments may be provided on an inpatient basis and other times as an outpatient. Some people will benefit from a long-term residential service while others may not. What follows is a brief description of the range of options, some of which will be necessary for all patients and others will be tailored to suit particular needs. It is based on information provided in various treatment literature and clinical guidelines (for example, Hulse, White, & Cape 2002; Jarvis et al 2005; Shand et al 2003; Ward, Mattick & Hall 1998).

### *Identification/screening/diagnosis*

It seems obvious that in order to be provided with effective treatment a person has to be identified as in need. While this may at first instance appear axiomatic, for pharmaceutical medicines such as benzodiazepines and narcotic analgesics this may not always be evident. Patients, and members of the community, do not always consider pharmaceutical use and misuse as potentially leading to drug-related problems and dependence:

One of the issues that we see, particularly in the hospitals and it is reflected in the treatment services, is that it is across all socioeconomic strata. It is not just typical drug users. In fact, they are probably easier to treat. It is the middle-class, middle-age women who come in with benzo abuse and trying to help them see that they have a problem – they usually hang on to, 'But my doctor gave them to me' – that they are in fact addicted, and how you treat them becomes problematic because they are from a different mindset.<sup>909</sup>

Even if such patients do understand they have a problem, they might not consider that they have a 'drug problem' and will resist any such identification, diagnosis or treatment programme. Others will actively disguise their drug use as a means to secure a further supply and, as indicated by a number of submissions to the Inquiry, some become quite skilled in this role.<sup>910</sup> Sometimes a medical practitioner will not see a patient frequently enough to be able to identify a problem:

One of the things to remember is that a particular practitioner may not see the problem, because it may not be captured temporally – they might see a patient for a week and then not see them again – or the patient may be going to multiple doctors and multiple pharmacies. So it can sometimes be very hard to even know that there is an issue. That is where we struggle sometimes when we have managed to reduce someone's dose in an inpatient setting or through ongoing management over a period of months and we do not really know how things are going because there is no way of centrally accessing information that is timely.<sup>911</sup>

Conversely, some medical practitioners do not have the requisite skills or inclination to apply these skills:

[W]e know from research in the drug and alcohol field, not only in this country but elsewhere in the world, that there is a widespread problem with medical practitioners under-recognising or under-diagnosing the condition of drug dependency. It is basically not well known or understood what the reasoning behind that is. Several theories are advanced but no-one fundamentally knows.

909 Ms Ros Burnett, Clinical Nurse Consultant, Interhospital Liaison Group, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 19 June 2006.

910 See for example the submission of Dr Rodger Brough to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006 and submission of the Australian Medical Association to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

911 Dr Frank Giorlando, Addiction Medicine Registrar, Interhospital Liaison Group, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 19 June 2006.

Some people say it may be prejudice; maybe they have not had enough education in the medical course or curriculum. On the other hand, it [the medical school curriculum] is too big and there are too many areas of advancement in medicine to be fitted into the medical course. So doctors are not ideally trained in everything. Sometimes the patients with these conditions are just overwhelmingly difficult for many doctors, and therefore it is simpler just to prescribe or move them on and not formally address the problem. There are all sorts of reasons. But it is a well known and commonplace coalface experience that many doctors do not appear to recognise the problem until too late.<sup>912</sup>

These submissions clearly indicate a need for the implementation of more effective education and training in recognising and treating drug related problems. The comments above from Dr McDonough are consistent with research into barriers to effective management of alcohol problems (Shaw et al 1978), which indicated that not 'raising the issue' of a patient's possible drug dependence could be related to several factors such as:

- ♦ **Role competence:** 'I haven't the skills to identify/diagnose the risks and raise the issue';
- ♦ **Role confidence:** 'I can't raise the issue'. This might be related to confidence in one's own skills, but it may relate to the degree of support that the medical practitioner has. For example, do they have the resources to manage and/or refer the patient if they identify a problem? Is it too difficult to raise the issue if one then cannot readily refer the patient into an accessible and affordable treatment service?; and,
- ♦ **Role legitimacy:** 'It's not part of my job to ask these questions'. While professional organisations have developed and delivered guidelines and training programmes that assert it is a legitimate part of a medical practitioner's role to identify and respond to pharmaceutical misuse,<sup>913</sup> as Dr McDonough has suggested it is possible that not all medical practitioners accept this.

### *Client/patient engagement*

The ability to effectively engage patients is critical during initial contact, and throughout any ensuing intervention. The Youth Substance Abuse Service (YSAS) explained:

The first step in any of our treatments is that engagement process, which means that the outreach worker would spend some time with the young person getting to know them and getting from the young person what their objectives are around a whole bunch of things, including drug use.

[Drawing from] the psychotherapeutic literature, the concept of therapeutic alliance is...the centrepiece of our intervention. We are creating an alliance between a worker and the young person and, through the mechanism of that relationship, create positive interactions and interventions with other options. Some of those options are available within YSAS and some of them are available in other systems. But the worker's job is to make the links and to keep persevering over time, rather than see it as a brief episode.<sup>914</sup>

Effective engagement with a client is important and requires some degree of skill. This should be a feature of any professional education and training. However, successful engagement is unlikely if the clinician does not believe that identification and treatment of pharmaceutical misuse is a part of his or her role, or if (as Dr McDonough suggests) some clinicians are prejudiced against patients who misuse pharmaceutical drugs. Prejudice is inimical to delivering quality treatment and strategies should be developed to counter it.

912 Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 13 July 2006.

913 See Chapter 5.1.

914 Mr David Murray, Chief Executive Officer, Youth Substance Abuse Service, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 20 June 2006.



### ***Assessment and treatment planning***

Assessment can help identify the nature of a drug problem, determine the need for intervention and help plan the nature and course of treatment. Effective assessment will identify the amount and patterns of use (how much, how often and for how long) and consequences of use. It may also involve:

- ◆ Identifying the drug using history
- ◆ What drugs are being used/misused? How much does the person use? For how long have they used? From where do they obtain the drugs?
- ◆ Assessing the consequences of drug use/misuse
- ◆ What problems are they experiencing? Are they dependent? Do they experience withdrawal symptoms? How severe are these symptoms?
- ◆ Assessing the existence of co-occurring problems. These may predate, coincide with or be the consequences of drug use. They might include other physical health problems, legal problems, family and relationship difficulties and mental health problems.
- ◆ Identifying the functions of drug use. For example, is the drug use related to dependence, drug substitution and/or is it related to coping with some trauma or other problems? Is it used to help with problems, which might re-emerge if use is stopped – for example, pain management, anxiety, sleeping disorder – and therefore require specific interventions for these problems?<sup>915</sup>
- ◆ Identifying high-risk situations
- ◆ Are there particular circumstances when the individual is more likely to use or find it particularly difficult to cope without the drugs?
- ◆ Identifying available internal and external resources
- ◆ An individual's resources (or lack of them) will determine the nature and intensity of intervention that is required. Thus, a homeless person will possibly require different interventions compared to someone who has an intact and supportive family.

The above list, drawn from key texts such as Jarvis et al (2005), is not intended to be comprehensive but aims to provide some indication of the nature and functions of assessment.

### ***Withdrawal management***

Withdrawal management is only one aspect of treatment and recovery from substance abuse problems. It is not a stand alone solution and needs to be complemented by intensive follow up therapies to be effective.

Nonetheless, withdrawal management is a particularly important aspect of pharmaceutical drug abuse, particularly benzodiazepine abuse, as 'coming off' these drugs can be a very long and protracted process.

People in rural areas often face the added disadvantages of living long distances from treatment centres and of having very limited treatment options available compared to metropolitan areas.

### ***Benzodiazepines***

Withdrawal from benzodiazepines can involve some health risks, including the risk of seizures from abrupt withdrawal. The original symptoms that prompted the prescription of the medications (such as chronic pain, anxiety or sleep problems) are likely to re-emerge during withdrawal and require management. Ms Gwenda Cannard of TRANX describes benzodiazepine withdrawal:

<sup>915</sup> Ms Gwenda Cannard, TRANX, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 19 June 2006.

The main issue with the benzodiazepines is the dependency. Once people become dependent on these drugs, actually getting off them can be extremely difficult. The withdrawal syndrome is pretty notorious. There are a lot of symptoms that people experience; a lot of physical pain, but also a lot of mental symptoms as well like depression, depersonalisation, which is where the person just does not feel like themselves, loss of balance, dizziness and those sorts of things. It is a very distressing withdrawal syndrome. I think the worst aspect of it is that it can go on for a period of time, so people can be quite unwell for weeks and even months after they have come off the drugs. While withdrawal from other drugs can be quite severe, you know you are going to be feeling okay after about a week or two. So it is something that is important to try to prevent because going through that process can be really difficult.<sup>916</sup>

For some benzodiazepines, the withdrawal process can be protracted, requiring longer clinical management than might be needed for other drugs. Typically, withdrawal from a short acting benzodiazepine is undertaken by replacing it with a long acting benzodiazepine (such as diazepam). This is usually then followed by a series of gradual dosage reductions over a number of weeks or more often months. The patient is given time to adjust to the lowered dose before the next dose reduction occurs. Ideally, counselling for management of sleep, anxiety or other issues that may re emerge should occur. On withdrawal from benzodiazepines, Professor Heather Ashton has written:

It is generally agreed that dosage should be tapered gradually in long-term benzodiazepine users. Abrupt withdrawal, especially from higher doses, can precipitate convulsions, acute psychotic or confusional states and panic reactions. Even with slow withdrawal from smaller doses, psychotic symptoms sometimes appear and anxiety can be severe. The rate of withdrawal should be tailored to the patient's individual needs and should take into account such factors as lifestyle, personality, environmental stresses, reasons for taking benzodiazepines and amount of support available. Various authors suggest optimal times of between 6-8 weeks to a few months for the duration of withdrawal, but for some patients may take a year or more. It has been suggested that very slow rates of withdrawal merely prolong the agony, and that although symptoms may be more severe with more rapid withdrawal, they do not last so long. However, this is an individual matter and in general the best results are achieved if the patient is in control of the rate of withdrawal and proceeds at whatever rate she/he finds tolerable. Occasionally, however, a therapist-controlled withdrawal rate with patient consent is more appropriate (Ashton 2002).<sup>917</sup>

Management of benzodiazepine withdrawal requires some degree of skill and understanding of the withdrawal syndrome. Importantly, traditional drug withdrawal services may not always be specifically geared to meet the needs of those who are dependent on benzodiazepines – either because the patients are not attracted to drug specialist services, services for withdrawal from benzodiazepines alone are very limited,<sup>918</sup> or because of the protracted nature of withdrawal as compared to the experience with other drugs.<sup>919</sup> The current time available for inpatient detoxification may not be sufficient for protracted withdrawal episodes. Conversely the development of specific withdrawal services where longer stays are possible or outpatient support can be provided over a longer

916 Ms Gwenda Cannard, TRANX, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 19 June 2006.

917 Professor Ashton provides detailed guidelines for withdrawing from benzodiazepines. See website [www.benzo.org.au/manual/index.html](http://www.benzo.org.au/manual/index.html)

918 Some respondents to this Inquiry believe there is a sizeable group of people who do not abuse benzodiazepines in association with any other drugs – licit or illicit. Darebin City Council for example argues there is a:

'[g]ap for those who experience medication-related harms who are not illicit drug users, where no services exist' (Submission of Darebin City Council to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006).

919 See for example Ms Ros Burnett, Dr Matthew Frei, and Dr Frank Giorlando, Interhospital Liaison Group, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 19 June 2006.



period may increase the success of these treatment interventions. Benzodiazepine users may be more attracted to a specialised service, or a specialised programme within a current service that can be identified to meet the specific needs of this treatment population.

Dr Matthew Frei pointed out that the current funding of withdrawal for a seven-day withdrawal programme may be insufficient for benzodiazepine withdrawal, and a different way of thinking about pharmaceutical withdrawal may be required:

There are the withdrawal units which are funded for an episode of care by the DHS for seven days. Seven days for a detox or treatment of withdrawal is probably not enough in that setting. You either need to do it in a very intensive setting like in a hospital, not in a detox centre – they are different. [A] hospital has around the clock nursing, very intense – or you do it slowly in the community. The ways to manage it are usually hospital beds – we have some in the Western [Hospital], but otherwise we do not have them – or counselling GPs about how to do it in the community, or [counselling] outpatient services about how to do it in the community.<sup>920</sup>

### **Opiate analgesic withdrawal**

According to Farrell (1994) opiate withdrawal is often described as being subjectively severe, but objectively mild. People who are dependent on opiates may also have changes in pain sensitivity as a result of long-term opioid use. In addition, opioid treatment may have been masking pain for some time, so underlying pain may reappear on opioid cessation. Opiate withdrawal symptoms often include insomnia, anxiety, agitation, abdominal cramps leading to diarrhoea, muscle aches, joint pain, back pain, sweats, hot and cold flushes, runny nose and eyes, yawning, gooseflesh, dilated pupils and opiate cravings.

The duration of withdrawal is governed by variables such as the half-life (time taken for blood level of a drug to reduce by half), dose, frequency of administration and duration of use, patient expectation, and underlying physical and psychological wellbeing. The majority of heroin withdrawal symptoms should abate within the first week to 10 days, but withdrawal from longer half-life opiates such as methadone can take weeks or months.

Opiate withdrawal, unlike alcohol or barbiturate withdrawal, is not generally regarded as life threatening, but is not without risk. In a healthy individual the withdrawal symptoms alone present limited risk, however withdrawal from opiates reduces opiates tolerance rapidly. On completion, the client's opiates tolerance will be much lower than prior to treatment.

Withdrawal from opiates can take place in the same environments as benzodiazepines, and in the case of opioid withdrawal there are a number of pharmacotherapies that can be used to reduce discomfort, in contrast to benzodiazepine withdrawal.

People entering treatment need to be advised that relapse is common, often requiring several attempts to successfully cease opioid use, and that after withdrawal patients are at higher risk of overdose than they were during dependent opioid use.

### **Pharmacotherapies**

Pharmacotherapies (drug treatments) might be used to assist withdrawal or as a maintenance treatment (for example, as is the case with buprenorphine or methadone maintenance treatment), or to help reduce the risk of relapse (for example, naltrexone).

Unfortunately, as mentioned earlier, there is a very poor evidence base regarding the most appropriate pharmacotherapies for benzodiazepine abuse and dependence (CASA 2005). Flumazenil is a potential pharmacotherapy which is still in the early stages of testing for benzodiazepine withdrawal and is discussed in more detail in Chapter 7.2.

920 Dr Matthew Frei, Addiction Medicine Physician, Interhospital Liaison Group, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 19 June 2006.

Most evidence about pharmacotherapies for pharmaceutical misuse refers to opioid dependence. In the treatment of opiate dependence, methadone and buprenorphine (including the buprenorphine-naloxone combination medication) are provided as substitutes for illicit opioids. There are a number of characteristics of opioid substitution treatment with methadone and buprenorphine that help reduce harms associated with illicit opioid use:

- ♦ Non-injecting route of administration – providing an orally active treatment reduces the harms and risks associated with injected opioids
- ♦ Known and controlled dose
- ♦ Long duration of action allowing once or less than once daily dosing
- ♦ Cost-effective.

Opioid substitution treatment also provides a regular stable and legal dose of opioid that prevents withdrawal and reduces the need and craving for illicit opioids. In addition, this treatment gives stability and takes away the need to source and fund illicit opioid use, thereby removing much of the chaos associated with these activities. The stability provided assists the patient to reintegrate into society through work, while reducing harms and significantly reducing the risk of mortality.

With regard to prescribing alternative medications to benzodiazepines, Dr Mike McDonough warns against a current trend toward substituting low dose antidepressants in place of benzodiazepines, noting:

A number of doctors are now prescribing tricyclics in small, non-antidepressant doses; e.g. one or two tablets at night. But what we are beginning to see is some doctors are saying, 'Gosh. Benzos are bad' and if you have one of those patients that presents problems, 'Maybe what I'll do is I won't give them [benzos], and I'll give these drugs instead because they will help you sleep'. Also they are non-addictive, that is kind of true. Antidepressants have not really been shown to be addictive drugs. They are also not 'trafficable' drugs like benzos can be. The doctors are probably right in thinking that, but the problem, again, in a public health sense, is that if a lot of doctors continue to do that and that practice starts to grow, we might be back to where we were with an increased exposure in the population to potentially toxic drugs being used as 'substitute hypnotics'. We know, unfortunately, overdosing behaviour is still going to be with us. It is, again, making available a more potentially toxic drug when a benzo, like it or love it, with all of its incumbent problems is still probably the lesser of two evils.<sup>921</sup>

### ***Alternatives to drug treatment***

There is a range of alternative and complementary therapies, as well as other treatments still in their experimental phases, which may hold some promise for the treatment of benzodiazepine dependence. Some of these treatments are discussed in Chapter 7.2.

### ***Counselling and post-withdrawal support***

After withdrawal management, a variety of counselling treatments may be required, depending on individual need. For example, counselling might be directed to underlying or co-existing disorders such as mental health problems or sleep disorders.<sup>922</sup> It may also involve engaging and retaining the client in treatment to develop informed decision making about drug use, and develop coping skills to help make changes. Some patients might benefit from cognitive-behaviour therapy and/or attendance at community-based support groups (see, for example, CASA 2005).

<sup>921</sup> Dr Mike McDonough, Evidence given to the Drug and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 20 June 2006.

<sup>922</sup> See for example Ms Ros Burnett, Dr Matthew Frei, and Dr Frank Giorlando, Interhospital Liaison Group, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 19 June 2006.



A submission from Darebin City Council has also suggested that community-based support services could play an important role in Victoria:

In one case, the group of women who met as a research discussion group decided to form their own support group, which continues to meet to this day.<sup>923</sup>

As Ashton (1994) notes, the two broad areas to address in withdrawal are gradual dosage reduction and anxiety management, with dosage reduction being the easier of the two components. A combination of medical withdrawal and psychological support is important. Access to counselling will be more feasible given that psychologists services are now covered as a Medicare item. Other co-occurring disorders (such as sleep problems, depression, other drug problems) may also benefit from this combination of medical and psychological support.

### *Relapse prevention*

In addition to pharmacotherapies and alternative medications, counselling strategies to prevent and manage relapse and address lifestyle issues are effective interventions in preventing relapse. David Murray from YSAS states that in relation to young people they see who are dependent on benzodiazepines and narcotic analgesics a similar focus is required:

Very often they do [relapse] and we take the view that [this] is not necessarily evidence of failure. Many young people need to come through our system a number of times, particularly through residential withdrawal. For young people, having access to withdrawal is a place of safety, support and reconsideration. If they needed to use that service a number of times, we would support them in that, rather than say, 'You failed, don't come back'. We would use withdrawal, again, probably a little bit differently to the adult system. It would be about saying to young people, 'This is a place of safety and support for you to come back and reconsider what you're doing', and that might happen a number of times.<sup>924</sup>

Sometimes relapse can be viewed as an inevitable result of the gaps in, and inadequacies of, the treatment service system itself. For example, research conducted on prescription drug abuse in the municipalities of Moreland and Darebin found that:

Few women [interviewed for the research study] had been linked to appropriate services as part of discharge planning. Several women agreed with the comment of one respondent that she had been 'in and out of hospital and never provided with a support service'. One woman who had overdosed on several occasions noted that 'The last time I came out of hospital after a medication overdose I was hooked up with a case manager and finally got the support I needed'.<sup>925</sup>

This was also certainly the view of individuals the Committee met with who had previously been dependent on prescription drugs:

[A lack of follow-up] is one of the huge problems. Right now, if you are in the public system, you get six nights to detox, no matter what the drug; alcohol, heroin, temazepam...

There is no point going onto a waiting list for counselling. How can you go onto a waiting list for counselling? If you need counselling, you need it now. But you cannot go onto a

923 Submission from Darebin City Council, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

924 Mr David Murray, Chief Executive Officer, Youth Substance Abuse Service, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 20 June 2006.

925 Submission of Darebin City Council to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006. As a result of such a lack of follow-up, some women in the Darebin/Moreland area formed their own discussion and social support group that continues to this day.

waiting list until you go into detox. You only have it for six nights. It does not make any sense.<sup>926</sup>

Another person who gave evidence to the Committee commented:

As soon as you come out of detox is probably when the suicide rates are at their highest, I would say. As 'Anne' said, you are on your own, going through hell. You cannot explain to anybody. When you have a very conservative background, in particular, you cannot ring up a family member to say what you are feeling. You cannot express what you are feeling. You just have to go into shutdown for that time.<sup>927</sup>

It is apparent through evidence given to the Committee that follow-up services such as counselling to prevent or manage relapse are an important component of treatment for prescription drug dependency.

### *Sleep hygiene and other sleep techniques*

Insomnia and other sleeping disorders may be a major reason why people use (and abuse) sedative drugs such as benzodiazepines. As such, it is important that information and techniques for addressing sleep problems through non pharmacological means are available.

Information about sleeping better without drugs is available from a number of sources. There is an excellent series produced by the Drug and Alcohol Services of South Australia. TRANX provides advice on methods of addressing anxiety without taking drugs, such as using relaxation techniques. There is also information for Victorians about sleep hygiene on the Better Health Channel.<sup>928</sup>

'Sleep hygiene' is a term used to mean habits that assist in a good night's sleep. The principle is that common sleeping problems are often caused by bad habits reinforced over a long period of time. Sleep can be dramatically improved by making relatively minor adjustments to bedtime habits. Sleep hygiene techniques focus on establishing a routine, becoming more mindful of one's body clock, and establishing healthy lifestyle practices. Other recommendations include making sure the environment is conducive to sleep (eg, a comfortable mattress, ambient room temperature, reduced noise), reducing use of alcohol and other drugs, engaging in regular relaxation exercises.<sup>929</sup>

These strategies are relatively easy to implement and monitor by a health professional. They may provide alternatives to the prescription of medication in the first instance and could be offered as a first line of treatment by medical and other practitioners, using the resources available as support. In addition, they may be useful during the post-withdrawal phase for dependent people to assist in symptom management.

926 'Anne' also told the Committee of her frustrations in seeking advice from drug and alcohol telephone helplines. In her opinion the 'kids' who staffed these services had very little knowledge about benzodiazepines or other prescription drugs. In her view most of the advice offered by these helplines was geared towards 'illicits'. 'Anne', Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 20 June 2006. The name of the person who gave evidence has been changed to protect her anonymity.

927 'Mary', Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 20 June 2006. The name of the person who gave evidence has been changed to protect her anonymity.

928 See: [www.betterhealth.vic.gov.au](http://www.betterhealth.vic.gov.au).

929 The Drug and Alcohol Services of South Australia have produced a number of useful brochures on insomnia management. These include the following topics:

- Sleep Medication
- Bedtime Restriction
- Sleep: Facts and Hygiene
- Relaxation
- Stimulus Control Therapy
- Bright Light Therapy
- Sleep Diary
- Sleep Assessment



### *Assertive follow-up*

One aspect of planning that is increasingly seen as an important part of any treatment regime and which may at least in part assist in relapse prevention is the concept of 'assertive follow-up'. Assertive follow-up has been described as:

the practice of contacting clients of services who may have missed an appointment or not made a follow-up appointment. Assertive follow-up practices are also important to use with potential clients who have been placed on waiting lists and for people who have been assessed by a service and referred to a more appropriate service. These two client groups face a high risk of falling through service gaps.<sup>930</sup>

During the research into prescription drug abuse undertaken in the Melbourne municipalities of Moreland and Darebin, assertive follow-up was overwhelmingly considered a key mechanism that assisted women in recovery. The authors continue:

Assertive follow-up was often the trigger that encouraged women to seek additional support. It was a symbol that these women mattered and that someone was interested in their wellbeing. During information dissemination at the end of the research project, assertive follow-up was raised with a range of services – particularly family violence services – as a simple and effective strategy. The author wonders if this was remembered by any service as an intervention, if it was even heard of in the first place. The overwhelming response from services when assertive follow-up was raised was that the services were already under significant pressure and that assertive follow-up was a luxury that encroached on worker time and resources. Yet emerging technologies are now available that would allow services to send a simple SMS to waitlist clients or as a reminder to those booked for their first appointment.<sup>931</sup>

### *Residential services*

Some people, such as those who are homeless or whose home situation is not conducive to changing harmful drug use (for example, where others in the household are abusing drugs) or who are otherwise enmeshed in harmful drug use, may benefit from residential services. In evidence to the Committee, YSAS elaborated on the residential programme their organisation provides for young people:

We have two small programs. One is called Reconnect, which is specifically designed for working with the young people and their families. Where they are at risk of homelessness because of their drug use, we would be working to try and keep the family intact. The second, which is becoming an increasing issue, is a parents program. We have young women, particularly, in our system who are children still, in a way, and they are having babies. So we have a one-person program focusing on the needs of parents, who tend to be young women, who have children already in our system. That is a difficult, sensitive question.

We are very good at engaging young people. I think that, where there is some type of adult and/or family support and some type of secure and safe environment to live in, we are likely to be more successful than if they have absolutely no family support, no human adult contact or support, and are transient. That tends to be a prescription for it being more difficult to provide an intervention. In our residential rehab program which is more focused on young people who are ready for a defined, intensive four- to six-month treatment process, the key things are: somewhere to live that is safe; then engage in education and/or employment and training; and significant contact with either a family member or supporter or a worker that is providing ongoing mentoring and support. These are the features of more

930 Submission of Darebin City Council to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

931 Submission of Darebin City Council to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

successful interventions. That is consistent with the evidence.<sup>932</sup>

However, access to these services, like all other services, is limited. Residential services in particular have substantial waiting lists:

You are asking about waiting times. Long-term drug treatment, where people live in a supported residential setting or live on a farm or in a therapeutic community, the waiting times for those are very long. They can be several months, which tends to be fairly impractical.<sup>933</sup>

### *Managing chronic pain*

#### **A changing culture of pain treatment**

In Australia in recent years there has been an exponential increase in the prescribing of opioids for both acute and chronic pain management. For example, drawing from Commonwealth data Mr John Galloway, Chief Pharmacist, Tasmanian Department of Health informed the Committee that:

In the 17-year period from 1991 to 2006, it is estimated that national per capita consumption of opioid analgesics (methadone 10mg tablets, morphine and oxycodone combined) increased by a factor of approximately 7. Essentially, this means that there are now approximately 7 times the amount of legally prescribed opioids found in the community on a per capita basis which are potentially available for misuse, abuse and illicit sale.

This combined figure has been calculated using a recognised model ('defined daily doses') and is based on data compiled by the Australian Government. This multiplication factor of 7 may be an under-estimate as it does not include a recently introduced novel drug form (fentanyl patches) which is yet to be included in calculations.<sup>934</sup>

According to some commentators, there are three main and interlinked reasons for this noticeable increase in the use of pain relieving analgesia.<sup>935</sup> Firstly, a new range of opioid analgesics such as OxyContin® has entered the Australian pharmaceutical market since the early 1990s. Secondly, these drugs have increasingly been used in treating *chronic* conditions, such as back pain, whereas previously strong opioid based analgesia may have been reserved for acute pain or pain associated with cancer and other malignant conditions. Thirdly, and related to these points, is a noticeable change in the culture of prescribing opioid analgesia, whereby medical practitioners are far more comfortable in prescribing these drugs than they may once have been. Mr John Galloway describes this change in prescribing culture as follows:

Until approximately 20 years ago, the indications for narcotic analgesics were limited to pain relief in cancer and acute trauma (including surgery). In the late 1980's, a movement commenced in the United States promoted the use of opioids in severe chronic non-cancer pain (such as back pain). This movement gradually spread to many other countries including Australia and coincided with the advent of long-acting forms of morphine and, more recently, oxycodone.

932 Mr David Murray, Chief Executive Officer, Youth Substance Abuse Service, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 20 June 2006.

933 Dr Matthew Frei, Addiction Medicine Physician, Interhospital Liaison Group, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 19 June 2006.

934 Submission of Mr John Galloway, Chief Pharmacist and Ms Mary Sharpe, Deputy Chief Pharmacist, Pharmaceutical Services Branch, Department of Health and Human Services Tasmania, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

935 See, for example, Evidence given to the Drugs and Crime Prevention Committee from: Mr John Galloway, Pharmaceutical Services Branch, Department of Health and Human Services Tasmania, 18 June 2007.

Professor Jason White, University of Adelaide/Drugs and Alcohol Services South Australia, 18 May 2007.

Dr Alex Wodak, Director, Drug and Alcohol Service, St Vincent's Hospital, Sydney, Public Hearing, Melbourne, 25 June 2007.

Dr Malcolm Hogg, Australian Pain Society/Australian and New Zealand College of Anaesthetists, Public Hearing, Melbourne, 26 June 2007.



Current clinical guidelines issued by expert medical bodies support and encourage the use of opioids in non-cancer pain and this is the major reason why per-capita consumption has increased so rapidly. The guidelines essentially reflect mainstream medical wisdom on the subject.

Where opioids were used only for cancer and trauma pain in the past, the treatment required was only for a short period. However, it is important to note that the cohort of chronic pain patients is a steadily growing pool and many patients are prescribed opioids over long periods. This results in a steadily growing total quantity of opioids being distributed in the community, a proportion of which is liable to diversion and misuse.<sup>936</sup>

Similar observations were made to the Committee by Dr Mike Tedeschi, a drug and alcohol clinician practising at the Canberra Hospital:

In terms of the opiates we're talking about, the problem is that the culture of prescribing these drugs has changed...when I graduated from medicine, opiates were used basically as a drug when you had a broken arm or you had cancer. They weren't used in neck pain, chronic undefined pain, non-malignant pain, migraine, or back pain...

The culture changed in the early 90s coinciding with the release of the long acting compounds and these were promoted to the medical profession. Now it was suddenly acceptable from the early 90s to prescribe opiates for non-malignant pain...<sup>937</sup>

According to Dr Tedeschi this culture is reinforced by the promotion of these drugs as appropriate for pain relief. Pharmaceutical companies and the medical establishment promote these drugs through professional journals, symposia and conferences.<sup>938</sup>

Clinicians are divided as to the efficacy of using strong (opioid) analgesia for the relief of chronic conditions. The practice clearly has its supporters. For example, Mr Geoff Anderson, Chief Pharmacist of the South Australian Drugs of Dependence Unit stated to the Committee that:

There was a large increase in the use of narcotics for pain in the early 1990s when the slow-release morphine products first came on the market, and that changed the way basic chronic pain was treated...[Despite this] a major problem is the under treatment of chronic pain – it is estimated that something like one in five of the population experience chronic pain at some time in their lives, so it is a very common condition. By 'chronic pain' I mean pain that continues for more than three to six months, and that is a different type of pain; people respond differently to acute pain which comes and goes quickly.

Chronic pain is very common and...most general practitioners do not appreciate that and it is under treated, and that results in a lot of unnecessary misery. Therefore the increase in narcotics generally [to treat chronic pain] has been a good move medically.<sup>939</sup>

936 Submission of Mr John Galloway, Chief Pharmacist and Ms Mary Sharpe, Deputy Chief Pharmacist, Pharmaceutical Services Branch, Department of Health and Human Services Tasmania, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

937 Dr Mike Tedeschi, Canberra Hospital/ANU Medical School, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Canberra, 16 May 2007.

938 Dr Mike Tedeschi, Canberra Hospital/ANU Medical School, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Canberra, 16 May 2007. Similar comments were made by Dr Malcolm Hogg, a pain specialist at the Royal Melbourne Hospital:

'What has happened is that as the morphine has plateaued off, OxyContin and oxycodone have taken off. That is possibly a pharmaceutical company issue. They are promoting it. They are in the marketplace. We are possibly the highest consumers of oxycodone in the world, per capita' (Dr Malcolm Hogg, Australian Pain Society, and Australian and New Zealand College of Anaesthetists, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 26 June 2007.

939 Mr Geoff Anderson, Chief Pharmacist, Drugs of Dependence Unit, South Australia Health, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Adelaide, 18 May 2007.

However, as discussed in Chapter 2.2, concerns have been expressed that medium- to long-term use of opioids can lead to dependency. In addition, as indicated in Mr Galloway's quote above, the more common the practice of prescribing opioids becomes, the greater the risk of those drugs being diverted for illicit purposes, including recreational drug abuse. Whilst Mr Geoff Anderson generally supports the controlled use of narcotics to treat chronic pain, he acknowledges that 'the more drugs you have in a community, the more risk there is of misuse and diversion'.<sup>940</sup>

Whilst the treatment of chronic pain is complex, and there are undoubtedly justifiable and reasonable concerns about the risk of dependence associated with prescribing of opioids for long periods of time, there is a strong body of opinion that supports controlled use of opioids for chronic pain. One of the tensions around control of pharmaceuticals is balancing effective regulation of supply and prevention of harm in the few that misuse these medications, while making the treatment sufficiently available to the majority of those that have a genuine need, particularly in the case of malignant pain. In his book on management of cancer pain (2003) Roger Woodruff states:

Even if it is anticipated that pain will be relieved by other means, opioid analgesia should not be withheld because of any concerns related to psychological dependence, although patients with a history of drug abuse should be managed carefully (Woodruff 2003 p.37).<sup>941</sup>

Whilst clearly the treatment of cancer pain is of a different level than non-malignant chronic pain, even in the latter case the American Pain Foundation believes that generally opioids for pain are under-utilised and the balance between law enforcement and patient need must be carefully weighed.<sup>942</sup>

Nonetheless, it may be that the pendulum has started to swing back from a too cavalier attitude to the prescribing of opioids for chronic pain relief. For example, not all American specialists necessarily endorse the views of the American Pain Foundation as to the under-utilisation of opioids:

Some concerns are emerging amongst clinicians. Dr Russell Portenoy, Head of Beth Israel Medical Centre's Pain Medicine facility in New York and [originally] a leader in the promotion of opioids for chronic pain, said in a 2004 interview that the way doctors had been taught to prescribe opioids was 'a big error' and that 'doctors have to have two sets of skills to use these drugs safely and effectively, or they should not use them'. Those skills are pain management and addiction medicine skills.<sup>943</sup>

940 Mr Geoff Anderson, Chief Pharmacist, Drugs of Dependence Unit, South Australia Health, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Adelaide, 18 May 2007.

941 One of the reasons clinicians, particularly general practitioners, may (sometimes against their better judgement) be unwilling to prescribe opioids to relieve pain is their fear that their prescribing practices will be unfairly scrutinised by health bureaucracies. This fear, termed opiaphobia in the United States, is particularly common in jurisdictions that have stringent prescription monitoring programmes. For a discussion of opiaphobia and the reluctance to prescribe pain relief in the context of prescription monitoring systems, see the discussion in Chapter 4.1.

A comment by Fishman et al quoted in that chapter is worth repeating in this context:

'These contradictions [between 'promoting' drug abuse and treating 'genuine' pain] can lead to the conclusion that the war on drugs is directly in opposition to the war on pain. This conflict has resulted in a variety of regulations that are intended to prevent drug abuse, but have inadvertently created barriers to the appropriate treatment of pain. This does not conform to the philosophy of national and international policies recognising that efforts to control abuse and diversion of pain medications must not interfere with their availability for legitimate medical purposes...Although physicians are encouraged to prescribe opioids to treat pain when they are the best treatment choice, they are largely hesitant to prescribe opioids, because they believe that doing so places them at risk for unwarranted regulatory oversight' (Fishman et al 2004, pp.309-311).

As noted in Chapter 4.1, to a lesser extent a similar reluctance on the part of doctors to prescribe opioids due to fear of bureaucratic intervention has been noted in Australia

942 Mr John Giglio, Executive Director, American Pain Foundation, in Testimony by the American Pain Foundation to the Senate Health, Education, Labor and Pensions Committee Hearing to Examine the Effects of the Painkiller OxyContin®, Focusing on Risks and Benefits, 12 February 2002.

943 Submission of Mr John Galloway, Chief Pharmacist and Ms Mary Sharpe, Deputy Chief Pharmacist, Pharmaceutical Services Branch, Department of Health and Human Services Tasmania, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.



According to Dr Portenoy and other specialists, it is not the use of opioids per se for pain relief that is inappropriate. Rather the issue is: Who should prescribe and administer these drugs and what level of training is required for them to do so? The issue of the level of expertise required for treating pain and the need for specialist interventions and clinics in this area are discussed later in this chapter.

### **Other interventions for chronic (non-malignant) pain**

It has been estimated that 20 per cent of the population experience chronic or persistent pain at any one time (Nicholas et al 2002). Chronic pain is pain that persists for longer than expected. It can be related to either tissue damage or injury to the nerves. In some instances chronic pain related to injury of the nerves (neuromathic pain) can result in a change in the nerves that results in persistent pain after the healing of the original injury.

Once pain has become chronic it is likely that the underlying physical problem will have become much more complicated than it was originally. Accordingly, a straightforward solution is unlikely. If a chronic pain problem has been extensively investigated and treated without success, it is likely that no cure is available at the present (Nicholas et al 2002).

Nicholas et al (2002) note that pain relieving medication in the treatment of chronic pain may not be appropriate, as the tolerance to the drugs combined with the possible side effects may actually lead to increased suffering. There are a number of pharmacological approaches to chronic pain other than narcotic analgesics. These may include non-narcotic analgesics, anti-inflammatory drugs, antidepressants, anticonvulsants and steroids. However, the place for non-drug therapies should not be underestimated, and the goal of removal of all pain is often unrealistic. As such, focusing on quality of life and ability to do daily tasks can be a more helpful way to define successful management of chronic pain. Other health professionals such as psychologists also play an important role in the assessment and management of chronic pain. This is exemplified in a position statement of the Australian Pain Society:

The experience of pain is not a purely physical phenomenon. Psychological factors play a significant role in each person's pain experience. The combination of cognitive, behavioral, emotional and physiological factors determine the individual's experience of pain, resulting in each person experiencing a unique response. Treatment of patients with persistent pain by a psychologist may include, but is not confined to, cognitive-behavioral treatment and teaching management strategies. Best practice is for patients with persistent pain to be managed within a multidisciplinary setting (Australian Pain Society 2002, pp.5-6).

Dr Tedeschi has made similar comments, as outlined in the following quote:

The treatment of chronic pain is a complex multidisciplinary effort. Most patients will benefit from an opinion from a pain clinic, and some will need drug and alcohol intervention. Non-opioid analgesia needs to be thoroughly explored before embarking on opioid medication. A 'step wise' approach will usually see the use of less potent and less potentially problematic medications such as tramadol tried at some point before a decision to initiate opioids. The World Health Organization ladder of analgesia is the most useful guide to progression of potency. The decision to commence a trial of opioids should not be taken lightly. The patient needs to be fully informed that opioids will inevitably cause physical dependence to some degree (not be confused with addiction or 'dependent behaviour'). It is a good idea to put the agreement in the form of a short 'contract' between the patient and the prescriber. It is important to stress to the patient that the commencement of use will be on a trial basis, and that if the trial is deemed successful, prescribing will continue. If the trial does not succeed, the drug will be increased depending on response. A common starting dose might be 10–20 mg of long acting morphine twice per day or 10–15 mg twice per day of long acting oxycodone. This may then be slowly increased depending on response. It is the author's experience that if good analgesia and improvement in function does not occur at moderate doses an increase to higher doses is unlikely to be of benefit. The opioid chosen should be a long acting oral agent. In chronic, non-malignant pain, there are few indications for short

acting opioids, and almost never an indication for parenteral opioids. ...Prescribing of the opioid should always be by the one practitioner, usually the patient's GP. Many patients find control of opioids difficult, and situations where the patient takes extra medication resulting in 'running out of medication early' are common. If a patient gets into this situation, the frequency of pharmacy pick up needs to be increased until control of the medication is regained. The prescribing practitioner needs to ensure that they abide by local regulations regarding gaining and regularly maintaining approval for ongoing S8 prescribing (Tedeschi 2006, p.510).

Other strategies suggested by Dr Tedeschi include the use of contracts at the outset of treatment such as that seen in Table 7.1a. Such contracts explain expectations regarding seeking medication from other prescribers and the duration of medication prescribing.

**Figure 7.1a: Sample opioid contract**

Contract between \_\_\_\_\_ and \_\_\_\_\_  
 I (patient) hereby agree to the commencement of a trial of (drug) for the treatment of my medical condition. I agree that all prescribing will be done by (doctor's name) and that I will let Dr \_\_\_\_\_ know of any other medication I am receiving from any other sources. I agree that I will be dispensed and use the medication in accordance with my prescribing doctor. I am aware that the use of opioid medication is associated with a risk of physical and/or psychological dependence. The use of this medication will initially be for a period of \_\_\_\_\_ weeks. At the end of that period, I and Dr \_\_\_\_\_ will make a decision as to whether the medication has been useful. The aims of the medication in my situation are:  
 1)  
 2)  
 3)  
 If it is thought that the medication has not been useful in my particular condition, I agree that Dr \_\_\_\_\_ will gradually reduce and cease the medication in a manner that will cause minimal discomfort to me. I also agree that if I am not compliant with any of the conditions of this contract, Dr \_\_\_\_\_ may make the decision to cease this trial of medication. I agree that the decision to cease or continue this trial always remains at the discretion of the prescribing doctor

Source: Tedeschi 2006, p.511.

Other non-pharmacological treatments for pain relief are discussed in Chapter 7.2.

### **Generalists and specialists: The need for advanced training and the role of the pain clinic**

Some commentators have argued that both the pharmacological and non-pharmacological treatment of pain should for the most part be the province of clinicians specially trained in that field. For example, according to Mr John Galloway, through no fault of their own, general practitioners simply are not equipped to deal with the complexities associated with ongoing and chronic pain conditions. Often the financial and structural constraints of general practice may mean that the doctor has few options other than the prescription of pain relieving medications:

One of the issues, when it comes to GPs in regard to this problem, is that anxiety, chronic pain, withdrawal issues are chronic conditions. A 10-minute session with a GP is not going to touch the surface of a problem like that. People cannot be managed on this particular medical model and really improve. All doctors really are left with is, 'What do I do now?' There is not a practical strategy in withdrawing people, other than to say no, and the patient moves on to another doctor. A lot of doctors feel very unhappy about all this because the doctors set out to do good but they eventually end up doing harm with these particular drugs. I guess all of us in the health system feel very uncomfortable about this.<sup>944</sup>

944 Submission of Mr John Galloway and Ms Mary Sharpe, Pharmaceutical Services Branch, Department of Health and Human Services Tasmania, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.



A number of submissions to this Inquiry have stated that whilst malignant and non-malignant chronic pain should be treated by pain specialists, there are far too few pain medicine or pain management clinics in Australia to meet the demand. In this regard the Committee received a comprehensive presentation from Dr Malcolm Hogg, a pain medicine specialist from the Royal Melbourne Hospital.<sup>945</sup> Dr Hogg stated that the situation had definitely improved since his medical training. For example, pain medicine through the Australian and New Zealand College of Anaesthetists is now recognised and reimbursed by the Commonwealth as a specialist medical field. It is also encouraging that the Victorian Faculty of Pain Medicine and the College of Anaesthetists have been encouraged to conduct some training in pain medicine for students, interns and residents at the Royal Melbourne Hospital. Nonetheless, in Dr Hogg's view there is still a severe paucity of both specialist clinics and specialist training facilities, particularly in Victoria.

The problem according to Dr Hogg arises when a patient suffering from pain is discharged from hospitals or clinics, where he or she may have been receiving specialist treatment, into the general community where few generalist health professionals have had the training to adequately monitor and treat the patient's condition:

I work in a big hospital so we do acute [pain] and we have chronic rehabilitation. A lot of hospitals do not have that. Acute pain is really that episode after the initial injury. Opioids are standard therapy, well accepted, good evidence, but we discharge them [the patients] to GPs in the community. We do not know what happens thereafter. There is a shortage [of information] in that persistent to chronic stage; we do not know enough about what happens there. We have a chronic pain clinic which there is generally fairly limited access to and which deals with patients for that three-six month period. There is this group in the middle who get opioids or remain on opioids when they should be coming off opioids.<sup>946</sup>

Dr Hogg explained to the Committee that general practitioners without specialist training in pain relief are essentially 'treading water'. Echoing the views of Dr Tedeschi, he remarked that the constraints on general practice result in health professionals not being able to undertake further training or allocate time to the most appropriate treatment services:

I think the idea of 'I want to give a five-year plan to this patient, or a one-year plan, and we are going to work over 10 visits', I do not think that comes about. It is crisis management or keeping them the same; they [general practitioners] are not challenging them and giving them a medium to long-term plan.

It worries me about just sending patients out of the hospital on opioids. We specialists have started them [on pain relief drugs] expecting the GP to drop them down. It does not get dropped down, and the GP just keeps prescribing them, saying, 'Oh well, if you have still got pain, we'll stop it'. He or she is not going to challenge them. He is not going to push them into rehab. He or she is not going to push them back to the specialist to say, 'Let's get them off it'.

What happens to the patient we start on opioids, and how do they go? Which ones should we not be prescribing or prescribing with more care? We need guidelines...and I think we then need further GP education. We need some unified processes across the state boundaries and possibly across Victoria. There is great inconsistency about access and management...And I think there needs to be a DHS policy framework for the provision of pain services. What is a pain service, what is a tertiary service, what is a community service? What should be part of it? Not just opioids or medication. There should be the psychological support, drug and alcohol liaison, psychiatry liaison...There is a role for opioids. Significant

945 Dr Hogg is also a member of the Australian Pain Society and the Australian and New Zealand College of Anaesthetists and gave evidence on behalf of both these bodies.

946 Dr Malcolm Hogg, Australian Pain Society and Australian and New Zealand College of Anaesthetists, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 26 June 2007.



numbers are maintained on opioids, and that is fine, but the doses and the prescription numbers are going up, and we are seeing it clinically as a problem.<sup>947</sup>

Dr Hogg explained to the Committee that whilst treating pain should in most cases be the responsibility of a person with specialist skills in pain medicine this did not necessarily mean that that person had to be a medical consultant. Increasingly health professionals from nurses to physiotherapists are receiving training in this specialist area. This is exemplified by the work of the Australian Pain Society, a member organisation of the International Association for the Study of Pain. This multidisciplinary body is comprised inter alia of doctors, nurses, physiotherapists and occupational therapists. It promotes both pharmacological and non-pharmacological treatments for the alleviation of pain.

In particular, Dr Hogg believes that in areas where medical facilities and personnel, particularly doctors, are relatively few, such as rural areas, the use of nurses and nurse practitioners with pain management skills can be highly beneficial:

We have looked at a number of strategies for our services...We have looked at doing a nurse-only clinic, and we have a trainee nurse with a view to her becoming a nurse practitioner, whereby that person sees them, goes over, issues and then calls the doctor in to say, 'I want you to check this'. That is what they are doing now in northern New South Wales with the Hunter Integrated Pain Service, where they have a screening process where they come in and see nursing staff and they get clicked in before they get the medical staff. They are improving their delivery of services.<sup>948</sup>

Ultimately Dr Hogg believes there needs to be a two-tiered process for dealing with pain management in this state. If he had a wish list it would involve a system similar to that in South Australia<sup>949</sup> whereby:

We give the GPs enough skills to improve their [basic pain] management. They then refer the ones who are high-risk, psychologically vulnerable, have previous drug-abuse issues or use high doses. They are the ones who [should] come to the pain clinic.<sup>950</sup>

Mr John Galloway made similar recommendations:

Essentially, it is [our] view that the issue is not that doctors should not prescribe these [opioid] drugs but that they need to have the skills and training to appropriately select those patients who can be treated safely and effectively and who are very unlikely not to sell or misuse their drugs. There is also an urgent need for more accessible specialist pain clinics to assess these patients before opioid treatment commences. There is also an urgent need for more comprehensive and accessible drug dependency services as many patients are

947 Dr Malcolm Hogg, Australian Pain Society and Australian and New Zealand College of Anaesthetists, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 26 June 2007.

948 Dr Malcolm Hogg, Australian Pain Society, and Australian and New Zealand College of Anaesthetists, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 26 June 2007.

949 Dr Hogg is referring to a recent document produced by Drug and Alcohol Services of South Australia entitled Chronic Pain Treatment; Guidelines for the Prescribing of Opioids. This document, primarily aimed at general practitioners, gives a comprehensive guide to best practice in prescribing opioids for pain relief. Dr Hogg summarised the approach in South Australia as follows:

'South Australian guidelines promote dose stratification. [They state that] if you have got someone on opioids, you have got a low dose and they are functioning well, you can supervise it under federal authority, and you be will given a permit [to prescribe]. But if your patients are escalating the doses or they are on very high doses...all those patients should be referred to the major pain clinics in South Australia. They get referred to the pain clinics to rationalise and justify [the opioid treatment]. In some patients it might be justified, but it means doing blood levels, it means having a specialist opinion and having a second opinion that is linked in with the drugs and poisons unit in South Australia, rather than allowing GPs to just keep prescribing, just pushing the dose up.'

It is Dr Hogg's understanding that Human Services Victoria will be producing a set of guidelines based on this model in the near future (Dr Malcolm Hogg, Australian Pain Society, and Australian and New Zealand College of Anaesthetists, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 26 June 2007).

950 Dr Malcolm Hogg, Australian Pain Society, and Australian and New Zealand College of Anaesthetists, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 26 June 2007.



currently being prescribed opioids nominally for a pain condition whereas ideally they should be managed by an expert drug dependency clinic.<sup>951</sup>

The Committee was impressed with the views of Dr Hogg and other witnesses who gave evidence to the Committee on the problems associated with effective pain management. At the very least this Committee believes further resources should be provided to establish additional specialised treatment services for pain management in this state. It is also essential in the Committee's view that general health practitioners who are treating patients for the relief of chronic pain be encouraged to engage in ongoing training for pain management and pain treatment. The issue of ongoing education more broadly is discussed further in Chapter 6.2 of this Report.

### ***Managing patients who have obtained their drugs through 'doctor shopping'***

Managing patients who have obtained their drugs through 'doctor shopping' requires tailored interventions. For example, providing withdrawal management and counselling will have limited value if the person continues to obtain medication from another source. Dr Mike McDonough described the challenges of managing such patients and suggested some strategies:

...I think a treatment plan is absolutely essential. Unfortunately, seeing some of the cases where things did go wrong, I cannot remember ever seeing a case where the doctors involved kept notes that indicated there was a treatment plan, and it is probably the most important and most commonly overlooked aspect of the care of these patients. These are, again, benzodiazepine-dependent patients who sometimes use multiple doctors or doctor shop and get into problems with the way they take these medications.

The treatment plan should always involve one doctor and one pharmacist – that is, one dispensing point – and ideally one or other pharmacies working around the clock or working different days, getting to know the patient and picking up on some days where the patient does not look well. [In such cases] they may choose not to dispense until the patient has been sent down to the GP. Something like that is a regularly used technique in the management of patients on a methadone program, but it is probably not that familiar to many GPs. So it is just an additional form of monitoring – checks and balances.<sup>952</sup>

The 'one doctor – one pharmacist'<sup>953</sup> approach to treatment has been utilised in international treatment settings.<sup>954</sup> Contracts such as shown in Table 7.1a are a suggested strategy to gain agreement about not seeking medications from other prescribers, with the onus being on the patient to comply with the contract.

Dr McDonough also suggested there was a need for a permit system to obtain certain drugs, similar to that used for Schedule 8 drugs. He argued that such a system is an additional 'check and balance' in the system, whereby before a permit is granted a treatment plan must be evident. He spoke also of the need to ensure that proper coordination of patient care occurred to reduce the likelihood of a patient receiving medications from more than one doctor.

If we had a permit system whereby a patient was going to be treated with these tranquillisers – [such as] the benzodiazepines – for an extended period of time, a permit, I believe, would

951 Submission of Mr John Galloway, Chief Pharmacist and Ms Mary Sharpe, Deputy Chief Pharmacist, Pharmaceutical Services Branch, Department of Health and Human Services Tasmania, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

952 Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 13 July 2006.

953 Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 13 July 2006.

954 Mr Bob Nakagawa, Assistant Deputy Minister, British Columbia Ministry of Health, Meeting with the Drugs and Crime Prevention Committee, Vancouver, 23 July 2007. Mr Nakagawa described a system to reduce 'multidoctoring' where restrictions can be placed on a patient to ensure they see only a specific prescriber and pharmacy.

be helpful. That would, as I have said previously, identify that this doctor is taking over the treatment, is attempting to be the one and only doctor...If another doctor sees that patient unbeknownst to the primary treating doctor holding the permit, it is the professional responsibility of all other doctors to make sure that someone else is not prescribing, because if they prescribe when someone else has a permit, they are in breach of the regulation.<sup>955</sup>

In addition to proposing a permit system, Dr McDonough also discussed the merits of a peer review system:

I think a better system would be to have a medical review panel where requests for permits or requests for continued prescribing long term of these potentially hazardous drugs is reviewed. Sometimes that may not be recommended and permits to treat may not be granted. Instead, the department may require that particular doctor to refer to a specialist agency for an intervention and reconsider the permit for that treatment later...The regulation requires that the permit is requested before the other one expires, so even if the permit is about to expire, the department generally allows extension if there are reasonable circumstances, such as that there is a need to continue treatment because the peer review panel, let us say, does not meet for another month. Currently what happens if a permit runs out is that the doctor rings up and says, 'I have so-and-so in a lot of pain. I cannot stop their morphine. I will need the permit to continue because the patient cannot get in to see the pain clinic for another six weeks'. So then instead of the permit being issued for three, six or even twelve months, it is issued for six or seven weeks, pending the outcome of further advice from the pain management clinic.<sup>956</sup>

In evidence to the Committee, a woman who was a 'doctor shopper' indicated that notification from the Health Department alone was not likely to result in a change of behaviour. She explained:

While the Health Commission seems to concentrate mainly on quantity of scripts dispensed, the problem of addiction somehow fails to be addressed – the addict receives a threatening letter stating that they may be charged & jailed or fined, if current behaviour continues. This in itself is humiliating and can lead to anger and further self-destruction.<sup>957</sup>

The need for *therapeutic* rather than merely *punitive* interventions to address 'doctor shopping' was highlighted by this submission. Due to the potential risks and the severe discomfort associated with abrupt medication withdrawal, the sudden cessation of medication should be avoided where possible. Care also needs to be taken to avoid alienating clients who are making a genuine attempt to seek treatment. A suggested strategy for managing potential doctor shoppers where further information is not immediately available is to provide a limited supply given on daily collection from a specified pharmacy for a short duration until a follow-up consultation and further information can be gathered and an appropriate treatment plan developed. If the client wants treatment, a suggested treatment plan for 'doctor shoppers', based on Turning Point Alcohol and Drug Centre's guidelines, is described below:

- ◆ Inform the client that medications provided are on the condition that they are not accessed elsewhere. If additional medications are being used, the treatment plan will be reviewed
- ◆ A treatment contract may need to be considered with clients who are at risk (or thought to be at risk) of continuing their abuse of prescribed medications (see Table 7.1a above)

955 Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 13 July 2006.

956 Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 13 July 2006.

957 Submission of 'Mary' and 'Anne' to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 22 April 2006.



- ◆ Limit the client's access to large quantities of medication, particularly if there are concerns regarding their ability to control intake. This can be achieved by a daily or every second day pick-up arranged at the outset of the programme, or having a parent/partner supervise the medication
- ◆ Medication should not be dispensed if the client presents in an intoxicated state
- ◆ Frequent review (at least weekly initially)
- ◆ Urine drug screens to identify additional drug use
- ◆ Treatment contract may require a letter to be sent to previous prescribers
- ◆ Treatment contract may include signing a Health Insurance Commission Privacy Release form (Murray et al 2002).

In the management of benzodiazepine dependent patients one strategy is the use of a verbal or written contract in which the patient agrees not to seek benzodiazepines from other prescribers, as in the opioid contract shown in Table 7.1a above. The patient is also required to submit the names of previous prescribers so that they can be contacted and advised of the contract. Currently only retrospective prescription data can indicate if the contract has been broken, and no way exists for other prescribers to be aware such a treatment plan exists. In smaller geographical areas one successful strategy is the circulation of a list of those that have agreed to be on a contract, which is supplied monthly to every doctor and pharmacy in the area.<sup>958</sup> Such a system adds significant control over benzodiazepine supply for patients in treatment.

### **What treatment services are available to respond to pharmaceutical misuse?**

There is a wide range of specialist drug services available in Victoria. Some of these are drug specialist services that respond to people who use prescription drugs in combination with other drugs (for example alcohol or illegal drugs). Some services may also see clients who are solely misusing pharmaceutical medications. Some individuals will not want to use drug specialist services, instead they may prefer to use more generalist services, such as a GP, a community-based service or be treated in a hospital. This may be particularly the case, as was discussed in Chapter 2.3, if the person does not perceive themselves as having a 'drug problem'.

TRANX<sup>959</sup> is an example of a service that specialises in responding to people who are dependent on prescription drugs, particularly benzodiazepines. TRANX provides education and training to professionals, and access to counselling and support. It also develops resources that help people cope with co-occurring problems, such as sleep disorders:

TRANX continues to provide a small counselling service and provides education & training activities to health practitioners working in alcohol & drug treatment, community health, and other related services to enable people with benzodiazepine dependency to access services close to home.

Information and education is also provided to a wide range of health practitioners, including doctors, nurses and aged care practitioners to encourage safe use and prescribing of the benzodiazepines. Sessions focus on safe use principles and alternatives to benzodiazepine use for anxiety disorders and sleep problems.

Sessions are also provided to members of the community on alternatives to benzodiazepines for anxiety and sleep problems. Community information sessions have focussed on women from culturally diverse backgrounds, seniors (including from culturally diverse backgrounds) and general sessions on anxiety and sleep management...

<sup>958</sup> Dr Mike Tedeschi, Canberra Hospital/ANU Medical School, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Canberra, 16 May 2007.

<sup>959</sup> As stated throughout this Report, the organisation known as TRANX is now known as ReConnexion.

TRANX has developed a number of resources:

- Relaxation CD/tape
- The Better Sleep Book
- 'Benzos- what do you want to know?' – information sheet for young people
- 'Pain relievers – what you should know' card
- Safe use of tranquillisers and sleeping pills information sheet in 17 community languages.

The primary target group for TRANX counselling has been for people using low, prescribed doses of benzodiazepines...Existing service users of Health Works wanting to do something about their benzodiazepine use are linked in with the GP at Health Works. The GP, Community Health Nurses and the Community Health Workers then work with the service user to develop a treatment plan. Treatment plans are based on goals self-determined by service users, as it is essential that they are making the decision about whether or not to reduce and when to reduce. In some cases the best outcome in the short term may be to stabilise the person and have them agree to only get their scripts from one doctor. Management of the dosage by one doctor lowers many of the risks associated with benzodiazepine use. Community Health Nurses and Community Health Workers are also able to provide the service user with extensive support around a range of issues in a way that a GP working in isolation wouldn't have the capacity to provide. A systematic long-term approach is required in managing people with benzodiazepine dependencies. The demand for people needing support and management around their benzodiazepine use exceeds Health Works capacity.<sup>960</sup>

### *An illustration of the treatment process*

It is useful to describe what might happen in the treatment process for someone who is misusing pharmaceutical medicines. In his presentation to the Committee, Dr Mike McDonough described how patients might be managed in his hospital services. His description is reproduced here in detail as it provides a practical illustration of the various steps of intervention. He described firstly the initial contact with the patient:

The patient would either come to us through the emergency department because there has been some drug-related medical problem, or they could be referred by a general practitioner or a drug and alcohol agency. It is rare in our service in the hospital to get people just walking in off the street; they are normally referred. Once they arrive they would be triaged. Some people would have predominantly psychosocial problems – for example, they have been thrown out of home, they are in trouble with the law, they have no money and are going into drug withdrawal and need detoxification or [a] time-out type intervention. Many of those presentations would be dealt with by a trained counsellor, who is often a registered nurse or a social worker, who would try to prioritise the immediate needs and slot that person into the treatment program or day-to-day contact or outreach.

However, if it is a medical problem, let us say the person has come in because they have had an overdose or a seizure related to the sudden withdrawal of drugs like benzodiazepines, I would firstly assess whether the person has an intermittent drug problem – sometimes called recreational drug abuse – or a dependency problem, meaning the person has acquired a daily habit that in turn requires that individual to have a supply that is regular and ongoing every day.<sup>961</sup>

As described earlier in the chapter, for many patients who are dependent on prescription drugs the first step will consist of withdrawal management. This will help stabilise patients and enhance their capacity to benefit from other interventions, such as relapse prevention.

<sup>960</sup> Submission from Ms Gwenda Cannard, Director, TRANX (Tranquilliser Recovery and New Existence) Inc., to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

<sup>961</sup> Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 13 July 2006.



There is also a need to identify and address any underlying problems such as mental health problems:

Secondly, sometimes people's underlying psychiatric or other diagnoses can be revealed once you have removed the drugs – for example, many people look like they are very memory disturbed or behaviourally disturbed when they are continually drug dependent, but once the drugs have been removed they look quite different and perhaps they do not have memory damage or brain damage or a severe anxiety problem; [in other words it was part of] just daily withdrawal.<sup>962</sup>

Whilst withdrawal management may be conducted in the hospital, the development of a rehabilitation plan is often conducted on an outpatient basis. However, a small number of patients who have multiple problems may continue with in-patient care, or be referred to a residential service:

An example would be Odyssey House. Someone will have gone through a detoxification period and had a couple of weeks safe off drugs, monitored. They may not go back home; they may be kept in the detox unit or they may step down into a safe house or into the care of a family who are watching and making sure that they have not relapsed. Then they go directly to a place like Odyssey House, where they might spend months, or longer.<sup>963</sup>

The next stage involves addressing relapse prevention, a particular concern for those who are opioid dependent. Dr McDonough suggests that for patients who have had multiple relapses, substitution therapy programmes are one way of avoiding future relapses:

...we know that the highest risk to their life is a drug overdose, and we know at the same time that the best medically proven preventer of overdose mortality for heroin addicts is pharmacological treatment, with things like substitute methadone or substitute buprenorphine.

...the best advice [in such cases] would be going onto methadone. Some patients might in fact make that decision for you by telling you, 'There is no way I am going to Odyssey House', or, 'There is no way I am going to stop using drugs, Doc, but I'll try the methadone' – or the buprenorphine. In those sorts of cases we recommend they start this sort of pharmacological treatment. That is started usually before they leave the detox unit or sometimes as an outpatient. The program continues in the outpatient sector. They are twice weekly at first, weekly and then eventually every couple of weeks and, when they are running reasonably stable, monthly.<sup>964</sup>

As can be seen, treatment consists of several steps, requires a range of clinical skills and sometimes coordination across services. It is evident that such responses can be resource intensive. This last point is important. A number of agencies that have actively engaged in responding to pharmaceutical misuse indicated in their submissions that effective responses, accessible throughout the community, are beyond their current resources and beyond the means of many clients.<sup>965</sup>

962 Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 13 July 2006.

963 Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 13 July 2006.

964 Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 13 July 2006.

965 See for example the submissions from TRANX (16 June 2006), Anex (22 June 2006), Western Region Health Centre (5 July 2006) and Dr Rodger Brough (21 July 2006) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria.

## Conclusion

Treatment for drug problems in general is effective (see, for example, Loxley, Toumbourou & Stockwell 2004; National Institute on Drug Abuse (NIDA) 2000; Ward, Mattick & Hall 1998). However, the available evidence indicates that a range of interventions will be required for the diverse needs of an individual as he or she progress through the different stages of treatment.

The Committee found there are limited options for treatment for pharmaceutical misuse and dependence, with the majority of evidence being related to treatment for opioid analgesic dependence. Specific treatment options and services for benzodiazepine misuse are more limited. Given the lack of evidence with regard to treatment of prescription drug misuse, a conservative approach is recommended. Procedures and guidelines that are applied to other drug problems should be adopted. Treating pharmaceutical misuse, however, requires specific treatment planning, with a particular focus on reducing the likelihood of the patient obtaining prescription medications from a health professional or other person who is not involved in the treatment process.



There is a clear need for a coordinated approach to the management of benzodiazepine dependence. The current fragmented approach, involving multiple agencies, is inefficient and costly. A coordinated approach, involving a single agency, would be more effective and efficient. This approach would involve the development of a coordinated policy and strategy, the establishment of a coordinated governance structure, and the implementation of a coordinated program of action.

The current fragmented approach to the management of benzodiazepine dependence is inefficient and costly. A coordinated approach, involving a single agency, would be more effective and efficient. This approach would involve the development of a coordinated policy and strategy, the establishment of a coordinated governance structure, and the implementation of a coordinated program of action. The current fragmented approach involves multiple agencies, each with its own mandate and priorities. This leads to duplication of effort, inefficiency, and a lack of coordination. A coordinated approach would involve the development of a coordinated policy and strategy, the establishment of a coordinated governance structure, and the implementation of a coordinated program of action. This approach would ensure that all agencies are working towards the same goals and objectives, and that resources are used effectively and efficiently.

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## 7.2 Challenges in Addressing the Treatment of Benzodiazepine and Other Pharmaceutical Misuse

### Introduction

There is a range of key areas that have been identified as challenges for the treatment sector. These include service provision in rural and regional Victoria, developing treatment strategies that are appropriate for the needs of culturally and linguistically diverse (CALD) communities and other populations with unique needs, managing the complex problems associated with pharmaceutical misuse, and the possible need for dedicated treatment services and holistic care.

In addition, there is the need to develop an evidence base for non-drug treatments for pharmaceutical dependence and specialist treatment services (including specialist programmes within existing treatment services and other health services). It is essential that treatment options and treatment capacity respond to the unmet needs of those affected by pharmaceutical misuse.

### Challenges in reaching the target population

Whilst there is a comprehensive literature and research base with regard to treatment for illicit drug users or people with alcohol dependence, the same cannot be said in relation to prescription drug abuse.

It is therefore difficult to determine whether treatment service provision for prescription drug misusers is adequate, as there is little data or evidence that accurately indicates the number of people who are misusing or abusing pharmaceutical drugs and the number of these people who successfully access treatment. This dearth of information is not unique to Australia. A recent review from the United States (U.S.) noted that:

No data exist that document how many of those who need treatment for prescription drug addiction receive it (CASA 2005, p.96).

Data and experience suggest that not all people with alcohol or illicit drug problems access specialist treatment and it is likely that people who misuse pharmaceutical drugs are less likely than illicit drug users to enter treatment (Hall et al 2000). This is likely to be the case because people who abuse prescription drugs only, particularly drugs supplied from a legitimate prescription, may not need to resort to criminal activity to pay for their drugs. For illicit drug abusers, however, financial, legal and other lifestyle issues may be a motivating factor to enter treatment. Moreover, people who misuse and/or are dependent on pharmaceutical drugs may not believe they have a 'drug problem'.

One of the problems really with people who are abusing prescription drugs is that they're quite happy [not] doing anything about it...they're quite happy with the status quo and they're not expressing a desire for treatment, whereas a heroin addict will eventually come in and say I need treatment, I'm sick of the drug, I can't afford the \$300 a day, I hate



prostitution, I've been arrested 60 times. These patients, provided they can get ongoing supply of their drug, will rarely come into treatment.<sup>966</sup>

The phrase 'my doctor gave them to me',<sup>967</sup> mentioned in a number of hearings, demonstrates a common perception that prescribed medications are harmless. A lack of recognition or lack of knowledge of the potential harms of these medications, including dependence, can significantly delay the person from seeking treatment.

## Challenges for service provision

One of the key debates in the area of treatment provision for those suffering from prescription drug abuse is whether treatment services can be supplied through generalist healthcare providers. Even if it is theoretically possible there are a number of factors that mitigate against this happening successfully in practice. These factors are detailed in this section.

### *Lack of consultation time*

Addressing pharmaceutical drug abuse is complex and time consuming. A comprehensive consultation is required in addressing the needs of prescription drug abusers. The current Medicare system does not allow sufficient remuneration for the time required to appropriately manage complex clients with multiple needs. This may act as a disincentive to treat these patients for some general practitioners (GPs). The provision of remuneration for extended consultation time to address more complex issues around insomnia, anxiety, stress and pain management may help engage prescribers in holistic treatment, including non-drug treatment options for patients reporting these conditions.

### *Lack of support and training for GPs*

There are a number of difficulties for medical practitioners in the management of patients with benzodiazepine or opioid analgesic dependence. Dependent users who do not disclose their use are often difficult to identify and may have multiple strategies to acquire pharmaceuticals. A lack of adequate training for GPs in both pharmacology and good prescribing practices is a concern. The Australian Medical Association (AMA) (Vic) has recommended that additional support and training may assist medical practitioners to identify prescription drug abusing patients.<sup>968</sup>

### *Lack of expertise in delivering non-pharmacological interventions*

GPs often do not have the training or the time to deliver cognitive therapies or other psychotherapeutic interventions. In addition, dependent pharmaceutical drug users may not be at a stage of change appropriate to such therapeutic interventions.<sup>969</sup> Medical practitioners now have access to new Medicare items for psychologists. People with mental health problems (including drug and alcohol problems) can now access six sessions of psychological counselling subsidised by Medicare. A care plan is required from a GP or a letter of referral from a psychiatrist. These sessions can be extended to 12 sessions after review by a medical practitioner, and in some cases up to 18 sessions can be obtained.<sup>970</sup>

966 Dr Mike Tedeschi, Canberra Hospital, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Canberra, 16 May 2007.

967 Ms Ros Burnett, Interhospital Liaison Group, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 19 June 2006.

968 Submission of Australian Medical Association (Vic) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

969 Submission of Dr Nick Carr, St Kilda Medical Group, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

970 See <http://www.psychology.org.au/medicare/psych.medicare.items/>

### *Lack of interest or expertise in drug and alcohol treatment*

One other possible barrier to providing effective treatment services may be the reluctance of some doctors or other healthcare professionals to practise or specialise in drug and alcohol treatment because this field may not be seen as an attractive career option.

### *Challenges specific to the patient group*

Patient groups such as those with chronic pain may be regarded as too complex for the medical profession to treat. For example in the U.S. 'medical schools now advise students not to choose pain management as a career because the field is too fraught with legal dangers' (Spencer 2004, p.1).

In Victoria it has also been noted that some practitioners may be reluctant to provide treatment to patients who are perceived as 'difficult'. For example, Dr Nick Carr, a Melbourne based practitioner with experience in addressing prescription drug abuse, noted that the medical practice he worked in had a policy not to prescribe to any new patients requesting opioid analgesics or benzodiazepines, regarding them as potential 'doctor shoppers'.<sup>971</sup> The intimidation and violence against doctors referred to in submissions to the Inquiry by the AMA<sup>972</sup> and the Pharmaceutical Services Branch of Tasmania,<sup>973</sup> may also explain why some healthcare professionals may prefer to disassociate themselves from this patient group.

### *Insufficient information to prescribe*

Some practitioners may feel they have insufficient data, such as the medication and prescription history of the presenting patient, upon which to base any clinical interventions. The lack of a centralised real-time online recoding system exacerbates this problem.

### *Shortage of prescribers and other practitioners*

The state-wide shortage of GPs and pharmacists currently engaged in delivering treatment to drug and alcohol dependent individuals limits the capacity of the current treatment system. This problem is more evident in regional and rural areas where there can be large distances between service providers. Some rural areas also may not have access to pharmacotherapy prescribers. Similarly, there are few psychologists and counsellors in regional areas and those that provide Medicare services in metropolitan and regional areas often have long waiting lists.

Dr Benny Monheit, a Melbourne based alcohol and drug clinician, also highlighted a number of challenges that occurred with the evolution of the Victorian system to a largely privatised system where GPs and commercial pharmacies deliver the majority of treatment. Dr Monheit suggests that attracting prescribers to work in the area of drug treatment, for example with methadone and buprenorphine, is made more difficult by the current GP shortage.<sup>974</sup>

### *Need for dedicated services*

The Victorian Alcohol and Drugs Association (VAADA) has highlighted the lack of knowledge about the efficacy of current treatments for misuse of pharmaceutical drugs, as

971 Submission of Dr Nick Carr, St Kilda Medical Group, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

972 Submission of Australian Medical Association (Vic) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2007.

973 Submission of Mr John Galloway and Ms Mary Sharpe, Pharmaceutical Services Branch, Department of Health and Human Services Tasmania, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

974 Submission of Dr Benny Monheit, Southcity Clinic, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.



well as the lack of specialist treatment services for pharmaceutical misuse.<sup>975</sup> For some people whose sole or primary drug of abuse is a prescription medication, entering treatment services that focus on the needs of illicit drug users may be daunting. Perceptions of 'hard drug' abusers, even if unfounded, may act as a disincentive to seek or continue treatment. Pharmaceutical drug users may not identify these services as appropriate for their needs, as they were developed in response to an increase in street-based heroin. In addition, some primary pharmaceutical users may be intimidated by street drug users. Professor Jason White of Adelaide University drew attention to these disincentives:

...people come in often quite hostile (a) because they do not want to be there and (b) because they see that they have had 20 years of treatment from a range of doctors and none of them have solved their problem...now (they are) being treated the same as heroin users from their point of view. They actually get treated differently, but from their point of view they are treated that way.<sup>976</sup>

A witness gave evidence to the Committee that exemplified the tensions apparent in having non-specialised treatment services, particularly detoxification services. 'Mary' is a self-described middle-class woman from a conservative background. She also has a severe dependence on benzodiazepines and has regularly 'doctor shopped' to access these drugs. She told the Committee how difficult it was to go into detoxification units that did not differentiate between drug types. For example, during her various stays in 'detox' it was not uncommon to share common facilities with potentially violent clients who had been placed in the unit as a result of a mandated court order:

I would hate to think how many times I have been in X detox. It is a horrible place to be. That is where you will meet – I am going to sound judgmental myself now and I have no right to be judgmental – some horrible people. This is going to sound a little bizarre, but that is where you will see the worst scenario. That becomes frightening when you are in the unit; so frightening that you stay in your room because you are too frightened to come out in case something happens.

You are locked in. Now, you are not locked in because you are a danger, you are locked in for your own safety, for other people not being able to get in. However more drugs can get into a detox unit, I experienced that – not personally. Yes, personally, I watched that happening or saw it, was witnessing that it was happening but you are too frightened to say anything, way too frightened, because there are some scary people that are in there truly because they have to be under court order.<sup>977</sup>

Dr Malcolm Hogg from the Australian Pain Society also identified a similar tension existing between chronic pain services and drug treatment services:

What we are seeing now is those in crisis. I get asked, 'Please can you give me back-up here; he is out of control'. I say, 'They need to go to the drug and alcohol service'. The drug and alcohol service are saying, 'He is on morphine. All we can do is put him on methadone'. We need something in-between...<sup>978</sup>

This gap – when chronic pain patients are unable to access chronic pain treatment – was also one of the two challenges Professor Jason White commented on. The other issue was when disagreement occurs between the patient and the service about whether the patient

975 Submission of Victorian Alcohol and Drugs Association, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

976 Professor Jason White, Director, Drug and Alcohol Services of South Australia and Head of Department of Pharmacology, University of Adelaide, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Adelaide, 18 May 2007.

977 'Mary', Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 16 July 2007. The name of the witness and the detoxification unit in which she stayed has been changed to protect her identity and privacy.

978 Dr Malcolm Hogg, Australian Pain Society, Australian and New Zealand College of Anaesthetists, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 26 June 2007.

should be treated in a service specialising in the treatment of chronic pain or one that specialises in treating substance abuse problems:

We have made efforts here to try and come up with better ways of dealing with these people, because they require enormous resources, so the resources that we input to those people compared to a heroin user, for example, is considerably more to the patient through pain medication. If it were able to provide a better service, which I think ideally would involve a liaison between people who specialise in pain and people who specialise in addiction, but they need to talk to each other more. In some places they do, and we try to here in South Australia, but it is very hard to do much with a pain clinic when they say, 'We've got a year or two waiting list for these people', and this person is out there in the community causing havoc and the GP says, 'I don't want to deal with him any more'. So our clinic often gets them and we do the best we can within the resources we have got.<sup>979</sup>

One proposed solution is the co-location of drug and alcohol services with community health services. This would allow medical treatment in a setting not clearly identified as drug dependence treatment. Co-located services could also provide a community based opportunity for preventing initiation into pharmaceutical use by offering non-drug methods to address the common problems of anxiety, sleep and chronic pain.

## **Service delivery issues – The need for accountability, proximity and flexibility**

### ***Access to treatment***

Evidence to this Inquiry suggests there are a number of problems that restrict access to drug treatment and services. One of the key problems is that there may be on occasion waiting lists of varying lengths before a patient can enter treatment or receive services.<sup>980</sup> Even in metropolitan areas access to treatment can be a problem, as there are often waiting lists to access treatment services. This is highlighted in the submission from Darebin City Council:

While the state-based TRANX service offers ongoing counselling for those with benzodiazepine dependence, the service is located in Glen Iris and is beyond the access of many local residents. It is understood that waiting lists also fluctuate for this service, which may act as a barrier for those seeking immediate assistance. Forthcoming changes to the drug treatment service system also pose a possible threat to such services where counselling is the main therapeutic modality. Initial work on the drug service system review suggests a curtailing of counselling activities in favour of medication-based therapies which are simply inappropriate for this target group.<sup>981</sup>

In the context of opioid misuse, Dr Alex Wodak of St Vincent's Hospital in Sydney noted that people may use pharmaceutical opioids because they cannot access opioid treatments due to long waiting lists:

...because people can not get onto methadone or buprenorphine programs, or alternatively they find the restrictions of the methadone buprenorphine programs too onerous, and so they use grey market prescription drugs.<sup>982</sup>

979 Professor Jason White, Director, Drug and Alcohol Services of South Australia and Head of Department of Pharmacology, University of Adelaide, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Adelaide, 18 May 2007.

980 For example, see submission of the Interhospital Liaison Group to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006, and submission made by Western Region Health Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

981 Submission of Darebin City Council, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

982 Dr Alex Wodak, Director, Drug and Alcohol Service, St Vincent's Hospital, Sydney, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 25 June 2007.



Whilst clearly illicit drug users have identified these barriers, they are greater for pharmaceutical misusers because of the significantly reduced number of specific treatment services available.

If this is the case, improving access to opiate pharmacotherapy treatment may reduce the demand for illicit pharmaceuticals.

### **Geographic barriers**

Geographic location may act as a barrier to accessing drug treatment services, particularly in rural and regional Victoria. For example, in his submission to this Inquiry Dr Rodger Brough commented on the difficulties in accessing services in rural and regional Victoria:

...access to psychiatric support and psychiatric medical services is so restricted for many 'public patients' who do not meet the 'major mental illness' qualification that they are effectively denied access to services. This makes access to appropriate treatment options more difficult for people with a significant drug problem.<sup>983</sup>

Metropolitan communities can also be affected by a lack of appropriate services. As a submission from Darebin City Council explained:

TRANX, based in Glen Iris is a statewide service, though metropolitan services have identified that both the waiting lists and the distance to travel can be a barrier to accessing treatment from a specialist service. Other than acute interventions the only other service for benzodiazepine dependence is a limited (6 session) counselling service which would be insufficient to manage the protracted nature of benzodiazepine withdrawal.<sup>984</sup>

The example of TRANX, now known as ReConnexion, highlights the need for a greater number of specialist services to manage benzodiazepine dependence. However, it is not only the number and location of services available that can be obstacles to patients accessing appropriate treatment for their prescription drug misuse but also the cost of and inflexibility in provision of some services.

### **Cost and flexibility of treatment services**

There are also cost issues pertaining to the supply of drug treatment that may directly and indirectly impact upon people who abuse prescription medicines. For example, for illicit drug abusers the cost of standard opioid substitution pharmacotherapies are typically \$5 a day in a community pharmacy and the patient is required to attend for dosing daily (methadone) or every second day (buprenorphine). This is significantly more costly than pharmaceutical opioids, where a month's supply can cost \$4.90. Therefore prescribed drugs such as morphine, legitimately or illicitly obtained, offer greater value for money and can be more conveniently or easily accessed. As a result, some people may turn to prescription opioids either for recreational purposes or to self-medicate. Mr Peter Muhleisen, Senior Pharmacist at Turning Point Alcohol and Drug Centre, highlighted some of these tensions:

...it is a lot cheaper and less undignified to get a morphine script than attending daily for methadone. To go once a month and get your month's worth of morphine, [is far preferable] They [morphine users] pay \$5 a month instead of \$5 a day for their treatment.<sup>985</sup>

Making opioid treatment more affordable and flexible may in turn reduce the demand for illicit or indeed licit pharmaceuticals accessed through 'doctor shopping'.

Another barrier to service access is hours of operation of some drug treatment and ancillary services. Most services operate during business hours, with few open after hours during the

983 Submission of Dr Rodger Brough to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

984 Submission of Darebin City Council, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

985 Mr Peter Muhleisen, Turning Point Alcohol and Drug Centre, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 9 July 2007.

week or on weekends. For example, Mr John Ryan from Anex (Association for Prevention and Harm Reduction Programs Australia) noted:

One of the other significant issues that this committee may consider in relation to benzo use is the hours of operation of NSP [needle and syringe program] services. Most NSPs operate during business hours. Most drug consumption is a 24/7 around the clock, seven days a week activity.<sup>986</sup>

However, Anex also noted that some service provision improvement has occurred:

We have seen in the last few years an increase in some services in the Melbourne metropolitan area called primary health care services. They have been very successful in terms of providing comprehensive holistic health access to people who are otherwise not accessing services, and that includes areas like Footscray and Dandenong, where there are high concentrations of vulnerable injecting drug users.<sup>987</sup>

Another positive change has been the relaxing of restrictions on unsupervised doses of pharmacotherapeutic medicines in Victoria. The introduction of the naloxone-buprenorphine combination medication (Suboxone®), and a change in policy to allow some patients on methadone or buprenorphine to receive up to five unsupervised doses per week may go some way towards addressing the challenge of the restrictive attendance requirements that are associated with these treatments and also address the issue of people using prescription medicines to self-medicate their withdrawal from illicit drug use.

This change in policy needs to be viewed alongside changes to the funding of withdrawal services for drug treatment introduced in July 2007. These changes were outlined in correspondence to the Committee by the Department of Human Services:

Previously, DHS regions purchased residential withdrawal capacity (beds) from specific agencies providing residential based alcohol and drug treatment services. For example, Hume region purchased capacity from St Vincent's Hospital so that people from the Hume region could access those specific services. On 1 July 2007, all residential based alcohol and drug treatment services became available statewide. This allows for any person from any area in Victoria to access services from any agency. Now a person from Hume is not limited to receiving services only from St Vincent's and can access services from anywhere in the State.<sup>988</sup>

Such flexibility within the system has generally been welcomed by drug and alcohol workers who have given evidence to the Inquiry. Some reservations have been expressed, however, that allowing more mobility between regions may mean that some provincial or rural areas may get 'swamped' with patients or clients from outside their traditional catchment areas. For example, clients from Melbourne could be sent to a rural town to undertake withdrawal treatment. According to Ms Kate Harrington-O'Brien of Bendigo Community Health Services this could be a cause for concern:

There was a decision recently to look at removing the borders, in a sense, around access to beds, because once upon a time people in Loddon Mallee could access one service in town, because our region was allocated beds in that particular service. Now they have taken those boundaries away and potentially anybody in the state should be able to access any bed anywhere.

That scared the living daylights out me for our four beds because, as Cheryl said, we are a low to moderate risk. We do not have 24-hour nursing coverage. We do not have GP access

986 Mr John Ryan, Chief Executive Officer, Anex, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 20 June 2006.

987 Mr John Ryan, Chief Executive Officer, Anex, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 20 June 2006.

988 Correspondence from the Mental Health Division, Department of Human Services (Victoria) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse and Abuse of Benzodiazepines and other Pharmaceutical Drugs in Victoria, 13 November 2007.



all the time. It is very limited, and we have struggled, as I said before, to attract and then retain staff.<sup>989</sup>

Her colleague, drug and alcohol nurse Cheryl Sobczyk agreed that there was a potential to 'flood' local beds with clients from other parts of the state:

On the question of access, at the moment we have fairly good control over even the referrals we get because the people that we work with, the withdrawal nurses who usually do the assessment for us, understand the requirements for our unit. If that opens up on a statewide basis, it will create some initial problems, I would imagine. However, I am sure we can deal with those. But currently we get people coming to Bendigo from Mildura, Horsham, Ballarat. It is a huge area. We still need to be able to maintain access to local people. If all of a sudden our four beds are getting taken up by people from anywhere in the state, that creates a bit of a problem.<sup>990</sup>

It was generally acknowledged by participants at the Drugs and Crime Prevention Committee's prescription drug rural and regional forums that the potential problems raised by workers in the field with regard to the introduction of the new system would need to be addressed over the ensuing months.

## Needs of specific populations

Whilst some of the basic attributes of drug treatment programmes may be comparatively similar, other aspects of a treatment programme may need to be modelled specifically for different drug using populations.

### *Rural and regional communities*

Rural and regional communities face some significant additional challenges in relation to prescription drug misuse. If illicit opiates such as heroin are not readily accessible in a given region, prescription medications may be the predominant opioids used, as is noticeable in Tasmania for example, particularly in rural sections of that state.<sup>991</sup> Despite this, treatment services for people wishing to cease pharmaceutical use are extremely limited in rural and regional areas. This may result in greater pressure on GPs to manage complex clients without the support of specialist alcohol and drug centres in the area. A number of people who gave evidence to this Inquiry noted that individuals seeking drugs travel long distances to acquire prescriptions. Dr Mike Moynihan, President of the Rural Doctors' Association of Victoria, commented that:

In terms of the locality, we found that drug seekers will try it from over quite a radius and try every doctor in the district. They will virtually go to everyone in their efforts to get things. From time to time I have resorted to mailing every single doctor and pharmacist within about 100 kilometres over certain individuals to try to limit their activities.<sup>992</sup>

Dr David Richards, a drug and alcohol clinician from Warrambool, informed the Committee that there is a street market for prescription opioids and benzodiazepines in rural communities:

For a very considerable time in my work here it has been very obvious to me that prescription opiates are a significant problem on the street...I only have anecdotal information, but what

989 Ms Kate Harrington-O'Brien, Operations Manager Alcohol and Drug Services, Bendigo Community Health Services, Drugs and Crime Prevention Committee, Inquiry into the Misuse and Abuse of Benzodiazepines and other Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Bendigo, 30 May 2007.

990 Ms Cheryl Sobczyk, Clinical Nurse Manager, Bendigo Community Health Services, Drugs and Crime Prevention Committee, Inquiry into the Misuse and Abuse of Benzodiazepines and other Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Bendigo, 30 May 2007.

991 See submission of Mr John Galloway, Chief Pharmacist and Ms Mary Sharpe, Deputy Chief Pharmacist, Pharmaceutical Services Branch, Department of Health and Human Services Tasmania, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

992 Dr Mike Moynihan, President, Rural Doctors Association of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Teleconference, 18 June 2007.

I hear is that the price of sustained-release oxycodone, which is the really popular drug, is around \$1 per milligram or \$50 for an 80-milligram capsule...Anecdotally, I hear stories of groups watching pharmacies and approaching people – not always without threat – when they have left the pharmacy, with offers for the medication that they might have picked up. I have heard stories of significant violence against people who have refused to sell...<sup>993</sup>

Whilst the lack of adequate treatment and ancillary service is a nationwide problem it is particularly acute in rural and regional areas of the country. Inadequate access to pain management clinics for example was identified in a submission from the Faculty of Pain Medicine<sup>994</sup> as a major obstacle in addressing prescription drug abuse in country areas.

### *Culturally and linguistically diverse (CALD) populations*

The Committee has noted the dearth of information available or research undertaken into drug use, both licit and illicit among people from non-English speaking or ethnically diverse backgrounds. Similar observations could be made with regard to the specific drug treatment needs of people from such communities. In the few studies undertaken of licit and illicit drug use among people from CALD communities, it is also unclear whether such drug use can be related to issues such as ethnicity or migration or due to confounding variables such as socio-economic status (Loxley et al 2004).

Whatever the nexus is between ethnicity and drug abuse, including prescription drug abuse, it does seem clear that CALD communities are particularly disadvantaged in accessing adequate drug treatment services. Mr John Ryan from Anex expressed the view that for many CALD communities service provision was not ideal:

It is difficult to generalize...There are some services that are working quite successfully but most services are not sophisticated in the way that they deal with cultural and linguistic diversity.<sup>995</sup>

In its submission to the Drugs and Crime Prevention Committee the Ethnic Communities Council of Victoria has made a number of recommendations that seek to provide better drug information and treatment services targeted at CALD communities. These include:

- The strengthening of referral protocols between ethno-specific agencies and mainstream providers;
- Increased availability of funding to ethno-specific agencies to enhance communication with CALD drug users;
- The involvement of CALD representatives in decision making with regard to drug policy; and
- The use of communication mediums, such as ethnic radio stations, newspapers channel SBS and 31 to publicise the effects, treatment and harms of benzodiazepines and the misuse of other pharmaceutical drugs and to advertise early prevention and other educational campaigns.<sup>996</sup>

Working with the families of members of CALD communities affected by drug problems has also been identified as vital in achieving successful outcomes. Some members of CALD communities are reluctant to use available services because they fear bringing shame and disrepute on their families or (erroneously) fear there will be legal implications in doing

<sup>993</sup> Dr David Richards, Addiction Medicine Physician, Western Region Alcohol and Drug Centre, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Warrnambool, 29 May 2007.

<sup>994</sup> Submission of Australian and New Zealand College of Anaesthetists to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

<sup>995</sup> Mr John Ryan, Chief Executive Officer, Anex, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 20 June 2006.

<sup>996</sup> Submission of the Ethnic Communities' Council of Victoria to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Forum for Culturally and Linguistically Diverse Communities, Melbourne, July 2007.



so. Addressing these issues may go some way towards improving the relevance, uptake and effectiveness of services for CALD communities (Department of Human Services (DHS) 2000).

Often the problems associated with providing drug and alcohol treatment services to non-English speaking communities are simplistically reduced to language and interpretation issues. In order to make information available, familiarity with effective communication appropriate to different communities and an understanding of different cultural perspectives on health, drugs and medicine is required.<sup>997</sup>

We have got ethnic workers, we have got bilingual workers, we have got information from the mainstream services. That information is readily available but how can we make it available to the community? And that I think is the big gap.<sup>998</sup>

Interpreters are required to work with doctors and pharmacists to ensure information about prescription medication is available and understood. However, a lack of information in different languages only forms part of the problem. Sharing of medication is often reported among CALD communities, according to participants in the Ethnic and Cultural Diversity Forum held by the Drugs and Crime Prevention Committee. This is as much an issue of 'culture' and cultural understanding as it is about information provision:

Some of them do not read and do not write, and it is very hard for them to understand how they are going to take their prescribed medicines. If one of the members asked, 'What type of medicine do you get?', and you explain you got chloroquine, for example, they will try to ask, 'How did you explain it to the doctor that you are feeling worse?' She might say I had a headache and I was having stomach ache. And she will say, 'Oh, that is the same for me. Can we divide the medicine? Give me a part of the medicine'. They will divide the medicine among themselves. That will not treat the sickness – the medicine you have been given because you did not take the full dose. So that is another problem.<sup>999</sup>

It is essential that people from CALD communities are involved in the planning of drug programmes and policy development in order to bridge problems associated with language and culture. Such involvement would assist in making drug treatment programmes more culturally relevant than they have been hitherto.

### *Indigenous Victorians*

In August 2007 the Drugs and Crime Prevention Committee held a forum for Indigenous drug and alcohol workers and other members of Victoria's Koori communities on prescription drug abuse. One of the issues raised was how drug use of any kind among Indigenous people should be addressed and treated.

Indigenous Victorians in metropolitan and rural and regional parts of the state are concerned about the lack of facilities and services for drug prevention, education and treatment for their communities. A major part of addressing these deficits is to provide a more holistic approach to healing. Holistic healing practices involve the community rather than just the individual and include traditional ways of healing:

The healing service incorporates cultural ways, so we have smoking ceremonies, we have meditation, exercise and practical meditation. We have community lunches, we have a place to get together.<sup>1000</sup>

997 Issues pertaining to language, culture and information provision with regard to (prescription) drug abuse by members of CALD communities is discussed in Chapter 6.2 of this Report.

998 Mr Loc Pham, Drug and Alcohol Worker, Australian Vietnamese Women's Welfare Association, Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Forum for Culturally and Linguistically Diverse Communities, Melbourne, 9 July 2007.

999 Mr Mayor Luk Lueth, Sudanese Lost Boys Association of Australia, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Forum for Culturally and Linguistically Diverse Communities, Melbourne, 9 July 2007.

1000 Mr Reg Blow, CEO, Maya Healing Centre, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Aboriginal Drug and Alcohol Workers Forum, Melbourne, 20 August 2007.

In the specific context of prescription drug abuse, Darebin City Council<sup>1001</sup> expressed similar concerns about identifying and meeting the needs of Indigenous people:

Anecdotal evidence from a number of Aboriginal agencies indicated that medication misuse – in particular medication mismanagement – was impacting significantly on Indigenous residents due to the high level of medications many Indigenous people are prescribed. However, working in partnership with Aboriginal agencies takes time and the building of trust was not possible [in the short term].<sup>1002</sup>

According to some participants at the Indigenous forum, the government funding model for both mainstream and Indigenous drug treatment services mitigates against the provision of culturally appropriate treatment programmes and interventions. For example, many mainstream services rely upon pharmacological interventions, which are not necessarily appropriate in all cases, as pointed out by Mr Alan Thorpe, an Indigenous drug and alcohol worker:

The Department of Human Services will fund [patients] for prescription drugs, but they will not fund them for alternatives [treatments].<sup>1003</sup>

His colleague Mr Mike Moran made similar criticisms:

I certainly know there is a reluctance among funding bodies to acknowledge and support traditional healing techniques that we know worked for 40, 60 thousand years prior to the white fella coming in. Though there might not be empirical evidence of that certainly they ought to look at setting up some research tasks to have a look at how these models work, the effectiveness of it, because we have developed over the years now even better ways of researching and gaining the valid evidence of brainwave pattern changes through using medication or spiritual practices, where 10 years ago we did not have that. Now we can scientifically measure these types of programs.<sup>1004</sup>

#### **Putting theory into practice – Winnunga Nimmityjah Indigenous Health Service**

During its trip to Canberra in May 2007 the Committee witnessed the workings of a holistic healing centre when it visited the Winnunga Nimmityjah Indigenous Health Service. The centre aims 'To provide a culturally safe holistic health service for the Aboriginal and Torres Strait Islander people of the ACT and surrounding areas'.<sup>1005</sup> In the area of substance abuse, including prescription drug abuse, substance abuse workers work with other Winnunga staff to ensure 'that the clients are helped as the whole person and [the focus] is not just on their substance misuse problem'.<sup>1006</sup> To achieve this the Winnunga service not only employs doctors, psychiatrists, dentists and nurses but also counsellors skilled in social and emotional health issues and suicide intervention, health promotion officers, parenting skills advisers and finance counsellors. Programmes include a women's art group, women's violence prevention programmes, Indigenous cultural camps for young people and an Uncle/Nephew mentoring programme for young Aboriginal males.

The Committee was impressed with the holistic model of health care provided by Winnunga Nimmityjah, particularly with its emphasis on prevention and addressing the lifestyle and risk factors that may lead to later health problems including substance abuse.

1001 A metropolitan local government authority in the north-eastern suburbs of Melbourne with a relatively high level of Indigenous residents.

1002 Submission of Darebin City Council, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

1003 Mr Alan Thorpe, Koori Withdrawal Access Worker (Koori Access Program) Ngwala Willumbong Cooperative, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Aboriginal Drug and Alcohol Workers Forum, Melbourne, 20 August 2007.

1004 Mr Mike Moran, Coordinator, Aboriginal Diversion Unit, Ngwala Willumbong Cooperative, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Aboriginal Drug and Alcohol Workers Forum, Melbourne, 20 August 2007.

1005 See Winnunga Nimmityjah website at <http://www.winnunga.org.au/about/about.htm>

1006 See Winnunga Nimmityjah website at <http://www.winnunga.org.au/about/about.htm>



Exemplifying the principles of holistic health, Winnunga Nimmityjah encompasses not only medical care and treatment but also a wide range of positive programmes to promote good health and healthy lifestyles.

## Responding to the challenges

### *The need for holistic treatment services*

Addressing pharmaceutical drug dependence in isolation is likely to lead to relapse, particularly where there is an underlying mental health problem that is being masked by the pharmaceutical use. A holistic approach is required that addresses the multiple needs of *all* clients. For example, addressing the multiple needs of those people that misuse substances has been adopted by the Youth Substance Abuse Service (YSAS) in the context of young people's drug treatment needs:

YSAS adopts and advocates a harm minimization approach by which to structure its treatment responses, in that simple, well integrated strategies can significantly reduce the harms associated with substance use, even when these are not directly related to reducing or ceasing substance use (e.g. use of clean drug using equipment; improved diet, and primary health interventions such as vaccinations and sexual health education).<sup>1007</sup>

The holistic approach to drug treatment therefore addresses both the primary drug problem, but also the other health, mental health and primary healthcare needs in a coordinated approach.

### *Alternative treatment approaches*

The development and availability of non-pharmacological treatment approaches for conditions such as insomnia or anxiety, which are often given a 'quick-fix' solution of benzodiazepines, needs to be further established in the mainstream treatment system.<sup>1007b</sup> When benzodiazepines are withdrawn, the symptoms of anxiety or insomnia for which they have been prescribed are likely to return. For this reason, especially where pharmaceuticals may have been masking the underlying symptoms, treatment of pre-existing issues will be required in order to prevent relapse back to pharmaceutical use.

Complementary therapies can be used to treat both the pharmaceutical drug dependence and the underlying mental health condition that may have first prompted use of the pharmaceuticals. For example, a recent study on insomnia has shown that a greater improvement in sleep time can be observed when cognitive behaviour therapy is combined with tapering benzodiazepine dose compared to dose reduction alone (Belleville et al 2007).

The holistic approach can be extended further to the use of complementary medicine. A few mainstream alcohol and drug services offer complementary therapies for their clients, such as Windana Alcohol and Drug Recovery,<sup>1008</sup> including aromatherapy and acupuncture. Many clients wishing to become abstinent from drugs are often reluctant to undertake pharmacotherapy. Alternative medicines are one means to attract clients into treatment. There are other alternative treatments that have some evidence base in treatment of sleep disorders, for example light therapy. The committee heard in South Australia that these therapies are useful adjuncts in addressing sleep disorders, particularly among benzodiazepine users (see for example Montgomery & Dennis 2002). Light, music and art

1007 Submission of Youth Substance Abuse Service (YSAS), Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

1007b Dr Matthew Frei, Interhospital Liaison Group, Evidence given to the Drugs and Crime Prevention Committee Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 19 June 2006.

1008 <http://www.windana.org.au/>

therapy were also all raised in the Aboriginal Drug and Alcohol Workers Forum as alternative treatments currently used.<sup>1009</sup>

Increasingly traditional practitioners of western medicine are supporting the incorporation of alternative therapies into traditional treatment approaches. For example, the Australian Nursing Federation supports the incorporation of complementary therapies into nursing practice as part of holistic care. Its guidelines on the use of complementary therapies add the caution, however, that an evidence base must support all complementary therapies (ANF 2005). There is nonetheless a range of potential treatment options that may be explored in developing new treatments for pharmaceutical dependence, whilst also observing this caution.

### *Improving professional collaboration*

Professional divisions may exacerbate access and service problems. These barriers restrict collaboration between different areas of the healthcare system including between GPs, pharmacists and drug and alcohol services. In a submission to the Productivity Commission's Health Workforce Study, the Australian Health Policy Institute stated that:

The health workforce is structured around professional silos which have jurisdiction over particular roles and are deemed to be inflexible and approach any encroachment on their jurisdiction with hostility...there's the silos that exist in health and these silos develop at an undergraduate level and even from year twelve...these narrow foci are already too developed by the time practitioners enter the workforce and are hard to break down.<sup>1010</sup>

As Dr Roger Brough notes in his submission to this Committee, 'there is a need to encourage GPs, Alcohol and other Drug Services, pharmacists and consumer groups to work together to identify the local problems and their local solutions.'<sup>1011</sup> He goes further to recommend that best practice strategies will '[encourage] local workable responses to the underlying issues'.<sup>1012</sup>

During discussions and meetings with various service providers, the Committee observed that in some communities there seemed to be problems with information sharing and professional collaboration. This was particularly the case between GPs and drug and alcohol service providers. Mr Michael Murray, an experienced drug and alcohol service provider at the Koori drug and alcohol service, Ngwala Willumbong, explained the ongoing problem:

There [is a] lack of dialogue with doctors from an Alcohol and Drug perspective. I know myself I do not have a real good relationship with doctors out there...there is a bit of a gap.<sup>1013</sup>

The pressures of general practice should in no way serve as a justification for the current system; rather they are an invitation to develop strategies to address misuse and abuse of benzodiazepines and opioid analgesics. Indeed, it becomes evident that action is required on a number of fronts. There is an urgent need to enhance professional education and training to increase the probability of medical practitioners and pharmacists providing

1009 Mr Mike Moran, Coordinator, Aboriginal Diversion Unit, Ngwala Willumbong Cooperative, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Aboriginal Drug and Alcohol Workers Forum, Melbourne, 20 July 2007.

1010 Submission of Australian Health Policy Institute to the Productivity Commission, May 2005. See <http://pc.gov.au>

1011 Submission of Dr Rodger Brough to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

1012 Submission of Dr Rodger Brough to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

1013 Mr Mike Moran, Coordinator, Aboriginal Diversion Unit, Ngwala Willumbong Cooperative, Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Aboriginal Drug and Alcohol Workers Forum, Melbourne, 20 August 2007.



quality patient education, recognising and managing drug-seeking behaviour, managing dependence and withdrawal and providing harm reduction information.<sup>1014</sup> However, it also needs to be stated, that while better training for healthcare professionals clearly must be provided in the area of prescription drug abuse, this is not akin to attributing 'blame' to these professionals, particularly prescribing doctors, for any shortcomings of the system. As explained by Mr Steve Marty, Registrar of the Pharmacy Board of Victoria:

What you have got to do is provide the relevant health professional with the tools to make a professional decision.<sup>1015</sup>

### ***Diversion programmes for nurses and doctors***

The risk of losing the ability to practise is likely to act as a disincentive to seek help, which consequently may delay treatment entry until the situation is much more severe.<sup>1016</sup>

A number of programmes have been established to address the issue of (prescription) drug abuse and diversion among Victorian health professionals. These include the Victorian Nurses Health Program (VNHP) and the Victorian Doctors Health Program (VDHP). These are respectively discussed in the following sections.

### **Victorian Nurses Health Program (VNHP)**

The VNHP is an independent, and confidential support service for nurses and student nurses with health concerns relating to mental health, alcohol and drug issues. The VNHP will assess clients and coordinate the required health services, review treatment, provide ongoing support, relapse prevention and monitoring strategies, and develop a re-entry to work plan if appropriate. The VNHP also conducts information seminars at health facilities outlining the service and how to identify if a colleague has a substance abuse problem.<sup>1017</sup>

The VNHP is an Australian Nursing Federation (ANF) (Victorian Branch) initiative supported and funded by nurses' registration through the Nurses Board of Victoria (NBV). However, the health programme runs independently of both the ANF and the NBV. Ms Heather Pickard, the Director of the VNHP, explained that whilst the programme was in its infancy, it had thus far been well received:

It is a program that has been set up to assist nurses and students of nursing with issues related to mental health and also substance use disorder. We have been operating for 12 months now, and statistically 9 per cent of the nurses that we have worked with have been presenting with benzodiazepine dependency or related concerns, and 8.2 per cent have presented with pharmaceutical opioid dependency or concerns...

I think the Nurses Board of Victoria has shown incredible courage to actually fund a program such as ours. We are an orphan program here in Australia, but in the United States in nearly every state there is a program similar to us. I think by having programs that are profession-specific and have a role of education and support that we will start to dispel some of the myths around this as a health problem. I am certainly not encouraging it, but encouraging people to access the right kind of help, the same as we encourage the general community.<sup>1018</sup>

1014 See for example evidence from Public Hearings given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, from: Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, 20 June 2006; Anex, 20 June 2006; and TRANX, 19 June 2006.

1015 Mr Steve Marty, Registrar, Pharmacy Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 26 June 2007.

1016 Ms Heather Pickard, Director, Victorian Nurses Health Program, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 9 July 2007.

1017 The VNHP is based on the Victorian Doctors Health Program, which was established for medical practitioners who may also be having alcohol- and drug-related issues. See discussion below.

1018 Ms Heather Pickard, Director, Victorian Nurses Health Program, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 9 July 2007.

This last point is one of the reasons that Ms Pickard believes preventive education and programmes for nurses is so crucial:

We are informed by our clients of the resistance to gaining treatment as a medical health professional provider due to things like fear of disciplinary action, reduced professional status and experience of shame and guilt. This is where preventive education and training is so important.<sup>1019</sup>

### **The Victorian Doctors Health Program (VDHP)**

Medical practitioners with a substance abuse problem, including dependence on prescription drugs, may be referred to or self-refer to the Victorian Doctors Health Program (VDHP). Similar to the nurses' Program, the VDHP is a confidential service for doctors and medical students with health concerns, including stress and anxiety problems, substance use disorders, mental health disorders, and other health problems.

The Victorian Doctors Health Program (VDHP) has been established to ensure that a full time dedicated service is available to meet the needs of sick and impaired doctors and medical students.

It is a fully independent legal entity, and operates independently from any other organisation.

We provide prompt advice to doctors and medical students who feel at risk, or who think that they may have a problem. Advice is also provided to anyone who is concerned about a doctor or medical student. This includes family, friends, professional colleagues, and hospital and clinical staff.

The practice of medicine confers no protection from illness, including substance abuse and dependence, and mental health problems.<sup>1020</sup>

The genesis of the service is explained as follows:

During the early 1990s there was an increasing awareness of shortcomings in the provision of health services to the medical profession, and in particular the provision of assistance to doctors and medical students who had health problems that were causing, or likely to cause, impairment. This concern was widespread throughout the profession, and investigations were made into possible solutions to the problem. The Victorian Doctor's Health Program (VDHP) was established as *a fully independent entity separate from the Medical Practitioners Board of Victoria and the AMA Victoria*. The program has broad support from across the medical profession, including the Learned Colleges and Universities.<sup>1021</sup> (Emphasis in original)

Since the commencement of the Program, the VDHP has assisted doctors and medical students who have presented with numerous problems ranging from those having a mild to moderate impact on quality of life, to those threatening careers and lives. VDHP deals with each individual case on its merits and offers a range of interventions:

The program is confidential, and [conducted] with the utmost discretion. In the first five years of operation, the VDHP assisted over 850 doctors and medical students. Common problems have included:

- Substance abuse and dependence (alcohol, narcotics, benzodiazepines and other mood altering drugs)
- Psychiatric problems including depressive, bipolar, psychotic and other disorders
- Stress / emotional problems including professional burnout
- Physical illness.

1019 Ms Heather Pickard, Director, Victorian Nurses Health Program, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 9 July 2007.

1020 Taken from the website of the VDHP at <http://www.vdhp.org.au/why.htm>

1021 Taken from the website of the VDHP at <http://www.vdhp.org.au/why.htm>



The types of doctors who have presented to the VDHP for assistance have included general practitioners, anaesthetists, surgeons, physicians, radiologists, pathologists, paediatricians, and doctors who are not in active clinical practice, as well as medical students.

In addition to clinical work, staff at VDHP also participate in numerous non-clinical activities including presentations to universities, hospitals, colleges, and other medical organisations, and on-going program development and promotion.<sup>1022</sup>

The VDHP received its first participant on 19 May 2001, and since then has seen a high demand for the Program's services across a range of clinical problems. The VDHP is believed to be the first such doctors' health programme outside of North America.<sup>1023</sup>

Dr Con Constantinou, Health Manager of the Medical Practitioners Board of Victoria (MPBV) told the Committee that the VDHP has been very well received and is a useful ancillary treatment service to refer doctors to who come to the attention of the MPBV.<sup>1024</sup>

### *The needs of families of drug users*

Families have an important role in the prevention of drug-related harm and can have a major influence on treatment outcomes. However, the needs of the family and its role in supporting treatment have historically been neglected. As the mother of a person once dependent on prescription drugs remarked in a letter to the Committee:

I feel strongly about all aspects of drug use, the impact on the user and the fear and grief caused to families. If I can have our voices heard that is wonderful for all of us and it means our experiences haven't been in vain...though we wish we didn't have them.<sup>1025</sup>

The neglect of families is also illustrated in a British study. In this study of illicit drug users Velleman and colleagues (1993) found the majority of participants (88%) received some kind of support. This was categorised into informal support, such as that offered by friends, clergy or work colleagues (used by 74% of the sample), formal support, such as from a GP, psychologist or drug treatment service (60%) and self-help group support (34%). However, most of the study participants were dissatisfied with the support offered by formal services. A large proportion believed they did not receive adequate help and/or that the help offered was not useful.

In considering the treatment needs of people who misuse and are dependent on pharmaceutical drugs, it is therefore also important to consider the needs of families and significant others.<sup>1026</sup> Such needs can often be served through the use of support and self-help groups as discussed in the following section.

### *Support and self-help groups*

The role and effectiveness of self-help groups in treatment for pharmaceutical drug abuse is not well researched. Support groups specifically for users of pharmaceuticals are few in Victoria. However there are a number of self-help groups and resources described that may be accessed by those seeking assistance with dependence on prescription drugs. International, non-drug specific groups such as Narcotics Anonymous (NA) are one such example. However, there may be both risks and aversions for people who have developed

<sup>1022</sup> Taken from the website of the VDHP at <http://www.vdhp.org.au/why.htm>

<sup>1023</sup> Taken from the website of the VDHP at <http://www.vdhp.org.au/why.htm>

<sup>1024</sup> Dr Con Constantinou, Health Manager, Medical Practitioners Board of Victoria, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne 9 July 2007.

<sup>1025</sup> Correspondence from Ms Margaret Quon to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 7 August 2006.

<sup>1026</sup> See for example the submissions to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, from Mr Leon Hain (3 April 2006), Ms Margaret Quon (23 June 2006) and 'Mary' (June 2006). The name of the author of the last mentioned submission has been withheld to protect her privacy and confidentiality.

dependence to pharmaceutical drugs, and who are not illicit drug users, in attending meetings with illicit drug users.<sup>1027</sup>

An alternative to NA is S.M.A.R.T (Self Management and Recovery Training), which facilitates a range of self-help groups including online support, tools and chat rooms. This option may appeal to those people who abuse pharmaceuticals but who are not attracted to the NA philosophy:

S.M.A.R.T. – Self Management and Recovery Training – is a peer managed, self-help group that assists you recover from alcohol and drug use. S.M.A.R.T. Recovery teaches practical skills to help you deal with your problems enabling you to abstain and achieve a healthy lifestyle balance.<sup>1028</sup>

A review of evidence based interventions for alcohol and other drug abusers identified that the evidence in support of self-help groups such as NA or AA as successful and effective treatment mechanisms is largely anecdotal. For example, there have been few controlled trials evaluating their effectiveness. Nonetheless, the review also stated that a lack of non-drug using social supports could be a significant predictor of relapse (Best Practice in Alcohol and Other Drug Interventions Working Group 2000).

Moreover, the literature regarding self-help groups has also indicated that:

- All counsellors should be familiar with self-help groups in their area;
- Irrespective of the theoretical orientation of the agency or its counsellors, AA/NA should be considered as an option for support for some clients; and
- All clients with inadequate non-using/non-drinking social support networks, or with high levels of dependence, should be made aware of AA/NA, and if they are willing to consider the goal of abstinence they should be encouraged to attend for at least three visits (Best Practice in Alcohol and Other Drug Interventions Working Group 2000).

A separate review of self-help literature (Roberts & Berends 2005) similarly supported the use of 12-step based programmes in maintaining continual abstinence and also noted the significant segment of the Victorian treatment system that self-help groups represent:

On a typical day in Victoria in 2002, an estimated 1,590 people attended a self-help group, forming 13 per cent of those attending any alcohol or drug related service and second only to pharmacies (63%) (Roberts & Berends 2005, p.8).

Nonetheless, with the exception of ReConnexion (formerly TRANX), the use of support groups for prescription drug abusers and their families does not appear to have played a great role in the repertoire of treatment and support modalities in Victoria. This is even more the case with regard to patient self-help groups, at least when compared to the groups in existence in Britain, Canada and the United States.<sup>1029</sup>

This is an area that needs to be further explored, developed and supported. Support and self-help groups according to many people, particularly prescription drugs abusers and former abusers, can serve as excellent adjuncts to a range of complementary treatment options and ancillary services to address prescription drug abuse in this state.<sup>1030</sup>

1027 Rightly or wrongly, some people with dependence on prescription drugs but who do not perceive themselves to be 'hard' drug users may be uncomfortable with the idea of attending groups with people who do identify themselves as illicit or 'hard' drug users. These concerns may also extend to receiving (residential) treatment in the same environment as illicit drug users. See for example, the comments of 'Mary' quoted earlier in this chapter.

1028 [http://www.smartrecovery.org/australia\\_website/index.htm](http://www.smartrecovery.org/australia_website/index.htm)

1029 See for example, [www.benzo.org.uk](http://www.benzo.org.uk) for an account of such groups in the United Kingdom, Canada and the United States.

1030 'Anne' and 'Mary', witnesses who have spoken to the Committee throughout this Inquiry about their struggles with prescription drug addiction have also testified to the importance of self-help, peer and mutual support groups in the area of prescription drug abuse. The real names of these witnesses have been changed to protect their privacy and confidentiality.



### ***Future treatment approaches***

The current knowledge base with regard to the efficacy of treatment approaches to prescription drug abuse is not strong. Nonetheless, several potential treatment approaches have been identified for further investigation. An example of this is the use of flumazenil in treating benzodiazepine dependent individuals. The research into flumazenil has been highlighted in a number of submissions.<sup>1031</sup> Flumazenil, a benzodiazepine partial agonist, has been examined in a number of studies and appears to be suitable for further investigation (See for example Gerra et al 2002; Lader & Morton 1992).

Cognitive harms associated with long-term benzodiazepine use require further evaluation and assessment in specific treatment groups, such as those people who are polydrug dependent. In addition, while there is a strong evidence base for opioid substitution treatment in illicit opioid users, similar treatments have not been widely evaluated for acceptability or efficacy in prescription opioid users. Finally, a variety of alternative and complementary treatment and support programmes for addressing prescription drug abuse have been put forward as being of benefit, particularly when used in conjunction with more traditional methods.

It is essential, however, that further research and evaluation of these various modalities is undertaken in order to develop best practice and evidence based approaches to addressing prescription drug abuse.

### **Conclusion**

The treatment of pharmaceutical drug dependence poses a number of challenges to Drug and Alcohol workers and clinicians, not least of which is the ongoing debate as to which treatment modalities are the most appropriate for those dependent on prescription drugs. Issues such as improving access to treatment services, particularly in rural and regional Victoria, developing a robust evidence-base for both pharmacological and non-pharmacological interventions and introducing treatment responses that are culturally appropriate to the needs of specific populations are only some of the matters that will need to be addressed.

The need for further and better resourced research and policy development appears to be as crucial in the treatment field as in so many aspects of prescription drug abuse and misuse. The area of targeted and directed research will be the topic of the next chapter.

<sup>1031</sup> See for example submission of Youth Substance Abuse Service to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

## PART C

# The Way Forward

## Section Eight: Strategies to be Implemented

### 8.1 The Need for Further Research

#### Introduction

A common theme that has arisen throughout the Inquiry is the paucity of appropriately targeted research being undertaken in the area of prescription drug misuse and abuse, particularly in regard to benzodiazepines and opioid analgesics.

This lack of focused research applies not only to medical treatment issues but also more generally to usage issues.

There is a substantial and generally under researched population of benzodiazepine and other pharmaceutical misusers among the general population in absence of illicit drug use (e.g. people who have been prescribed excessive doses for prolonged period of time but do not have alcohol or other drug dependence)...A similar lack of Australian research exists for the market characteristics and patterns of misuse for other types of prescribed pharmaceuticals, despite evidence of emergent illicit markets from studies such as the Illicit Drug Reporting System [IDRS]...There is also a dearth of research examining the efficacy of intervention strategies to reduce benzodiazepines and pharmaceutical opioid use among illicit and licit users.<sup>1032</sup>

In a submission to the Inquiry the Victorian Alcohol and Drug Association (VAADA) stated that statistical data was urgently needed to:

- Help policy makers contextualise responses to the misuse of pharmaceutical drugs relative to those aimed at the misuse of alcohol and other drugs
- Help policy makers assess the value of responding to misuse of pharmaceutical drugs relative to the value of responding to other health and welfare problems

<sup>1032</sup> Submission of Turning Point Alcohol and Drug Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.



- Help policy makers target responses to misuse of pharmaceutical drugs by allowing them to respond to the greatest harms to drug users and to the community more widely
- Help policy makers in the Mental Health & Drugs Division coordinate their work with policy makers in other government departments.<sup>1033</sup>

## The importance of evidence based research

Research plays a crucial and central role in shaping the direction of drug policy, programmes and initiatives in Australia and internationally. The need for evidence based interventions has been widely recognised and accepted by the alcohol and other drugs sector.

The Alcohol and other Drugs Council of Australia (ADCA), argue that research for its own sake is insufficient:

Evidence based practice should be seen as equally important in the areas of policy formulation, policy implementation and direct service delivery. For this ideal to be realised, we need effective, adequately funded structures for the dissemination of research findings to policy makers and practitioners and for feedback from these groups to alcohol and other drug researchers (Alcohol and other Drugs Council of Australia 2003a, p.2).

Australia has an international reputation for the quality of its evidence based research on the prevention and treatment of drug abuse. The major national alcohol and other drug research centres in this country, the National Drug Research Institute (NDRI), the National Drug and Alcohol Research Centre (NDARC) and the National Centre for Education and Training on Addiction (NCETA) produce world acclaimed research to address harmful use of most licit and illicit drugs. At a local level, research institutes such as Turning Point Alcohol and Drug Centre in Melbourne, Victoria, do excellent work.

Notwithstanding the excellent work produced by such research bodies, research into prescription drug abuse, particularly from a qualitative research perspective, does not have such a high profile as that pertaining to licit drugs such as alcohol or illicit substances such as heroin, marijuana and amphetamines. This is particularly the case for the benzodiazepines and opioid analgesics. Organisations such as NDARC in conjunction with the Turning Point Alcohol and Drug Centre track the illicit use of narcotic analgesics, for example morphine and oxycodone, through data collections such as the Illicit Drug Reporting System (IDRS). However, the licit use of benzodiazepines including temazepam, alprazolam and diazepam is not profiled to the same degree. Moreover, most research into improper use of benzodiazepines involves their ingestion by street users, often as a substitute or adjunct drug for illicit substances. Research, particularly good qualitative research, into the inappropriate use of benzodiazepines by other populations seems to be less prevalent. Research into the extent, patterns and culture of use with regard to the licit use of narcotic or opioid analgesics is also insufficient.

As stated by the ADCA:

A need exists, however, for a better balance between research on legal and illegal drugs, and between prevention and treatment...Despite its considerable achievements, the Australian alcohol and other drugs research field experiences a number of problems in the areas of:

- research quality [in some areas]
- evidence based policy development and service delivery
- balance between commissioned and researcher-initiated research
- access to research output
- the operation of human research ethics committees

<sup>1033</sup> Submission of Victorian Alcohol and Drug Association (VAADA) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

- national monitoring systems
- the evaluation and monitoring of outcomes
- the absence of a national drug research strategy (2003a, pp.1–2).

ADCA's call in particular for a balance of investment on research across drug types – licit and illicit – is extremely important.

When Mr Sam Biondo, Executive Director of VAADA gave evidence to the Committee at a public hearing in June 2007 he also stressed the need for research that examines benzodiazepine and opioid analgesic misuse across a wide variety of groups and populations:

There is a clear need for a range of focused research projects. In our view there are large information gaps around the misuse of pharmaceuticals amongst a broad range of population groups, particularly the elderly, the indigenous and CALD (Culturally and Linguistically Diverse) communities. As with issues affecting the elderly there is very limited research on the impact of benzos and other pharmaceuticals on the CALD community, and indigenous communities, and we make a call for specific research in those areas. There is a problem with data collection and research. Along with the call for additional research into misuse on those specific populations I have mentioned, we recommend improvements in the collation of statistical data related to social and criminal harms associated with the misuse of pharmaceuticals. This should be complemented with qualitative research looking at cultures and patterns of polydrug abuse. Essentially we are recommending the use of ethnographic research to better understand those who misuse.<sup>1034</sup>

## Priority areas for research

### *Collation and dissemination of monitoring and other data*

A number of national and state monitoring systems exist with regard to both licit and illicit drugs. Some of the main ones with regard to prescription drug use and abuse include:

- ◆ National Drug Strategy Household Survey (Australian Institute of Health and Welfare (AIHW))
- ◆ Alcohol and Other Drug Treatment Services National Minimum Data Set (AIHW)
- ◆ Australian School Students' Alcohol and Drugs Survey (ASSADS)
- ◆ Clients of Treatment Service Agencies census (COTSA) (NDARC).

Whilst the data collected from these agencies are undoubtedly valuable, a criticism coming from a variety of sources during the course of this Inquiry is that such data are not coordinated across the country, are not readily disseminated and are rarely disaggregated to local level.<sup>1035</sup>

In particular, criticism has been expressed that whilst being collected federally, data with regard to the extent of 'doctor shopping' is not readily available. As discussed in Section Four, the introduction of a prescription drug monitoring programme at state level should address this paucity of data at least in Victoria. It is only through the collection of such data that further research into the cost of 'doctor shopping' to the state and federal economies can be undertaken.

<sup>1034</sup> Mr Sam Biondo, Executive Director, VAADA, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 25 June 2007.

<sup>1035</sup> See for example Evidence provided by Dr Rodger Brough, Drug and Alcohol Physician, South West Healthcare, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Warrnambool, 29 May 2007.



### *Medical and pharmacological research*

Whilst there has been significant research devoted to the pharmacological properties, side effects and clinical efficacy of various prescription drugs including benzodiazepines and opioids, there have been fewer medical research projects that have examined interventions for addressing abuse of these drugs. One research suggestion brought to the attention of the Committee by a number of submissions is the use of the drug flumazenil for treating benzodiazepine dependence and withdrawal. The Interhospital Liaison Group has argued that there is potential for using this drug in hospital based settings and further trials and research into its efficacy are warranted.<sup>1036</sup>

With the growth of the hospital-based addiction services...there is capacity for initiation of new and hospital based therapies to treat dependence on prescription drugs. One such therapy is reversal of benzodiazepine dependence by slow flumazenil (Anexate) infusion. This agent is indicated for overdose of benzodiazepines, and acts by antagonising the effect of benzodiazepines at receptor sites. Growing [research] evidence for its use as a therapeutic agent for the treatment of benzodiazepine dependence is arising from centres in NSW, WA and internationally.<sup>1037</sup>

The Interhospital Liaison Group also believes there is potential for the use of new and emerging treatments for opioid dependence, including dependence on opioid analgesics:

Rapid opioid withdrawal using antagonist agents, or rapid opioid detoxification, is another treatment that has potential for wider use in the hospital setting. This treatment has been available for some years, but is mainly administered in private clinics. It employs the use of opioid blocking drugs (antagonists) to rapidly reverse dependence on opioids. While this treatment has limitations, its use, particularly in public hospitals, has yet to be fully explored.<sup>1038</sup>

Other areas of required medical research recommended to the Committee include:

- ◆ The effect of long-term use of benzodiazepines on cognitive functioning<sup>1039</sup>
- ◆ The long-term efficacy and therapeutic value of benzodiazepines
- ◆ Problems associated with (long-term) withdrawal from benzodiazepine use.

A pharmacological strategy to reduce the abuse potential is the reformulation of drugs by pharmaceutical companies. Reformulation can include:<sup>1040</sup>

- ◆ formulations that affect the solubility of a drug (thereby reducing the potential for injection);
- ◆ adding a drug such as naloxone to buprenorphine. This means that if such a drug is injected an opioid dependent person will experience withdrawal symptoms, but will not experience such an outcome if the drug is taken as intended; or
- ◆ adding a dye, to prevent surreptitious administration of a drug by a sexual predator.

<sup>1036</sup> Currently discussions are being held between Dandenong Hospital and the benzodiazepine support group ReConnexion (formerly TRANX) as to trialling the use of flumazenil in benzodiazepine withdrawal treatment. This is not an intervention that has been uniformly welcomed however, and in certain quarters it is quite contentious. For example, Dr Mike McDonough, Drug and Alcohol Clinician at the Western Hospital, Melbourne told the Committee that such a treatment is largely experimental and unproven. Dr McDonough believed that whilst the use of this pharmacotherapy may merit consideration in the future, further clinical trials of flumazenil need to be undertaken before it could be considered a valid treatment option.

See correspondence of Dr Mike McDonough, Drug and Alcohol clinician, Western Hospital to the Drugs and Crime Prevention Committee, Inquiry into the Misuse and Abuse of Benzodiazepines and other Pharmaceutical Drugs in Victoria, 14 November 2007.

<sup>1037</sup> Submission of Interhospital Liaison Group to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

<sup>1038</sup> Submission of Interhospital Liaison Group to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

<sup>1039</sup> See for example, the submission of Mr Ange Vassallo and Ms Susan Evans to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

<sup>1040</sup> For further discussion on reformulation see Chapter 5.1.

It is the Committee's view that pharmaceutical companies and their peak bodies such as Medicines Australia should be encouraged to continue research and development into reformulating medicines, particularly those with narcotic properties, without jeopardising their therapeutic use for legitimate patients.

### ***Treatment***

As discussed in Section Seven, research needs to be undertaken into the efficacy of various treatments available to address benzodiazepine and opioid analgesic dependence. In addition, there is the need to develop an evidence base for non-drug treatments for pharmaceutical dependence and specialist treatment services (including specialist programmes within existing treatment services and other health services).

An encouraging move in this direction is a project currently being jointly undertaken by state and federal governments. The Victorian Department of Human Services through the National Intentional Misuse of Pharmaceuticals Prevention Initiative has contracted Turning Point Alcohol and Drug Centre, with partner organisations in Tasmania, WA and Queensland:

[t]o investigate the role of pharmaceutical drugs in clients presenting for treatment to drug and alcohol treatment agencies, and to examine the nature and extent of diversion and intentional misuse of pharmaceutical drugs, and associated health harms, within this group. This project is due for completion in mid 2008.<sup>1041</sup>

The Department of Human Services has also contracted Dr Raymond Martyres of the Melbourne Division of General Practice to undertake a project to examine the patterns and role of drug-seeking behaviour for prescription drugs prior to heroin-related and methadone-related deaths in Victoria.<sup>1042</sup>

Whilst such projects will make important contributions to understanding the treatment needs of prescription drug abusers, it is essential that further research be undertaken to respond to the unmet needs of those affected by pharmaceutical misuse.

For example, one particular research issue that could be examined is developing alternative pain management techniques to address acute and chronic pain conditions, and whether these treatments could be provided in mainstream locations in addition to specialist pain clinics.

### ***Qualitative, ethnographic and cultural research***

Qualitative or social research, particularly ethnography, does not concentrate only on the epidemiology and pharmacology of the drug or the individual psychology of the user. It also examines the social context within which these two variables are located and the values, beliefs and sanctions that are brought to drug use by various individuals and social groups (Moore 1992). It is the interaction between the drug taken, the individual psychology of the user, and the cultural or social milieu in which it is taken that is crucial in attempting to understand drug use and thus formulate appropriate interventions (Zinberg 1984).

Much ethnographic research, particularly that which is based on participant observation, also takes place in the natural settings of the user. Such a method also does not concentrate exclusively on the negatives, problems or harms of drug use. Researchers, educators and policy makers need to understand the social world of the drug user in formulating effective interventions to reduce the harms associated with the drug.

1041 Correspondence from Gill Callister, Executive Director, Mental Health and Drugs Division Department of Human Services (Victoria) to the Drugs and Crime Prevention Committee, 13 November 2007.

1042 Correspondence from Gill Callister, Executive Director, Mental Health and Drugs Division Department of Human Services (Victoria) to the Drugs and Crime Prevention Committee, 13 November 2007.



The Australian Drug Foundation has recommended a range of research agenda items that are qualitative in nature, including:

- Research, including monitoring for trends and development of effective prevention strategies, into older people using prescription and over the counter medication who also engage in recreational drug use, including alcohol.
- Research into community attitudes and practices regarding over the counter medications, particularly painkillers.
- Research into community understanding and practices regarding pharmaceutical drug use (especially benzodiazepines) and driving practices.<sup>1043</sup>

In short, social research, particularly ethnography, promotes the 'insider' view of drug use as understood by the users themselves. Moore explains that:

Various types of drug experts, policymakers and law enforcement personnel all contribute to the formation of policy and practice but drug users, who are presumably entitled to some say in policy which affects them, do not. Their view is labelled 'anecdotal' and given little intellectual, political or social weight (Moore 1992, pp.82–83).

The Western Region Health Centre also argues that it is important to 'Conduct further research into the culture and attitudes to benzodiazepine use among benzodiazepine users'.<sup>1044</sup>

### *Prescription drug use and abuse and its relationship to driving*

Drug driving is an extremely complex issue. Whilst there is increasing evidence that some pharmaceutical drugs, particularly benzodiazepines, are evident in a considerable number of road accidents and road trauma, there has been limited research undertaken in the area.<sup>1045</sup> A recent study undertaken for the Australian Drug Foundation (ADF), *Drugs and Driving in Australia* (Mallick et al 2007), has already been discussed in the context of the harms associated with drug driving and the need for education strategies to address this. It also makes a number of pertinent observations with regard to the need for further research in the area of drug driving generally and the issue of driving whilst using prescription drugs specifically:

Clearly, pharmaceutical drugs are a very complex issue from a road safety perspective. Not only is there a huge variety of classes of pharmaceutical drugs, with differing levels of potential for impairment, but there are issues around patterns of use (for example, whether taken according to therapeutic dose) and the impact of pre-existing medical conditions. These are all areas in need of further research, to enable clear information to be provided to drivers (Mallick et al 2007, p.45).

It is apparent that far more research needs to be undertaken to ensure that any counter measures developed to address the problem are evidenced based. Mallick et al list numerous areas requiring further exploration. In particular there is an urgent need for further research that determines the extent and nature of pharmaceutical drug driving on Australian roads. In particular the Report recommends that:

'Better techniques need to be developed in order to gain an accurate indication of the prevalence of pharmaceutical drug-impaired driving' (Mallick et al 2007, p.96)

In particular it is argued that any future research needs to utilise methods that are able to gain a more rigorous measurement of impairment alongside prevalence data:

<sup>1043</sup> Submission of the Australian Drug Foundation to the Drugs and Crime Prevention Committee, *Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria*, June 2006. The need for further research into the relationship between benzodiazepines and driving practices is discussed below.

<sup>1044</sup> Submission of Western Region Health Centre to the Drugs and Crime Prevention Committee, *Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria*, July 2006.

<sup>1045</sup> See also Chapter 3.2 for a discussion of drug driving and the law and Chapter 6.2 for an examination of the need to provide educational information to drivers with regard to driving whilst using pharmaceutical and prescription drugs.

'There is a need for more research to examine pharmaceutical drug driving on Australian roads at the general population level' (Mallick et al 2007, p.96).

For example, the Report states that questions regarding pharmaceutical drug driving 'should be added to routinely collected population-level surveys, such as the NDSHS' (Mallick et al 2007, p.96).

The Report also states 'there is a need for more research to examine pharmaceutical drug driving within specific groups. For example, the gender differences in terms of propensity to drive within three hours of using benzodiazepines (that is, to ascertain why more males take drugs and drive)' (Mallick et al 2007, p.97).

The Report also strongly recommends that further research is needed on the issue as to: 'whether pharmaceutical drugs are being used according to prescription, or without a prescription, and the impact upon driving ability and road safety, requires further investigation' (Mallick et al 2007, p.97).

Just as important as the issue of the *extent* of pharmaceutical drug driving are questions related to the nature of the impairment or effect on driving performance through the ingestion of pharmaceutical drugs either prior to or during the course of driving.

As the Report states:

it is crucial that further research is conducted to ascertain reliable and accurate data as to the impairing effects of pharmaceutical drugs. These findings will contribute to the development of evidence-based, education and information countermeasures (Mallick et al 2007, p.97).

One important research question for example would be what effect does the development of tolerance to various prescription drugs have on driving performance? Similarly, the question of how benchmarks can be developed that calibrate dosage with driving performance is an important issue that requires much further research attention.

Pharmaceutical and prescription drugs, particularly benzodiazepines clearly give rise to concern in the context of road safety and driving. They are, however, perceived to be less impairing to driving ability than either alcohol or illicit drugs (Mallick et al 2007, p.95). Issues pertaining to pharmaceutical drug driving are also further complicated by the fact that drivers may use the drugs in one of three ways – according to prescription, not used according to prescription or used illicitly [without a prescription] (Mallick et al 2007, p.96). Moreover there is limited evidence to suggest that in some cases following regular stable use prescription drugs may in fact enhance or improve driving ability (Mallick et al 2007, p.97). These complicating factors and further issues for consideration show just how important it is that further research of both a scientific, medical and sociological nature utilising a variety of methodologies needs to be undertaken with regard to pharmaceutical drug driving in Victoria.

## **The need for evaluation**

Evaluation research provides a useful but often under-utilised resource to decision-makers. Should resources be devoted to those policies that have at best a modest effect, or should they be directed to policies that have a chance for a broader and more substantial impact? Decisions about which strategies to implement, phase out, or modify should be informed by findings from systematic evaluation (Babor et al 2004, p.98).

Dietze notes that in the Australian context many community programmes, and particularly education programmes, claim to prevent alcohol and other drug problems 'but there is often little evidence to indicate whether or not the program has achieved significant change' (Dietze in ADCA 2003b, p.16).

Many drug prevention and intervention programmes are not formally evaluated, which may often be due to the smallness of the project and/or the lack of resources available to the implementers. In addition, sometimes the objectives of programmes are not clear; for example, is the programme about preventing the use and uptake of drugs or about reducing



harms associated with drug abuse. As noted above, this is particularly the case with education programmes:

A...problem with evaluating drug education is defining 'effectiveness'. Effectiveness can be measured by an increase in knowledge about alcohol and other drugs, a change in attitudes, or a change in behaviour, the latter being the most difficult to measure. It has been argued that most drug education programs are not formally evaluated and those that are tend to be evaluated at a superficial level... A formal review of the Victorian Government's strategy to enhance and sustain drug education in Victorian schools found that while there had been close monitoring of the development of drug education programs in government schools, there had been no monitoring of changes in student knowledge, attitudes and social competencies that may arise from drug education programs (ADCA 2003b, p.13).

There is a need for some objective key indicators that can measure the effectiveness (or otherwise) of efforts to address prescription drug-related harms. Ideally, such indicators could be developed at national, state and local levels and include data on a wide range of subjects (crime rates, hospitalisation and ambulance attendances, treatment outcomes).

Further evaluation of the outcomes is essential not only in terms of cost effectiveness but also in ensuring that the interventions implemented to address problematic prescription drug use are best practice and result in positive outcomes.

## Further research

### *Benzodiazepine use and young people*

The Youth Substance Abuse Service (YSAS) has stressed the importance of further research into the reason why young people, particularly young marginalised people with a history of developmental trauma, may use benzodiazepines, either on their own or more commonly in conjunction with illicit drugs, alcohol or, increasingly, antidepressants and/or anti-psychotic drugs.<sup>1046</sup>

According to YSAS, it is also important to ascertain why and when benzodiazepines may become a drug of choice. Is it, for example, in response to some external circumstance such as the so-called 'heroin drought' apparent in 2000–2002. Or is it through a 'desire to potentiate the euphoric/sedative effects of other drugs including alcohol, methadone and buprenorphine?'<sup>1047</sup>

### *Benzodiazepine use by men*

A submission from the Darebin City Council recommends that, 'There is a need for further research to be carried out to identify the impact of benzodiazepines on men'.<sup>1048</sup> The major research project (in conjunction with Moreland City Council) that examined prescription medication misuse within their respective communities found it was relatively easy to examine the issue of benzodiazepine use and abuse by women in the municipalities, largely due to the 'established health structure through which women could be contacted'. However, it was almost impossible, despite some attempts to contact men's health and support services, to look at benzodiazepine use and misuse by men, even though 40 per

1046 The Australian Drug Foundation supports calls for research in this area. In a submission to this Inquiry they state there is a need for:

'Research, including monitoring for trends and development of effective prevention strategies, into pharmaceutical drug use by young people who are on prescription drugs for behavioural disorders, anxiety and/or depression, and who are also engaging in recreational drug use' (Submission of the Australian Drug Foundation to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006).

1047 Submission of Youth Substance Abuse Service to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

1048 Submission of Darebin City Council to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

cent of hospital admissions due to medication overdose in the local government areas were by men.<sup>1049</sup>

Darebin Council's research also is indicative of the need for good quantitative and qualitative research conducted at micro or local level for local communities.

### *Benzodiazepine use by multicultural and Indigenous communities*

There is limited research regarding the extent of misuse of benzodiazepines and other pharmaceutical drugs within Victorian culturally and linguistically diverse communities. Many representatives from ethnic communities made this observation when they met with the Committee at the Forum for culturally and linguistically diverse communities held in July 2007:

There is not a lot of research in the field of prescription drug abuse [and migrant communities]. There is no concrete data to show that migrant communities are more vulnerable to the risk of misuse of prescription drugs. Everything is anecdotal from friends, family and co-workers. It is evident that some migrant communities are not exposed to western medication in the country they come from, especially rural parts of some countries like South America or Africa. Taking tablets is something very foreign to them...There definitely needs to be some more research in this field as to whether culture actually plays an effect on the misuse of [prescription] drugs.<sup>1050</sup>

Another participant at the forum made similar observations:

The first question is about the extent of the misuse and abuse in the CALD [culturally and linguistically diverse] community. We noticed that there is limited research in this area, but anecdotal evidence actually suggests there are some concerns around prescription medication. Older members of CALD communities tend to abuse their medication more than others, especially for some older women over 50 years. We say that they actively abuse medication more than others. However, this varies between different communities. Even though there may be information those people may not have access to that information. They may be isolated or they may be new to the community so they do not know where to get that information.<sup>1051</sup>

The submission from VAADA stated that anecdotal evidence it has received suggests:

That misuse of pharmaceutical drugs is commonplace among these population groups. VAADA considers that research is needed to examine the misuse of benzodiazepines and other pharmaceutical drugs among CALD and Indigenous communities. Specifically it should examine issues such as:

- Harms related to stigma associated with misuse of pharmaceutical drugs
- Problems associated with delivering education, prevention, and treatment services to CALD and Indigenous communities
- Complications arising from misuse of pharmaceutical drugs in a context of polydrug use.<sup>1052</sup>

1049 Submission of Darebin City Council to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

1050 Ms Wesa Chau, Multicultural Network Coordinator for north-west CALD partnership, Action on Disability within Ethnic Communities, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, CALD Communities Prescription Drug Forum, Parliament House, Melbourne, 9 July 2007.

1051 Mr Jacob Lee, Manager, Aged Care and Disability, South Eastern Region Migrant Resource Centre, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, CALD Communities Prescription Drug Forum, Parliament House, Melbourne, 9 July 2007.

1052 Submission of VAADA to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.



### *Locations of diversion*

The pharmaceutical company Mundipharma has argued that insufficient attention has been paid to identifying diversion locations. In other words, research is needed to ascertain the geographical locations in which prescription drug abuse, 'doctor shopping' and prescription drug diversion is most prevalent: 'This will allow for more effective targeting of existing and future programs' in addressing prescription drug abuse.<sup>1053</sup>

### *Accessing prescription drugs from the Internet*

As discussed in Chapter 5.3, the worrying trend of people, particularly young people, accessing prescription drugs, including opioid analgesics, through unauthorised Internet pharmacies does not appear to be confined to the United States, the country where such practices are most prevalent. The problem is, however, that there has been little research undertaken in Australia to determine the extent of the problem in this country. This is a gap in our knowledge of prescription drug abuse that needs to be remedied.

### *Prescription drug use and the workplace*

There has been very little research undertaken into the effect of prescription drug abuse on workers and in the workplace, particularly with regard to workplace accidents and injury caused through their ingestion.<sup>1054</sup> Despite this paucity of research, a variety of organisations have told this Inquiry that this is an area of concern and one that requires further research. For example, Ms Bev McIlroy, Service Manager, Glenelg and Southern Grampians Drug Treatment Service, spoke of the experience of prescription drug abuse among workers in engineering companies in the south-west region of Victoria. When a drug-testing programme was initiated, whilst it was expected there might have been some evidence of alcohol, marijuana and amphetamine ingestion, the levels of prescription drugs found, particularly benzodiazepines, were surprising:

In Portland we have several engineering companies, such as Alcoa, Kempe Engineering, Silcar Engineering and Prince Engineering, all of whom have invited us to be part of their education program. They invited us in because urine drug screen testing is about to become part of their new drug treatment plans. They have not quite gone as far as random urine drug screens. They are waiting to see what the next federal government election does, I think, but that was their intent.

What they actually found people talking about was alcohol use and driving to work whilst still under the influence of alcohol. They then started talking about benzos. It was not only their own use of benzos, which was high, but the effect that benzo use in their family setting had on their work performance, whether it be the wife taking the benzos and cannot look after the family, or a lack of sleep at night because of a whole heap of other things that could be affected by benzos. There is a lot of chronic pain medication out there; people are under the influence of that pain medication. These are people who are working in smelters, in very high-risk areas.<sup>1055</sup>

<sup>1053</sup> Submission of Mundipharma to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

<sup>1054</sup> The Committee sought information from WorkSafe Victoria with regard to any interventions or programmes that may exist which address prescription drug use and misuse in Victorian workplaces. Correspondence from the Minister for WorkCover, Mr Tim Holding MP stated:

'At this stage WorkSafe Victoria's system for coding drug use related injuries does not differentiate between drug types. Consequently, WorkSafe is unable to precisely determine the extent of benzodiazepine and other prescription drug abuse in Victorian workplaces' (Letter from the Hon Tim Holding MP, Minister for Finance, WorkCover and the Transport Accident Commission, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 20 September 2007).

<sup>1055</sup> Ms Bev McIlroy, Service Manager, Glenelg and Southern Grampians Drug Treatment Service, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Warrambbool, 29 May 2007.

The Committee also received anecdotal evidence from the South Australia Police Service to the effect that in South Australia 'there is a high number of people involved in workplace injuries, particularly tradesmen who have drugs in their system'. A high percentage of those drugs were benzodiazepines.<sup>1056</sup>

Ms McIlroy and other groups with whom the Committee met reinforced the need to examine further the links between prescription drug abuse and workplace accidents.<sup>1057</sup>

## Conclusion

The Committee believes that any strategies, interventions or policies aimed at addressing prescription drug misuse and abuse must be based on the best available evidence and/or best practice.

Policy makers should be more involved in the research process. Garretsen and Van de Goor suggest that policy makers and prevention workers should be involved in joint meetings with researchers and, conversely, that researchers can learn a lot from the 'hands on' experience of those working in policy and in direct alcohol and other drug practice (2004, p.148).

Up-to-date and focused research that covers a range of quantitative and qualitative methodologies is an essential aspect of delivering effective policy outcomes in this complex area of drug use.

<sup>1056</sup> Superintendent Paul Dixon, Drugs Unit, South Australian Police Service, Meeting with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Adelaide, 18 May 2007.

<sup>1057</sup> See also the evidence of participants in the Drugs and Crime Prevention Committee Prescription Drug Forum, Bendigo, 20 May 2007.



The Commission also reviewed evidence submitted by the Victorian Government and the Victorian Health Services Commission (VHSC) in response to the Commission's request for information. The Commission also reviewed evidence submitted by the Victorian Health Services Commission (VHSC) in response to the Commission's request for information. The Commission also reviewed evidence submitted by the Victorian Health Services Commission (VHSC) in response to the Commission's request for information.

## Conclusion

The Commission's investigation into the misuse/abuse of benzodiazepines and other forms of pharmaceutical drugs in Victoria has identified a number of key findings. The Commission has found that there is a significant problem of misuse/abuse of benzodiazepines and other forms of pharmaceutical drugs in Victoria. The Commission has found that this problem is caused by a number of factors, including the over-prescription of these drugs, the lack of adequate monitoring and control, and the lack of adequate education and training for health professionals. The Commission has found that the Victorian Government and the Victorian Health Services Commission (VHSC) have a responsibility to address this problem. The Commission has found that the Victorian Government and the Victorian Health Services Commission (VHSC) have a responsibility to address this problem. The Commission has found that the Victorian Government and the Victorian Health Services Commission (VHSC) have a responsibility to address this problem.

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## 8.2 Concluding Remarks

This Final Report has demonstrated the complexity of responding to the misuse and abuse of benzodiazepines and other forms of pharmaceutical drugs. The Inquiry has focused on two major groups of drugs that are misused: benzodiazepines and narcotic analgesics.

The Committee acknowledges that there are clear benefits associated with the safe and effective prescription and use of these drugs. However, evidence presented in this Report has shown that there can be substantial harms for individuals, their families and the broader community if these drugs are not used safely and effectively and/or if they are intentionally misused. A major problem associated with pharmaceutical drug misuse is that many people in the community do not equate it with illegal or other harmful drug use. To some extent, compared to the attention given to illegal drugs, the issue has also been neglected by policymakers. As a result, the responses to the harms caused by pharmaceutical drug abuse have been inconsistent in terms of availability and quality. The Committee has been particularly concerned by evidence which suggests that some doctors continue to prescribe these medicines inappropriately despite the existence of professional and clinical guidelines and standards.

A range of legislative responses, regulations and practice guidelines have been developed and implemented that directly and indirectly aim to ensure quality prescription, dispensing and use of medicines and to prevent pharmaceutical misuse. Other responses have included prevention and information strategies, legal and regulatory reform, policing initiatives and new treatment services.

Nevertheless, despite such valuable efforts, pharmaceutical misuse continues to contribute to significant harm in the community. There are many issues pertaining to pharmaceutical drug misuse/abuse that this Committee has explored.

### **Findings of the Drugs and Crime Prevention Committee**

The following discussion reiterates some of the key views that the Committee holds with regard to the direction in which prescription drug misuse and abuse can be addressed and associated strategies be developed and implemented.

#### ***Research***

Research that can inform evidence based strategies to address harmful use of prescription drugs is an essential aspect of developing and implementing good policy in this area.

In the process of preparing this Report, it was evident that there were gaps in the evidence base. There are many research issues pertaining to pharmaceutical drug misuse/abuse that this Committee believes need to be explored in greater detail. These include:

- ◆ The long-term effects of benzodiazepines, in particular, the impact of long-term use on cognitive functioning;
- ◆ The long-term efficacy and therapeutic value of benzodiazepines and any problems associated with withdrawal from these drugs;
- ◆ The development by the pharmaceutical industry of 'tamper proof' prescription drugs;



- The extent to which prescription drugs can be purchased, accessed or traded on illegal Internet sites;
- The issue of 'doctor shopping' in Victoria and Australia. Such research should not only address the extent to which 'doctor shopping' occurs in Australia but also the cost of this practice to the economy;
- Current and emerging treatment modalities for benzodiazepine abuse and their effectiveness;
- The extent of misuse and abuse of prescription medication in particular communities such as culturally and linguistically diverse communities, Aboriginal communities, and among young people and elderly people; and
- The diversion of prescription drugs, including for profit, as a means of accessing illicit drugs and for drug sharing.

### **Driving impairment**

One specific area of research that is required as a matter of urgency is inquiry into the links between prescription drug use and driving impairment. In particular, the possibility of establishing benchmarks at which to measure impairment due to the ingestion of benzodiazepines needs to be explored. Research is also needed to determine to what extent people who are using prescription drugs legitimately and under a validly authorised prescription are affected by these drugs in terms of driving performance, and should their rights to drive be circumscribed in such circumstances?

### **Formulation of drugs**

There is also a need to review the procedures for new formulations and examine the benefits of reformulating some medicines. Pharmaceutical companies are constantly developing new formulations of drugs to enhance effectiveness and reduce side effects. In some countries, systems are being developed to ensure that any deleterious and unintended consequences do not increase the potential for misuse and/or increase the risks associated with that misuse. It is important that pharmaceutical companies are encouraged to consider the value and practicality of such a system in Australia. Pharmaceutical companies have also reformulated medicines to reduce their abuse potential. They should also be encouraged to explore the potential of such strategies.

### **Evaluation**

In addition to new research programmes and research agendas, it is crucial that any programmes or interventions developed and implemented to address prescription drug abuse are subject to initial and ongoing evaluation.

### ***The need for effective information and monitoring systems***

Quality information and monitoring systems are a crucial aspect of developing a range of effective strategies to help prevent and reduce pharmaceutical misuse. Although there have been some information/advisory and monitoring services developed to try to reduce 'doctor shopping/prescription shopping', the programmes that are currently available, including the Medicare Australia Prescription Shopping Service, could be improved. The Committee believes it is essential that a real-time online prescription drug monitoring programme is introduced at state level with the possibility that eventually such a programme is rolled out on a national basis. A new monitoring system for Victoria ideally should:

- Identify community-wide patterns of pharmaceutical drug use and misuse;
- Assist in ensuring quality prescribing and dispensing practices;
- Assist in the implementation of effective compliance measures;
- Reduce intentional and inadvertent over-prescription;

- ◆ Identify individuals who are 'doctor/prescription shopping';
- ◆ Help in patient diagnosis and development of individual treatment plans;
- ◆ Assist in quality patient management, i.e. be used as a therapeutic rather than punitive tool;
- ◆ Assist in preventing diversion; and
- ◆ Contribute to effective monitoring and evaluation of other responses to pharmaceutical misuse.

Ways will need to be found to align any new prescription drug monitoring programme in Victoria with those already existing at Commonwealth level.

As identified by a number of people who responded to this Inquiry and as witnessed by the Committee during its tour of North America, a combination of the best features of the PharmaNet system in British Columbia and some of the American systems could be optimal in the Victorian context.

### *Electronic prescribing of prescription drugs*

New Internet and web technologies are capable of being used to illegitimately access prescription drugs through unauthorised cyber pharmacies. Conversely, new technology can also address prescription drug abuse. For example, with regard to prescription fraud and forgery, it is conceivable that the introduction of an electronic prescribing service will help reduce the opportunities for people to forge or present forged prescriptions to pharmacies in the future. As such, the Committee considers it appropriate that consideration be given to a system of electronic prescribing being developed on a state-wide basis with a view to the Australian Health Ministers' Conference recommending the implementation of such a system at a national level.

### *Scheduling and quality of prescription drugs*

One of the key issues discussed in this Final Report has been the need for good prescribing practices in reducing benzodiazepine and opioid analgesic drug abuse. To address this the Committee considers there needs to be consultation with the relevant medical and pharmacy bodies with the object of conducting a review into the current prescription drugs permit system and drug controls. Such a review should include but not be restricted to:

- ◆ Whether benzodiazepines as a general class of drug be considered for rescheduling to schedule 8 by the National Drugs and Poisons Schedule Committee (NDPSC);
- ◆ Whether alprazolam (Xanax) only be considered for rescheduling to schedule 8 by the NDPSC;
- ◆ Whether there should be consideration of revised regulations and guidelines for the prescribing of benzodiazepines, and in particular whether consideration should be given to the period for which benzodiazepines are permitted to be prescribed (including the prescribing of repeats).

Another important issue that requires consideration is the issue of the package size and amounts of drugs that can be prescribed to a patient during any one consultation. It is the belief of the Committee that unless circumstances otherwise require, there is no need to package prescription drugs in amounts that are more than necessary for short- to medium-term therapeutic needs. A review of the current arrangements into the packaging of pharmaceutical drugs is therefore timely.

### *The need for both general and targeted education and information programmes*

#### **General information campaigns**

A range of information and education programmes have been developed for patients and the general community on the dangers of inappropriate prescription drug use and abuse. Nonetheless, there appears to be variable knowledge about the risks associated with misuse



of pharmaceutical drugs. Many people in the broad community, including users and misusers of benzodiazepines and narcotic analgesics, are ignorant of, or underestimate, the risks. Throughout the deliberations of this Inquiry it was apparent that a barrier to effective intervention, at individual and community levels, was the perception by many that pharmaceutical misuse was not a major concern, and was not equivalent to other forms of drug dependence. It is crucial that any strategies emanating from this Report respond to this misperception, as it has implications for the implementation of effective prevention and treatment strategies.

Although a number of organisations have developed and disseminate relevant information with regard to those drugs, there are some gaps in the information provided. It is apparent that a more systematic and coordinated approach is needed.

As such the Committee believes that a state-wide comprehensive general information campaign should be developed. This campaign should include information on the:

- ◆ Risks and harms associated with misuse
- ◆ Questions to ask your doctor and pharmacist
- ◆ Negative effects of sharing medication
- ◆ Appropriate storage of medicines; use-by dates and appropriate disposal
- ◆ Treatment options and support services
- ◆ The harms associated with poly drug use.

The Committee also considers that this information should be targeted to particular demographic groups such as middle-aged drug users, young people, culturally and linguistically diverse communities, Indigenous groups, older-aged users, males (all ages) and intravenous drug users. The information should be tailored to meet their specific needs.

### **Professional groups**

Professional education and training at undergraduate, postgraduate and ongoing levels needs to more comprehensively prepare doctors, pharmacists and allied health professionals to use best practice in prescribing and dispensing benzodiazepines, opioid analgesics and other prescription drugs. Good prescribing is a skill that needs to be developed as the result of a concerted period of intense training and experience in the field. It is apparent that there is room for improvement in current methods of training with regard to good prescribing practices.

In particular, the Committee believes that relevant professional bodies, universities and other organisations develop and deliver undergraduate, professional and ongoing education and training for Victorian doctors, nurses and allied health professionals on best practice benzodiazepine and opioid analgesic prescribing and management. Such training should be updated regularly and provided on an ongoing basis. The Committee considers that such training could include:

- ◆ Risks associated with long-term use of benzodiazepines and analgesic opioids;
- ◆ Importance of regular reviews of benzodiazepine dosing;
- ◆ Alternatives to pharmacological treatments for patients suffering from pain, anxiety or sleep disorders;
- ◆ Appropriate management of benzodiazepine withdrawal (including tapering);
- ◆ Identifying signs of dependence in patients and making appropriate referrals to a service that can appropriately manage that person's misuse or abuse; and
- ◆ Importance of liaison and communication between general practitioners and pharmacists at a local level.

The Committee considers that education and training on benzodiazepine and opioid analgesics prescribing, management and treatment should be a compulsory requirement of undergraduate and postgraduate education and training, as well as ongoing professional

development for doctors. Moreover, the Committee believes that the Medical Practitioners Board of Victoria should take responsibility for ensuring that this occurs. A useful comparison can be made with the Australian legal profession. As it stands, legal practitioners in all Australian states have a requirement to undertake a minimum number of professional development activities each year. The amount to be completed is governed by the state or territory in which they practice. For example, all legal practitioners who hold a Victorian Practising Certificate are required to complete 10 hours of continuing professional development activities every year (even if the holder practises interstate or overseas).<sup>1058</sup> The Committee is of the view that a comparable system of mandatory continuing medical education should be introduced for doctors in Victoria.

Pharmacists and nurses are also an important professional group for whom information and education strategies must be further developed. For example, the Committee considers that undergraduate education and training and postgraduate and ongoing professional development should be provided to pharmacists on:

- ◆ Best practice benzodiazepine and opioid analgesic dispensing and pain and sleep disorder management;
- ◆ Pharmacists' duty of care to patients/clients;
- ◆ Customer education with regard to taking benzodiazepines and opioid analgesics; and
- ◆ Alternatives to pharmacological treatments for patients suffering from pain, anxiety or sleep disorders.

The Committee believes that the Pharmacy Board of Victoria and the Nurses Board of Victoria respectively be assigned responsibility for ensuring that Victorian pharmacists and nurses receive ongoing education and training on benzodiazepine and opioid analgesic use and management.

The Committee also believes that pharmacy organisations should encourage their members wherever practicable to provide counselling rooms/private space for detailed consultation and advice.

#### *The need for better treatment models and services*

The Committee has carefully examined all the evidence and considers there is a need to investigate emerging treatment models in this area including non-pharmacological treatments for anxiety, sleep disorders and pain management. The Committee also believes it is essential to establish additional specialised treatment services for pain management, either through stand-alone pain clinics or through specialist pain services attached to mainstream services such as Community Health Services.

Another issue of importance is whether discrete forms of treatment for dependence to drugs such as benzodiazepines are appropriate or should prescription drug dependence continue to be treated through the mainstream and non-differentiated alcohol and drug services. The Committee believes that benzodiazepine-specific treatment services, including inpatient withdrawal, do need to be established.

In particular, further resources need to be provided to extend the drug treatment services available in rural and regional Victoria.

There is also a need to extend the number of Aboriginal community based and managed holistic healing centres available. Such centres should be equipped to cater for

<sup>1058</sup> See website of the Law Institute of Victoria for details, at <http://www.cpd.liv.asn.au/categories.asp?clD=4&c=254932>.



the specific cultural needs of Aboriginal communities with regard to substance abuse issues including the misuse of benzodiazepines and opioid analgesics.

The Committee also believes some structural changes need to be implemented to facilitate better services for patients undergoing treatment for drug abuse. In particular two reforms are necessary.

First, where appropriate, the current length of stay for patients going through benzodiazepine withdrawal should be extended and funded accordingly.

Second, it is the Committee's belief that currently doctors and other health professionals have insufficient time to consult with patients on alternative treatments for conditions such as sleep disorders, anxiety and pain management. Given the constraints of the current system it is understandably easy for medical practitioners to rely solely on pharmacological measures (i.e. prescriptions) to treat these conditions. As such the Committee recommends that the Victorian Minister for Health propose at the next Australian Health Ministers' Conference that Medicare Australia develop extended consultation times and Medicare billing codes that will enable doctors to adequately explore non pharmacological treatments for these conditions where in the opinion of a medical professional such treatments are clinically warranted.

Finally, the Committee believes that it is not only the immediate treatment needs of those suffering from prescription drug abuse that need to be addressed. There is also a need for ongoing support, including the extension of self-help and support groups. The benzodiazepine abuse support group ReConnexion serves as a good model in this area. Similarly, the needs of family and friends of people who abuse prescription drugs must be taken into account in any overhaul of treatment and management services.

### *The need for a range of harm reduction strategies*

Even the best prevention and treatment strategies need to be accompanied by harm reduction strategies – some people will continue to divert and misuse these medications, potentially causing harm to themselves and other people. People who misuse such drugs can experience a range of harms such as increased risk of overdose, increased risk of aggression and violence, increased risk of vascular injury and disease, and other health problems. In particular, the Committee believes that it is important to ensure that there are adequate harm reduction services in place for those who misuse pharmaceutical substances, either alone or in combination with other drugs. This is especially true for those who administer these drugs by injection. As such, the Committee has recommended that resources be provided for Victorian Needle and Syringe Services to deliver ongoing health education programs for injecting drug users. Such programs should include specific information on benzodiazepines and narcotic analgesics.

While needle and syringe programmes, consumer organisations and drug treatment services are critical contributors to providing advice about reducing the harms associated with pharmaceutical drug abuse, there will be many at-risk people who do not perceive these services as being valid to their needs. This might include those who see their pharmaceutical misuse as being distinct from other harmful drug use. Older patients and users of these drugs from some culturally and linguistically diverse groups may fall into this category. Therefore it is important to acknowledge that the nature of harm reduction strategies, the content of such strategies and the most appropriate modes of delivery of harm reduction information will vary between various target groups.

### *The need to engage in extensive consultation*

There is a wide range of people who have a role in preventing and responding to pharmaceutical misuse. Pharmacists, medical practitioners and nurses are obvious examples of such groups. However, effective responses will also involve, for example,



the police, consumer groups, local governments, hospitals, needle and syringe programmes, drug specialist services, the pharmaceutical industry, coroners, legislators and those responsible for monitoring pharmaceutical use. While it is evident that a number of these groups have developed responses that are consistent with quality practice, there is little evidence of coordination across the various sectors. Strategies and interventions must enhance coordination of prevention, harm reduction, treatment and other responses.

***The need to manage the tension between the benefits and costs of the use and misuse of benzodiazepines and other forms of pharmaceutical drugs***

Throughout the Inquiry it was apparent that any effective responses to pharmaceutical misuse must carefully address the tension between the benefits of safe and effective use of these drugs and the risks of misuse. It is imperative that any future interventions developed to address pharmaceutical drug abuse do not negatively impact on those people who are using these drugs for legitimate purposes.

***The use of new technologies: Internet access to prescription drugs***

One area that will need to be examined in further detail in the next few years is the issue of accessing prescription drugs from unauthorised cyber pharmacies. The Internet is a relatively new source of legitimate and illicit pharmaceutical drugs. The Internet is also a potential source of information and advice that might be used to prevent and respond to pharmaceutical misuse. The relative recency of this source of medication and information about drug use means there is limited evidence about its impact. Whilst the access to these drugs through such measures does not seem to have reached the same level in Australia as it has in the United States, there are some indications that there is an upward trend in the use of the Internet to access these drugs for both therapeutic (self-medication) and recreational reasons. More research and data analysis is needed in this area to determine the extent of this trend. Whatever strategies are put in place with regard to the use of the Internet to access pharmaceutical drugs, it is true that to a large degree Internet use is an international phenomenon with consequences that cross national boundaries. Therefore any comprehensive solution to the problems associated with 'cyber-pharmacy' need to be tackled concurrently at national and international level. The Committee therefore considers that a World Health Organization or United Nations sponsored international convention on unauthorised Internet access to prescription drugs is a necessary strategy to combat unauthorised use of Internet pharmacies and requests the Commonwealth government to advocate for such.

## **A Final Note**

Perhaps more than any other single issue, the most difficult of the challenges posed by this Inquiry is countering the perception that prescription drugs are somehow not 'drugs of abuse' nor cause dependency. Challenging the culture of drug use and abuse, indeed contesting ideas as to what does or does not count as a 'drug', is a very difficult task. Alcohol and 'pills', it would seem, simply are not viewed with the same gravity as heroin or 'designer' drugs.

Australia, and in particular Victoria, is not unique in facing the challenges of prescription drug abuse. In a recent American review it was concluded that:

If we are to curb this growing problem [of prescription drug abuse] and curb its disastrous consequences, we must train doctors, pharmacists and other healthcare professionals to spot the problem and know how to respond; educate the public about risks; tailor prevention and intervention to the unique characteristics of abusers; and assure appropriate and accessible treatment.

At the same time we must reduce availability by stopping the sale of controlled prescription drugs on the Internet, improving our ability to monitor diversion,



...regulating advertising and marketing practices and reformulating drugs where possible to reduce their abuse potential (National Center on Addiction and Substance Abuse (CASA) 2005, p.99).

These recommendations are equally applicable to the Australian context. It is hoped that the findings and recommendations of this Final Report serves a similar role in highlighting the dangers of the illegitimate, illicit or inappropriate use of prescription medications.

**Adopted by the Drugs and Crime Prevention Committee  
Parliament House, East Melbourne  
5 December 2007**

# Appendices

## Appendix 1: List of Submissions

### Submissions received during 55th Parliament

Submission Number	Name of Individual/Organisation	Date Received
1	Mr Leon Hain .....	3 April 2006
2	Confidential Submission .....	24 April 2006
3	Ms Sue White Manager, Access Health Salvation Army Crisis Centre .....	2 May 2006
4	Mr David Murray Chief Executive Officer Youth Substance Abuse Service (YSAS) .....	5 May 2006
5	Confidential Submission .....	5 May 2006
6	Dr Frank Giorlando Addiction Medicine Registrar Interhospital Liaison Group, Southern Health .....	5 May 2006
7	Dr Mark Stooze, Research Fellow Ms Rebecca Jenkinson, Research Fellow Turning Point Alcohol and Drug Centre .....	5 May 2006
8	Ms Carol Andrew Psychiatric Nurse Moreland Continuing Care Program, NW Mental Health Program .....	10 May 2006
9	Ms Sue Morrell Group Manager, Community Services City of Melbourne .....	13 June 2006
10	Ms Gwenda Cannard Director TRANX Inc. ....	16 June 2006
11	Mr Colin Bridge A/g General Manager Program Review Division, Medicare Australia .....	19 June 2006
12	Mr Michael Burt Chief Executive Officer Forensicare, Victorian Institute of Forensic Mental Health .....	19 June 2006
13	Ms Rosemary McClean Policy and Program Adviser Australian Drug Foundation .....	19 June 2006
14	Mr Stephen Marty Registrar Pharmacy Board of Australia .....	19 June 2006
15	Mr John Illott Chief Executive Officer Pharmaceutical Society of Australia (Vic) .....	19 June 2006



Submission Number	Name of Individual/Organisation	Date Received
16	Mr George Mavroyeni General Manager, Road Safety VicRoads. ....	19 June 2006
17	Confidential. ....	20 June 2006
18	Mr John Ryan Chief Executive Officer Anex. ....	22 June 2006
19	Ms Margaret Quon. ....	23 June 2006
20	Ms Louise Milne-Roch Chief Executive Officer Nurses Board of Victoria (NBV) . ....	28 June 2006
21	Ms Lydia Wilson Chief Executive Officer City of Yarra . ....	29 June 2006
22	Judge Paul Grant President Children's Court of Victoria. ....	4 July 2006
23	Ms Sharon Read General Manager Primary Care and Information Management Western Region Health Centre . ....	5 July 2006
24	Dr Paul Woodhouse Director of Policy Australian Medical Association (Victoria) Limited (AMA). ....	7 July 2006
25	Professor Olaf Drummer Head (Forensic and Scientific Services) Victorian Institute of Forensic Medicine. ....	20 July 2006
26	Dr Rodger Brough Drug and Alcohol Physician Western Region Alcohol and Drug Centre (WRAD) . ....	21 July 2006
27	Mr Mark Boyd Community Health and Safety Project Coordinator Darebin City Council . ....	25 July 2006
28	Dr Nick Carr St Kilda Medical Group . ....	26 July 2006

### Submissions received during 56th Parliament

1	Ms Mavis Budde. ....	23 May 2007
2	Ms Rosemary McClean Policy and Program Adviser, Australian Drug Foundation . ....	24 May 2007
3	Mr John Ryan Chief Executive Officer, Anex. ....	25 May 2007
4	Mr William Dear Chief Executive Officer, Youth Projects Inc. ....	25 May 2007
5	Mr David Murray Chief Executive Officer, Youth Substance Abuse Service (YSAS). ....	25 May 2007
6	Ms Sally Mitchell Executive Officer, Yarra Drug and Health Forum. ....	25 May 2007
7	Mr Tim Bloxsome Community Legal Education and Law Reform Officer Essendon Community Legal Centre. ....	28 May 2007
8	Ms Dot Moon Alcohol and Other Drugs Withdrawal Co-ordinator Echuca Regional Health. ....	29 May 2007

Submission Number	Name of Individual/Organisation	Date Received
9	Ms Antoinette Mertins Manager Community Support and Health, Hume City Council. ....	30 May 2007
10	Ms Sonia Berton Chief Executive Officer, Arbias Ltd. ....	5 June 2007
11	Mr Sam Biondo Executive Officer, Victorian Alcohol and Drug Association (VAADA). ....	6 June 2007
12	Confidential Submission. ....	7 June 2007
13	Dr Benny Monheit Southcity Clinic. ....	12 June 2007
14	Mr Angelo Vassallo. ....	16 June 2007
15	Dr Mike Moynihan President, Rural Doctors Association of Victoria. ....	18 June 2007
16	Mr George Mavroyeni Director Road Safety and Network Access, VicRoads. ....	19 June 2007
17	Mr Ben Harris Director Policy and Government Relations Australian Medical Association (Victoria) Limited. ....	20 June 2007
18	Mr John Galloway Chief Pharmacist  Ms Mary Sharpe Deputy Chief Pharmacist Pharmaceutical Services Branch Department of Health and Human Services Tasmania. ....	20 June 2007
19	Confidential Submission. ....	20 June 2007
20	Ms Linda Weatherson Director Community and Places, City of Melbourne. ....	21 June 2007
21	Dr Alex Wodak Director Alcohol and Drug Services, St Vincent's Hospital Darlinghurst  Ms Mary Osborne Senior Policy Officer, Royal Australian College of Physicians. ....	25 June 2007
22	Mr Steve Marty Registrar, Pharmacy Board of Victoria. ....	26 June 2007
23	Mr Alan Eade Paramedic Team Manager  Mr Bill Barger Manager Clinical Standards and Audit, Metropolitan Ambulance Service. ....	26 June 2007
24	Professor Olaf Drummer Head Forensic and Scientific Services and Adjunct Professor in the Department of Forensic Medicine at Monash University. ....	26 June 2007
25	Ms Helen Morris Executive Officer, Australian and New Zealand College of Anaesthetists. ....	28 June 2007
26	Confidential Submission. ....	17 July 2007
27	Ethnic Communities Council of Victoria. ....	19 July 2007
28	Mr Geoff Anderson Manager, Drugs of Dependence Unit Drug and Alcohol Services South Australia. ....	19 July 2007
29	Ms Prue Elletson Policy Officer, Federation of Community Legal Centres (Vic) Inc. ....	23 July 2007
30	Confidential submission. ....	24 August 2007
31	Mr Neal Daly Community Health Nurse/Koori Community Drug and Alcohol Worker Latrobe Community Health Service Inc. ....	29 August 2007
32	Dr Michael Aufgang Royal Australian College of General Practitioners. ....	11 September 2007



## Appendix 2: Witnesses appearing at Public Hearings

### Witnesses appearing at Public Hearings during the 55th Parliament

#### Hearings in Melbourne – 19 June 2006

Name	Position	Organisation
Mr George Mavroyeni	General Manager, Road Safety	VicRoads
Dr Philip Swann	Manager, Drugs, Fatigue and Alcohol	VicRoads
Ms Ros Burnett	Clinical Nurse Consultant	Interhospital Liaison Group
Dr Matthew Frei	Addiction Medicine Physician	Interhospital Liaison Group
Dr Frank Giorlando	Addiction Medicine Registrar	Interhospital Liaison Group
Mr John Illott	Chief Executive Officer	Pharmaceutical Society of Australia (Vic)
Mr Irvine Newton	Chairman, Harm Minimisation Committee	Pharmaceutical Society of Australia (Vic)
Mr Dipak Sanghvi	President	Pharmacy Guild of Australia (Victorian Branch)
Mr Maurice Sheehan	Director	Pharmacy Guild of Australia (Victorian Branch)
Ms Gwenda Cannard	Director	TRANX
Ms Julie Harrick	Manager	Transport Accident Commission (TAC)
Dr Peter Harcourt	Chief Health Officer	Transport Accident Commission (TAC)
Mr Steve Marty	Registrar	Pharmacy Board of Victoria

#### Hearings in Melbourne – 20 June 2006

Name	Position	Organisation
In Camera	-	-
Mr John Ryan	Chief Executive Officer	Anex
Dr Mike McDonough	Medical Director, Drug and Alcohol Services	Western Hospital
Mr David Murray	Chief Executive Officer	Youth Substance Abuse Service (YSAS)
Mr Tony Palmer	Trainer and Consultant	Youth Substance Abuse Service (YSAS)

#### Hearings in Melbourne – 13 July 2006

Name	Position	Organisation
Professor Olaf Drummer	Head (Forensic and Scientific Services)	Victorian Institute of Forensic Medicine (VIFM)
Dr Mike McDonough	Medical Director, Drug and Alcohol Services	Western Hospital

## Witnesses appearing at Public Hearings during the 56th Parliament

### Hearings in Ballarat – 29 May 2007

Name	Position	Organisation
Mr Chris Lynton-Moll	Executive Director	Australian Healthcare Messaging Laboratory
Mr Colin Dorn	Manager Professional Services	UFS Dispensaries

### Hearings in Bendigo – 30 May 2007

In Camera

### Hearings in Melbourne – 4 June 2007

Name	Position	Organisation
Mr Shaun Singleton	Manager, Innovation and Development (Queensland Branch)	Pharmacy Guild of Australia
Ms Sue Bond	Training Manager (Victorian Branch)	Pharmacy Guild of Australia
Mr Dipak Sanghvi	President (Victorian Branch)	Pharmacy Guild of Australia

### Hearings in Melbourne – 25 June 2007

Name	Position	Organisation
Mr Alan Eade	Paramedic Team Manager	Metropolitan Ambulance Service
Mr Bill Barger	Manager, Clinical Standards and Audit	Metropolitan Ambulance Service
Mr David Healy	Senior Manager, Road Safety	Transport Accident Commission
Dr Alex Wodak	Director, Alcohol and Drug Services	St Vincent's Hospital, Darlinghurst and Fellow of Chapter of Addiction Medicine, Royal Australasian College of Physicians
Ms Mary Osborn	Senior Policy Officer, Policy and Programs	Royal Australasian College of Physicians
Mr Sam Biondo	Executive Officer	Victorian Alcohol and Drug Association
Ms Chloe Duncan	Policy Officer	Victorian Alcohol and Drug Association
Professor Olaf Drummer	Head, Forensic and Scientific Services	Victorian Institute of Forensic Medicine
Dr Peter Cameron	Head, Victorian State Trauma Registry Department of Epidemiology Prevention Medicine – Director Research Emergency and Trauma Centre	Alfred Hospital
Mr George Mavroyeni	General Manager, Road Safety	VicRoads
Dr Phillip Swann	Manager, Drugs Fatigue and Alcohol	VicRoads
Inspector Steve James	Manager, Drug and Alcohol Policy Unit	Victoria Police
Superintendent Wendy Steendam	Detective Superintendent Crime Department	Victoria Police
Dr Edward Ogden	Senior Medical Officer	Victoria Police
Inspector Martin Boorman	Officer in Charge Traffic Drug and Alcohol Section	Victoria Police

### Hearings in Melbourne – 26 June 2007

Name	Position	Organisation
Mr Angelo Vassallo	—	—
Mr Steve Marty	Registrar	Pharmacy Board of Victoria
Mr Mark Durran	Director, Information Service	Australian Drug Foundation
Ms Rosemary McClean	Policy and Program Adviser	Australian Drug Foundation



Dr Malcolm Hogg	Doctor	Australian Pain Society, Australian and New Zealand College of Anaesthetists, Melbourne Health
Ms Gwenda Cannard		Reconnexion (formerly TRANX)
Dr Mark Yates	Vice President	Australian Medical Association (Vic)
Dr Harry Hemley	Vice President	Australian Medical Association (Vic)
Mr Ben Harris	Director, Policy and Government Relations	Australian Medical Association (Vic)

#### **Hearings in Melbourne – 9 July 2007**

Name	Position	Organisation
IN CAMERA	-	-
Name	Position	Organisation
Mr Mark Stooze	Research Fellow	Turning Point Alcohol and Drug Centre
Mr Peter Muhleisen	Senior Pharmacist	Turning Point Alcohol and Drug Centre
Ms Jill Clutterbuck	Senior Professional Officer	Australian Nursing Federation (Victoria)
Mr Darren Tyrrell	Industrial Relations Organiser	Australian Nursing Federation (Victoria)
Ms Heather Pickard	Director	Victorian Nurses Health Program
Dr Con Constantinou	Health Manager	Medical Practitioners Board of Victoria

#### **Hearings in Melbourne – 16 July 2007**

In Camera	-	-
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#### **Hearings in Melbourne – 20 August 2007**

Name	Position	Organisation
Mr Graeme Johnstone	State Coroner	State Coroner of Victoria

## Appendix 3: International Meetings during 56th Parliament

### ***Vancouver 23–25 July 2007***

<b>Name</b>	<b>Position</b>	<b>Organisation</b>
Mr Kevin Lamb	Honorary Consul and Post Manager	Australian Consulate, British Columbia
Hon Bill Barisoff	Speaker	Legislative Assembly of British Columbia
Mr Bob Nakagawa	Assistant Deputy Minister Pharmaceutical Services Branch Strategic Innovation Division	British Columbia Ministry of Health, Pharmaceutical Services
Mr Eric Lun	Executive Director Drug Intelligence	British Columbia Ministry of Health, Pharmaceutical Services
Ms Pam Scott	Executive Coordinator	British Columbia Ministry of Health, Pharmaceutical Services
Ms Darlene Therrien	Executive Director Pharmaceutical Services Branch Policy Outcomes Evaluation and Research	British Columbia Ministry of Health, Pharmaceutical Services
Ms Lynda Chiu	Senior Pharmacist Special Authorization and Special Projects	British Columbia Ministry of Health, Pharmaceutical Services
Mr Gerrit van der Leer	Director Mental Health and Addictions Branch Health Authorities Division	British Columbia Ministry of Health
Mr Wayne Fullerton	Policy Advisor Mental Health and Addictions Branch Health Authorities Division	British Columbia Ministry of Health
Mr Leon Jung	Manager	Burrard Pharmacy
Mr Ken Foreman	Manager Pharmacy Innovation	British Columbia Pharmacy Association
Mr Ken McCartney	Deputy Chief Executive Officer and Director Professional Services	British Columbia Pharmacy Association
Ms Linda Lytle	Manager Quality Outcomes Program	British Columbia College of Pharmacists
Ms Cathy Craig	Coordinator Professional Services	British Columbia Pharmacy Association
Ms Susanne Murphy	Representative	Psychiatric Medication Awareness Group
Ms Janet Currie	Representative	Psychiatric Medication Awareness Group
Ms Joan Gadsby	Founder	Prescription Drug Awareness Group
Mr Rafe Mooney	Acting Executive Director Communicable Disease and Addictions Prevention Branch Population Health and Wellness Division	British Columbia Ministry of Health

### ***Washington 26–30 July 2007***

<b>Name</b>	<b>Position</b>	<b>Organisation</b>
Mr David McLean	Counsellor (Police Liaison)	Australian Federal Police Embassy of Australia
Ms Muriella Wheatley	Operational Support Officer	Australian Federal Police Embassy of Australia
Mr Westley Clark	Center Director	Substance Abuse and Mental Health Services Administration (SAMHSA)
Ms Winnifred Mitchell-Frable	Lead Public Health Analyst Office of Policy, Planning and Budget	Substance Abuse and Mental Health Services Administration (SAMHSA)
Mr Nicholas Reuter	Senior Public Health Advisor, Division of Pharmacologic Therapies	Substance Abuse and Mental Health Services Administration (SAMHSA)



Name	Position	Organisation
Mr James Colliver	Mathematical Statistician Office of Applied Studies	Substance Abuse and Mental Health Services Administration (SAMHSA)
Mr Michael Lowther	Director Division of State Programs	Substance Abuse and Mental Health Services, Administration (SAMHSA)
Mr Kenneth Hoffman	Medical Officer Division of Pharmacological Therapies	Substance Abuse and Mental Health Services, Administration (SAMHSA)
Ms Sherry Green	Executive Director	National Alliance for Model State Drug Laws
Ms Sarah Kelsey	Legislative Attorney	National Alliance for Model State Drug Laws
Ms Ruby Qazilbash	Senior Policy Advisor for Substance Abuse Bureau of Justice Assistance	Harold Rodgers Prescription Drug Monitoring Program
Ms Rebecca Rose	Policy Advisor for Substance Abuse and Mental Health Bureau of Justice Assistance	Harold Rodgers Prescription Drug Monitoring Program
Mr Joseph Rannazzisi	Deputy Assistant Administrator Office of Diversion Control Drug Enforcement Administration	U.S. Department of Justice
Ms Janet Barrow	Chief, International Visitor Program	U.S. Department of Justice
Ms Tanya Crandall	Program Analyst Office of International Programs	U.S. Department of Justice
Mr Gary Boggs	Executive Assistant Office of Diversion Control	U.S. Department of Justice
Congressman Mark Souder	Chair	United States House of Representatives Committee on Government Reform, Subcommittee on Criminal Justice, Drug Policy and Human Resources
Ms Mandy Bowers	Senior Professional Staff Member Republican Staff	Committee on Homeland Security
Mr Dale Weis	International Program Office of Science Policy and Communications	National Institute on Drug Abuse
Ms Moira O'Brien	Health Scientist Administrator Epidemiology Research Branch	National Institute on Drug Abuse
Ms Aria Crump	Health Scientist Administrator Prevention Research Branch	National Institute on Drug Abuse
Mr Richard Denisco	Services Branch	National Institute on Drug Abuse
Ms Carol Krause	Public Information Officer	National Institute on Drug Abuse
Mr Steve Gust	Director, International Program	National Institute on Drug Abuse
Mr Geoffrey Laredo	Senior Advisor Office of Science Policy and Communications, Legislative Liaison	National Institute on Drug Abuse
Mr Richard Baum	Chief for International Policy Office of Supply Reduction	Office of National Drug Control Policy
Ms Charlotte Sisson	Policy Analyst Executive Office of the President	Office of National Drug Control Policy
Ms June Sivilli	Policy Analyst Office of Supply Reduction	Office of National Drug Control Policy
Ms Maureen Russell	Policy Assistant Office of Supply Reduction	Office of National Drug Control Policy
Mr Terry Zobek	Deputy Assistant Director Counter Drug Technology Assessment Center	Office of National Drug Control Policy
Mr Dennis Richardson	Ambassador to United States of America	Australian Embassy

**Kentucky 31 July–1 August 2007**

Name	Position	Organisation
Mr Steve Davis	Inspector General	Kentucky Cabinet for Health and Family Services
Mr Michael Lawrence	Deputy Inspector General	Kentucky Cabinet for Health and Family Services
Ms Stephanie Hold	Assistant Director Division of Fraud, Waste and Abuse Identification and Prevention	Kentucky Cabinet for Health and Family Services
Mr Zach Ramsey	Director Office of the Inspector General	Kentucky Cabinet for Health and Family Services
Mr David Hopkins	Project Manager Office for the Inspector General	Kentucky Cabinet for Health and Family Services
Mr Dave Sallengs	Branch Manager Drug Enforcement and Professional Practices Branch	Kentucky Cabinet for Health and Family Services
Mr Neal Rosenblatt	Project Epidemiologist  Office of Information Technology	Kentucky Cabinet for Health and Family Services
Mr Ganesh Babu	Development Lead Office of Information Technology	Kentucky Cabinet for Health and Family Services
Mr Michael Smithson	Project Manager Office of Information Technology	Kentucky Cabinet for Health and Family Services
Sgt Bill Strivers	Prescription Drug Squad	Louisville Metro Police
Mr Mike Pelonero	Internal Policy Analyst Compliance Branch Office of Drug Control Policy	Kentucky Justice and Public Safety Cabinet
Mr David James	Commissioner Kentucky Bureau of Investigation	Office of the Attorney General
Ms Lynne Thompson	Agent	Kentucky Bureau of Investigation
Mr Mike Burseson	Executive Director	Kentucky Board of Pharmacy
Mr Jeff Osman	Coordinator Pharmacy Inspections and Investigations	Kentucky Board of Pharmacy
Ms Donna Hillman	Division Director Division of Mental Health and Substance Abuse	Cabinet for Health and Family Services
Ms Karyn Hascal	Deputy Executive Director Office of Drug Control Policy	Kentucky Justice and Public Safety Cabinet
Dr Carl Leukefeld	Director Center on Drug and Alcohol Research	University of Kentucky
Ms Deborah Murray	Associate Director Health Education through Extension Leadership Program	University of Kentucky

**Sacramento 1–3 August 2007**

Name	Position	Organisation
Ms Judi Nurse	Supervising Inspector	California State Board of Pharmacy
Ms Carol Stanford	Manager, Diversion/Probation Program	California State Board of Registered Nursing
Ms Renee Zito	Director	California Department of Alcohol and Drug Programs
Mr Michael Cunningham	Chief Deputy Director	California Department of Alcohol and Drug Programs
Ms Rebecca Lira	Deputy Director of Licensing and Certification Division	California Department of Alcohol and Drug Programs



Name	Position	Organisation
Ms Marjorie McKisson	Acting Assistant Deputy Director Program Services Division Treatment	California Department of Alcohol and Drug Programs
Mr Tom Leigh	Research Program Specialist	California Department of Alcohol and Drug Programs
Ms Joan Robbins	Manager Program and Policy Support Branch Licensing and Certification Division	California Department of Alcohol and Drug Programs
Ms Denise Kincaid	Assistant to Director	California Department of Alcohol and Drug Programs
Dr Ernie Vasti	Medical Director Substance Abuse Services	San Joaquin County, California
Mr Thomas Renfree	Executive Director	County Alcohol and Drug Administrators Association of California
Ms Beth Finnerty-Rutkowski	Associate Director of Training and Epidemiologist	Integrated Substance Abuse Programs University of California Los Angeles
Ms Wendy Tully	Program Manager Drug and Alcohol Abuse Prevention	Attorney General's Crime and Violence Prevention Center
Ms Kathy Ellis	Controlled Substances Utilization Review and Evaluation System Bureau of Narcotic Enforcement	Department of Justice
Ms Carla Watkins	CIIS Bureau of Narcotic Enforcement	Department of Justice
Ms Kristine Woodson	Criminal Intelligence Specialist Bureau of Narcotic Enforcement	Department of Justice
Ms Julianna Dougherty	Criminal Intelligence Specialist Bureau of Narcotic Enforcement	Department of Justice
Ms Dawn Curtis	Criminal Intelligence Specialist Bureau of Narcotic Enforcement	Department of Justice
Ms Deborah White	Information Technologist Bureau of Narcotic Enforcement	Department of Justice
Ms Gloria Pengray	Special Agent in Charge Bureau of Narcotic Enforcement	Department of Justice
Mr Douglas Morrow	Special Assistant to the Speaker	Californian State Assembly
Mr Roger Dunstan	Principal Consultant Senate Committee on Health	California State Assembly
Ms Kimberly Horiuchi	Senior Consultant Assembly Committee on Public Safety	California State Assembly
Mr Ross Warren	Principal Consultant Assembly Business and Professions Committee	California State Assembly
Ms Shannon Shellenberg	Deputy Director Californian Senate Office of International Relations	California State Senate

## Appendix 4: Interstate Meetings and Site Visits during 56th Parliament

### *Meetings in Canberra – 16–17 May 2007*

Name	Position	Organisation
Dr Narelle Bowen	Consultant	Medicines Australia
Dr Mike Tedeschi	Senior Lecturer	Australian National University Medical Hospital
Dr Toni Makkai	Director	Australian Institute of Criminology
Dr Judy Putt	Director	Australian Institute of Criminology
Dr Jenny Mouzos	Senior Research Analyst	Australian Institute of Criminology
Mr Lance Smith	Research Assistant	Australian Institute of Criminology
Ms Janet Smith	Manager, Library	Australian Institute of Criminology
Ms Khin Win May	Policy Officer	Pharmacy Guild of Australia
Ms Jenny Bergin	Director Community Pharmacy Practice	Pharmacy Guild of Australia
Dr Phyll Dance	Research Fellow National Centre for Epidemiology	Australian National University
Ms Julie Tongs	Chief Executive Officer	Winnunga Nimmityjah Aboriginal Health Service
Mr David Templeman	National Program Manager	Alcohol and Other Drugs Council of Australia
Ms Kerry Deans	Chief Executive Officer	Pharmaceutical Society of Australia
Dr Kay Sorimachi	Director of Policy Development	Pharmaceutical Society of Australia
Mr Gino Vumbaca	Chief Executive Officer	Australian National Council on Drugs
Mr Malcolm Wares	Manager, Compliance Policy	Medicare Australia
Ms Victoria Callioni	Manager, Consumer Compliance	Medicare Australia

### *Meetings in Adelaide – 18 May 2007*

Name	Position	Organisation
Superintendent Tony Rankine	Traffic Support Branch	South Australia Police Service
Ms Debra Rowett	President	Pharmacy Board of South Australia
Mr Peter Halstead	Registrar	Pharmacy Board of South Australia
Superintendent Paul Dickson	Drug Investigation Branch	South Australia Police Service
Chief Inspector Paul Harvey	Officer in Charge of the Drug and Alcohol Policy Section	South Australia Police Service
Dr Ann Rathjen	Analyst, Chemical Division	South Australia Police Service
Professor Jason White	Director of Treatment and Rehabilitation	Drugs and Alcohol Services of South Australia
Mr Keith Evans	Chief Executive Officer Drugs of Dependence Unit	Drugs and Alcohol Services of South Australia
Mr Geoff Anderson	Chief Pharmacist Drugs of Dependence Unit	Drugs and Alcohol Services of South Australia



## Appendix 5: Expert Witnesses appearing during 56th Parliament

### Meeting – 26 March 2007

Name	Position	Organisation
Dr Malcolm Dobbin	Senior Medical Officer Drug Policy and Services Branch	Department of Human Services

### Meeting – 30 April 2007

Name	Position	Organisation
Dr Mike McDonough	Medical Director, Drug and Alcohol Services	Western Hospital

## Appendix 6: Roundtable Meetings and Forums during 56th Parliament

### **Forum in Warrnambool – 29 May 2007**

Name	Position	Organisation
Mr David Atkinson	Mayor	Warrnambool City Council
Mr Geoff Soma	Director	Western Region Alcohol and Drug Centre
Dr David Richards	Addiction Medicine Physician	Western Region Alcohol and Drug Centre
Dr Rodger Brough	Drugs and Alcohol Physician	South West Healthcare
Ms Annette Ludeman	Administrative Supervisor	Gunditjmara Aboriginal Co-operative Ltd
Acting Inspector Peter Langdon	Warrnambool Police Service Area	Victoria Police
Ms Bev McIlroy	Service Manager	Glenelg and Southern Grampians Drug Treatment Service
Mr Norman Ferrier	Manager	Monaghan's Healthwise Pharmacy – Warrnambool

### **Forum in Ballarat – 29 May 2007**

Name	Position	Organisation
Mr Raymond Beacham	Alcohol and Other Drug Team Leader	Ballarat Community Health Centre
Mr Brett Vallance	Withdrawal Nurse	Ballarat Community Health Centre
Ms Alice Neville	Withdrawal Nurse	Ballarat Community Health Centre
Mr Damon Boon	Mobile Drug Safety Worker	Ballarat Community Health Centre
Ms Sue Adam	Manager Alcohol and Drug Program	Uniting Care Ballarat
Mr Darren Cutts	Withdrawal Nurse	Uniting Care Ballarat
Ms Sue Scott	Comorbidity Case Worker	Uniting Care Ballarat
Ms Alison Doodt	Regional Drug and Alcohol Coordinator	Department of Human Services

### **Forum in Bendigo – 30 May 2007**

Name	Position	Organisation
Ms Kate Harrington O'Brien	Operations Manager Drug and Alcohol Services	Bendigo Community Health Services
Ms Cheryl Sobczyk	Clinical Nurse Manager	Bendigo Community Health Services
Ms Penny Buykx	Research Officer	Faculty of Health Sciences La Trobe University Bendigo
Ms Jane Tydd	Regional Alcohol and Drug Coordinator	Department of Human Services – Loddon Mallee
Ms Kerry Donaldson	Manager	Youth Substance Abuse Service (YSAS)
Mr Brian Baxter	Manager Community Health	Mclvor Health and Community Services
Mr Mark Powell	Safe Community Forum Executive Officer	City of Greater Bendigo
Mr Richard Michell	Coordinator Post Withdrawal	Bendigo Community Health Service
Ms Judy Rossignolo	Rural Outreach Diversion Worker	Castlemaine Community Health
Ms Toni Riley	Pharmacist	Toni Riley Pharmacy

### **Forum for Culturally and Linguistically Diverse Communities in Melbourne – 9 July 2007**

Name	Position	Organisation
Mr Eddie Micallef	Executive Member	Ethnic Communities' Council of Victoria
Mr Jieh – Yung Lo	Policy Project Officer	Ethnic Communities' Council of Victoria



Ms Thuy V. Bui	Drug and Alcohol Worker	North Richmond Community Health Centre
Mr Jacob Lee	Manager Aged Care and Disability	South Eastern Region Migrant Resource Centre
Mr Loc Pham	Drug and Alcohol Counsellor	Australian Vietnamese Women's Welfare Association
Ms Wesa Chau	Multicultural Network Coordinator	Action on Disability within Ethnic Communities
Mr Bullent Mangar Agau	Member	Sudanese Lost Boys' Association of Victoria – Australia
Mr Tut Pal Ding	Deputy Director	Sudanese Lost Boys' Association of Australia
Mr Mayor Luk Lueth	Public Officer	Sudanese Lost Boys' Association of Australia

**Pharmaceutical Forum in Melbourne – 16 July 2007**

Name	Position	Organisation
Dr John Whitlam	Director Medical Affairs	Mundipharma
Dr Gregory Alan Pearce	Medical Advisor	Alphapharm
Mr Tom Liebelt	Government Affairs Manager	GlaxoSmithKline
Mr Peter James Thomas	National Security Manager	Sigma Pharmaceuticals

**Aboriginal Forum in Melbourne – 20 August 2007**

Name	Position	Organisation
Mr Michael Moran	Coordinator Aboriginal Diversion Unit	Ngwala Willumbong Cooperative
Mr Alan Thorpe	Outreach Worker	Ngwala Willumbong Cooperative
Mr Matthew Graham	Outreach Worker	Ngwala Willumbong Cooperative
Ms Chasity Prior	Outreach Worker	Ngwala Willumbong Cooperative
Mr David Dryden	Koori Outreach Worker	South Eastern Alcohol and Drug Service (SEADS)
Mr Reg Blow	Chief Executive Officer	Maya Healing Centre
Ms Tina Dimauro	Observer	

## Appendix 7: Teleconferences held during 56th Parliament

### Teleconference – 9 June 2007

Name	Position	Organisation
Mrs Margaret Brown	National Chair	Health Consumers of Rural and Remote Australia Association
Ms Carmel Brophy	Project Manager	Health Consumers of Rural and Remote Australia Association
Ms Diane Walsh	NT Member	Health Consumers of Rural and Remote Australia Association
Mr Keith Williams	NT Member	Health Consumers of Rural and Remote Australia Association
Ms Val Lang	Vic Member	Health Consumers of Rural and Remote Australia Association
Ms Alva Courtis	WA Member	Health Consumers of Rural and Remote Australia Association
Ms Moya Sandow	QLD Member	Health Consumers of Rural and Remote Australia Association
Ms Jenny Hutchinson	Representative	National Rural Women's Association

### Teleconference – 18 June 2007

Name	Position	Organisation
Mr John Galloway	Chief Pharmacist Pharmaceutical Services Branch	Tasmanian Department of Health
Ms Mary Sharpe	Deputy Chief Pharmacist Pharmaceutical Services Branch	Tasmanian Department of Health
Dr Mike Moynihan	President	Rural Doctors Association of Victoria



## Appendix 8: Glossary

- **Abuse:** 'A term in wide use but of varying meaning. In international drug control conventions 'abuse' refers to any consumption of a controlled substance no matter how infrequent. In the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV, American Psychiatric Association 1994), 'psychoactive substance abuse' is defined as "a maladaptive pattern of substance use leading to clinically significant impairment or distress, as manifested by one (or more) of the following within a 12 month period: (a) recurrent substance use resulting in a failure to fulfil major role obligations at work, school or home; (b) recurrent substance use in situations in which it is physically hazardous; (c) recurrent substance-related legal problems; (d) continued substance use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of the substance" (United Nations International Drug Control Program, 2000, p.1).
- **Addiction, addict:** One of the oldest and most commonly used terms to describe and explain the phenomenon of long-standing drug abuse. In some professional circles it has been replaced by the term 'drug dependence'. According to the WHO Lexicon of Alcohol and Drug Terms, addiction is defined as: the repeated use of a psychoactive substance or substances, to the extent that the user (referred to as an addict) is periodically or chronically intoxicated, shows a compulsion to take the preferred substance (or substances), has great difficulty in voluntarily ceasing or modifying substance use, and exhibits determination to obtain psychoactive substances by almost any means. ... In the 1960s the WHO recommended that the term 'addiction' be abandoned in favour of dependence, which can exist in various degrees of severity as opposed to an 'all or nothing' disease entity. Addiction is not a diagnostic term in the ICD-10, but continues to be very widely employed by professionals and the general public alike' (United Nations International Drug Control Program 2000, pp.2-3).
- **Dependence, dependence syndrome:** According to the WHO Lexicon of Alcohol and Drug Terms, dependence, dependence syndrome is defined as: as applied to alcohol and other drugs, a need for repeated doses of the drug to feel good or to avoid feeling bad. The terms 'dependence' and 'dependence syndrome' have gained favour with WHO and in other circles as alternatives to 'addiction' since the 1960s. Their use was recommended as an acknowledgment of new evidence that 'addiction' was not a discrete disease entity but could exist in degrees, as indeed could its constituent signs. For example, 'loss of control' over drug use was replaced with 'impaired control'. In the DSM-IV, dependence is defined as "a cluster of cognitive, behavioural and physiological symptoms indicating that the individual continues use of the substance despite significant substance-related problems" (United Nations International Drug Control Program 2000, p.19).
- **Detoxification:** The process by which a person who is dependent on a psychoactive substance ceases use, in such a way that minimizes the symptoms of withdrawal and risk of harm. While the term 'detoxification' literally implies a removal of toxic effects from an episode of drug use, in fact it has come to be used to refer to the management of rebound symptoms of neuroadaptation, i.e. withdrawal and any associated physical and mental health problems. The facility in which the procedure takes place is usually called a detoxification centre. Traditionally detoxification has been provided on an in-patient basis either in a specialist treatment facility or on the wards of a general or psychiatric hospital. There is an increasing trend to provide detoxification services in informal settings including the clients' own homes. Home-based detoxification usually involves visiting medical staff and informal support provided by family or friends. As a clinical procedure, detoxification is undertaken with a degree of supervision. Typically, the individual is clinically intoxicated or already in withdrawal at the outset of detoxification. Detoxification may involve the administration of medication. When it does, the medication given is usually a drug



that shows cross-tolerance and cross-dependence to the substance(s) taken by the patient. The dose is calculated to relieve the withdrawal syndrome without inducing intoxication, and is gradually tapered off as the patient recovers. Detoxification as a clinical procedure implies that the individual is supervised until recovery is complete, both from intoxication and physical withdrawal (United Nations International Drug Control Program 2000, pp.20–21).

- **Half-life:** The term refers to the time needed for the blood level of a particular drug to decline to half of the maximum level (peak). After absorption, the various drugs are transported to the various sites of action through the blood stream. During this transportation and distribution process, the drugs already in the blood or in the various organs are gradually transformed into various metabolites, and either deposited or excreted from the body. All these processes proceed parallel. The metabolic process of drugs usually involves several stages and transformation steps, usually performed by specific body enzymes. The rate of metabolism at each stage varies from substance to substance and between individuals, as influenced by several internal and external factors. Different drugs are distributed and metabolized through quite different routes and the blood level of each drug as a function of time tends to be substance-characteristic. Half-life is a generally accepted characteristic value in comparing the metabolic and pharmacological characteristics of various drugs. It is an indication of the relative duration of a drug's effects. Heroin, for example, has a short half-life, while morphine has a longer one. The various benzodiazepines and barbiturates also have greatly varying half-lives (United Nations International Drug Control Program 2000, p.30).
- **Illicit Use:** Illicit use is defined as use of medication that was not obtained on prescription in the individual's name (Stafford, Degenhardt, Black et al 2006).
- **Misuse:** According to the WHO Lexicon of Alcohol and Drug Terms, misuse is defined as: the use of a substance for a purpose not consistent with legal or medical guidelines, as in the non-medical use of prescription medications. The term is preferred by some to 'abuse' in the belief that it is less judgmental. It may also refer to high-risk use, e.g. excessive use of alcohol in situations where this is not illegal (United Nations International Drug Control Program 2000, p.45).
- **Tolerance:** A term for the well-established phenomenon of reduced drug effects following repeated drug administrations. Tolerance develops fastest with more frequent episodes of use and with larger amounts per occasion. It is useful to distinguish between metabolic tolerance and functional tolerance. Metabolic tolerance arises usually as a consequence of an induction of liver enzymes which result in the faster metabolism of a given drug dose, thereby reducing the level and duration of blood-drug levels. Functional tolerance refers to diminished effects of a given blood-drug level. This is thought to occur both by virtue of neuroadaptation, as well as by the user learning to anticipate and accommodate intoxicating effects (United Nations International Drug Control Program 2000, p.71).
- **Withdrawal:** A term used to refer to either the individual symptoms of, or the overall state (or syndrome), which may result when a person ceases use of a particular psychoactive drug upon which they have become dependent or after a period of repeated exposure. The level of central nervous system arousal and the accompanying mood state is usually directly opposite to the direct action of the drug. Thus withdrawal from central nervous system depressants typically involves increased anxiety and heightened arousal level (increased heart rate, blood pressure and perspiration). Withdrawal from central nervous system stimulants involves reduced arousal, lethargy and depression. Withdrawal states and symptoms exist in degrees as a direct consequence of the frequency, intensity and recency of drug use. Withdrawal or 'rebound' phenomena have been demonstrated after relatively brief periods of heavy drug use for a wide range of drug types and are not experienced exclusively by severely dependent individuals (United Nations International Drug Control Program 2000, p.75).



## Appendix 9: Pro-forma Patient Activity Report

California Department of Justice  
 P.O. Box 160447, Sacramento, CA 95816  
 Telephone: (916) 319-9062  
 Fax: (916) 319-9448



## Patient Activity Report (PAR)

Please complete the following information by typing or printing in the required fields.

PHYSICIAN INFORMATION			
Physician DEA No.:		License No.:	
Physician Name (As it Appears on your DEA Certificate)			
Physician Address			
	City:	State:	Zip Code:
Telephone No.:		Fax No.:	

PATIENT INFORMATION			
Last Name		First Name	
AKA (Also Known As)		Maiden Name	
Patient Address			
	City:	State:	Zip Code:
Telephone No.:			
Social Security No.:			Date of Birth

ADDITIONAL COMMENTS OR INFORMATION

AUTHORIZATION
---------------

By signing below, I certify that I am a licensed health care practitioner eligible to obtain controlled substance history dispensed to the patient in my care identified above, based on data contained in the Controlled Substance Utilization Review and Evaluation System (CURES). I understand that any request for, or release of a controlled substance history shall be made in accordance with Department of Justice guidelines, that the history shall be considered medical information subject to the provisions of the Confidentiality of Medical Information Act (Civil Code §§ 56 et seq.)

Please FAX your request to (916) 319-9448

Or mail to: California Department of Justice, P.O. Box 160447, Sacramento, CA 95816

Physician Signature \_\_\_\_\_ Date \_\_\_\_\_

For Department of Justice Use Only	Date Received	Date Completed	Initials
	Comments		

BNE1176 (06/2003)

## Appendix 10: Pro-forma Patient Summary Report

## IN-CONFIDENCE



Australian Government  
Medicare Australia

Prescription Shopping  
Information Service  
1800 631 181

## Patient Summary Report produced for Dr Sample on DD/MM/YYYY

## Patient details

Patient name	Date of birth	Last address known to Medicare Australia
Sample	DD/MM/YYYY	Address

Summary of Pharmaceutical Benefit Scheme (PBS) items<sup>1</sup> supplied in the period that the patient has met the Prescription Shopping Program criteria<sup>2</sup>

From	To	No. of Drs	No. of Target <sup>3</sup> items	Total No. of items <sup>4</sup>	No. of different items <sup>5</sup>
01/08/2005	31/10/2005	15	35	43	13

## Details of PBS items supplied

PBS item description <sup>6</sup>	No. of Drs <sup>7</sup>	No. of items <sup>8</sup>	Pack Size <sup>9</sup>	Total Qty <sup>10</sup>
OXYCODONE HYDROCHLORIDE TABLET 80MG (CONTROLLED RELEASE)	8	22	20	526
CELECOXIB CAPSULE 200MG	9	19	30	550
OXAZEPAM TABLET 30MG-(NON AUTH)	2	16	25	400
LANSOPRAZOLE CAPSULE 30MG~ (MAX QTY 28, MAX RPT 5) (CODE 2241Y)	9	12	30	390
ESCITALOPRAM OXALATE-SPC EXEMPT-NO TIME TO CHANGE PROGRAM - BACK DATED TO PAY TABLET 20MG (BASE)-PRESCRIBED PRIOR 1/8/05 AND DISPENSED PRIOR 1/3/06	6	9	28	252
CODEINE PHOSPHATE WITH PARACETAMOL TABLET 30MG-500MG	8	8	20	160
OESTROGENS - CONJUGATED-(56) TABLET 625 MICROGRAMS,~56 (AFTER 1/11/96)	5	7	56	392
METOCLOPRAMIDE HYDROCHLORIDE TABLET 10MG	5	6	25	150
IRBESARTAN TABLET 300MG	4	6	30	180
INDOMETHACIN CAPSULE 25MG	3	6	50	600
ALPRAZOLAM TABLET 2MG	2	6	50	300
IRON POLYMALTOSE COMPLEX INJECTION 100MG (IRON) IN 2ML	5	5	5	25
BROMOCRIPTINE MESYLATE-(SP AFTER 1/5/00) TABLET 2.5MG (BASE)	3	5	60	300
THYROXINE SODIUM (BP 1980) TABLET EQUIVALENT TO 100 MICROGRAMS ANHYDROUS THYROXINE SODIUM	3	4	200	800
BETAMETHASONE VALERATE CREAM 200 MICROGRAMS PER G (0.02%), 100G	3	3	1	6
ESCITALOPRAM OXALATE TABLET 20MG (BASE)	3	3	28	84

Note: see EXPLANATORY NOTES on the following page for details on numbered headings

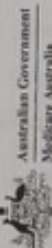
**Disclaimer:** This report has been prepared from information collected during the period displayed. The information contained in this report may not be accurate or up to date and does not represent the full list of pharmaceutical medicine a patient may have had prescribed to them. (See explanatory notes shown below). Medicare Australia takes no responsibility for any action/s or behaviours, any loss, damage or injury caused or resulting from the use of this information by any person, including a prescriber, patient or supplier. Health professionals should not make clinical judgments solely from this information and should obtain a complete pharmaceutical history from their patients. Health professionals should be mindful of their obligations under the National Privacy Principles contained in the Privacy Act 1988 in handling medical and pharmaceutical information. This includes information which has been provided to you by Medicare Australia. This report is for information purposes only and does not prohibit doctors from prescribing to the patient.

Prescription Shopping Information Service ~ Patient Summary Report  
1 of 2

IN-CONFIDENCE



## Facsimile



Date:	<auto date>
To:	
Phone number:	Fax number:
From:	Prescription Shopping Information Service
No of pages:	(including cover sheet)
Subject:	1800 631 181
	Patient Summary Report

Please find attached a Patient Summary Report, containing your patient's PBS information, as requested from the Prescription Shopping Information Service.

It is recommended that you let your patient know that you have obtained this information from Medicare Australia at their next visit.

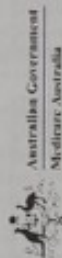
To assist you in understanding this important information, visit Medicare Australia's website for supporting materials.

The Prescription Shopping Program's information can be found at:

[http://www.medicareaustralia.gov.au/providers/programs\\_services/pbs/prescription\\_shop.htm](http://www.medicareaustralia.gov.au/providers/programs_services/pbs/prescription_shop.htm)

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National Office PO Box 1001 Taggessong DC ACT 2601 Phone: 1800 631 181 Fax: 02 6124 7929  
www.medicareaustralia.gov.au



## Prescription Shopping Information Service 1800 631 181

### EXPLANATORY NOTES

**1. Pharmaceutical Benefit Scheme (PBS) Items:** Include all medicine subject to Australian Government subsidy under the PBS.

**THIS REPORT DOES NOT INCLUDE THE FOLLOWING:**

- PBS medicine supplied to a patient that has not yet been claimed by the pharmacist, as there is a 4 - 6 week lag between a patient being supplied with their PBS medicine, the pharmacist claiming and the data being available
- PBS Schedule Section 100 Medicine (including programs for Highly Specialised Drugs, Botulinum Toxin, Human Growth Hormone, IVF/GIFT, Opiate Dependence Treatment, Special Authority)
- PBS medicine where the full cost is less than the patient contribution, this is the amount a patient pays for PBS medicine based on their status, either concession or general
- Emergency (doctor's bag) supplies
- PBS medicine supplied but rejected for payment by Medicare Australia
- Medicine subsidised under the Repatriation Pharmaceutical Benefit Scheme (RPBS)
- Prescription medicine that does not qualify for a PBS benefit (non-PBS medicine, such as private scripts and medications dispensed by public hospitals)
- Over-the-counter medicine
- PBS medicine supplied by a pharmacist in an emergency
- Samples

**2. Prescription Shopping Program Criteria:** where a person, within any 3 month period, has had supplied to them:

- PBS items prescribed by 6 or more different prescribers (excluding specialists and consultant physicians);
- a total of 25 or more Target PBS items; or
- a total of 50 or more PBS items.

**3. Target items:** are analgesics, antiepileptics, anti-Parkinson medicine, psycholeptics, psychoanaleptics (including antidepressants) and all other nervous system medicine.

**4. Total No. of Items:** is the total number of PBS subsidised medicine supplied to the patient.

**5. No. of different items:** is the number of different PBS subsidised medicine that have been supplied to the patient.

**6. PBS item descriptions:** is the generic name of the drug, dosage and form (eg Diazepam 5 mg tablets).

**7. No. of Drs:** is the number of doctors that have prescribed PBS subsidised medicine in the period that the patient met the criteria. Note that the total number of doctors from whom the patient obtained prescriptions for the PBS items supplied may include doctors located in the same practice.

**8. No. of items:** is the number of times the medicine was supplied to the patient.

**9. Pack size:** For oral dosage forms, pack size will indicate number of tablets/capsules per supply as defined in the PBS schedule. In other dosage forms, such as topical, the number of dosage units will either appear in the item description OR be adjusted in the total quantity.

**10. Total Qty:** is the total number of tablets/capsules, representing quantity, etc supplied to the patient plus or minus adjustments for the following supply scenarios:

- PBS Authority supplies: Where an increased quantity per prescription has been made by authority, for example 200 Panadene Forte tablets (dispensed as 10 x 20 packs).
- Less than pack size supplies: Where the patient was supplied less than the full pack (eg 10 tablets out of a pack of 25).

These adjustments explain why the 'Total Qty' may not always equal the 'Pack size' multiplied by the 'No. of items'.

# Appendix 11: Key statistics – Prescription Shopping Program

## KEY STATISTICS – PRESCRIPTION SHOPPING PROGRAM (@ 30 June 2007)

### PRESCRIPTION SHOPPING INFORMATION SERVICE

**Doctor registrations**  
 Number Registered at 30 June 2007 13,065  
 Number Registered at 30 June 2006 11,757  
 Per week-7 days 25 (3.6 per day)

**Calls received**  
 2006-07 19,282  
 2005-06 15,790  
 Per week-7 days 370 (53 per day)

**Patient summary reports requested**  
 2006-07 3903  
 2005-06 3,127  
 Per week-7 days 75 (11 per day)

### ANALYSIS & SUPPORT FUNCTION

#### Interventions 2006-07

- Sent letters to or met with 9,166 prescribers
- Covered 4,879 patients

#### Interventions 2005-06

- Sent letters to or met with 9,988 prescribers
- Covered 4,638 patients

#### 2005-06 Communications

- Issued 30,929 brochures 'getting more medicine than you need'
- Articles in Forum Magazine, Divisions of General Practice newsletters
- Advertised in MIMS
- Materials provided to doctors when registering for PSIS

### SIZE OF PATIENT POOL

**Number of unique patients identified**  
 2005-06 unique patients identified = 54,474

**Breakdown of unique patients by number of quarters in which they were identified,**

**2005-06**  
 - Identified 1 Qtr only 34,586 63.5%  
 - Identified 2 Qtrs 9,693 17.8%  
 - Identified 3 Qtrs 4,842 8.9%  
 - Identified 4 Qtrs 5,353 9.8%

**Breakdown of total patients identified by quarter 2005-06**  
 2005-06 total patient count (some patients are identified more than once across quarters)

- Qtr ended Sep 23,411  
 - Qtr ended Dec 32,650  
 - Qtr ended Mar 14,525  
 - Qtr ended Apr 19,326  
 Total count 89,912

### PBS ITEMS SUPPLIED TO PERSONS IDENTIFIED UNDER PRESCRIPTION SHOPPING PROGRAM

**Top 5 most commonly supplied PBS items 2005-06 (supplied to persons identified under the Program)**

	Supplies
1. Diazepam Tablets 5mg	227,203
2. Codeine Phosphate Tablet 30mg-500mg	224,070
3. Temazepam Tablet 10mg	135,176
4. Oxazepam Tablet 30mg	120,733
5. Nitrazepam Tablet 5mg	79,134

*NB: Oxycodone hydrochloride and Tramadol Hydrochloride also rate highly when different tablet strengths are combined*

**Selected trends in supply (PBS supplied to persons identified under the Program)**

	Quarter ended			%
	Dec 03	Dec 04	Dec 05	03-05
Diazepam Tablets 5mg	67,582	67,492	66,922	-10
Codeine Phosphate Tablet 30mg-500mg	87,368	85,505	71,675	-18
Temazepam Tablet 10mg	45,007	46,478	44,310	-2
Oxazepam Tablet 30mg	40,540	38,842	36,759	-9
Nitrazepam Tablet 5mg	26,445	26,307	24,950	-6
<b>Patient Pool size</b>	<b>28,743</b>	<b>32,459</b>	<b>32,650</b>	<b>+14</b>

Source: Compliance Strategies and Projects Section  
 Medicare Australia



## Appendix 12: Drugs of Dependence Unit Privileged Circular



**Drug Policies & Programs**  
**Drugs of Dependence Unit**  
MET/113/0129  
Last updated – 6<sup>th</sup> December 2006

Telephone 1300 652 584  
Facsimile 1300 658 447

[www.dassa.sa.gov.au](http://www.dassa.sa.gov.au) – health professionals-legal controls over medicines

### The Controlled Substances Act, 1984

### PRIVILEGED CIRCULAR

**TO: MEDICAL PRACTITIONERS, PHARMACISTS, MEDICAL ADMINISTRATORS DENTISTS,  
VETERINARY SURGEONS AND PRESCRIBED PERSONS.**

**RE: CIRCULATING DRUG SEEKERS**

Subsections (1) and (1a) of section 58 of the *Controlled Substances Act 1984*, provides for the Minister responsible for that Act, to publish information where the Minister believes, on reasonable grounds, that a person has:

- a) a history of consuming poisons or therapeutic substances in a quantity or manner that presents a risk to that person's health, or
- b) obtained or attempted to obtain a poison, therapeutic substance or therapeutic device;
  - (i) by false pretences or other unlawful means or
  - (ii) for an unlawful purpose.

The information is published to medical practitioners, pharmacists, managements of hospitals etc by the Minister for the purpose of preventing or restricting further supply of these substances or devices to those people. It must not be used for any other purpose and it is an offence to communicate this information to other persons except so far as is necessary to prevent or restrict further supplies of these substances or devices. National Privacy Principles require these circulars to be disposed of when no longer required to ensure information is current. It is recommended that this document is destroyed within twelve months from the issue date.

I, Geoff Anderson, as Manager, Drugs of Dependence Unit, exercise the authority delegated to me by the Minister under section 62A of the *Controlled Substances Act 1984*, publish information under section 58(1) of that Act relating to the following persons seeking therapeutic devices or substances:

- |                |                |
|----------------|----------------|
| 1. Aaaaa AAAAA | 5. Eeee FFFFFF |
| 2. Bbbbb BBBBB | 6. Gggg GGGG   |
| 3. Cccc CCCCC  | 7. Hhhh HHHH   |
| 4. Dddd DDDDD  | 8. etc         |

Name & Alias Used	Date of Birth	Addresses Used	Claimed Condition (s)	Drugs Abused	Recommended Action & Drugs of Dependence Unit Ref.
AAAAA Aaaa  Added 6 <sup>th</sup> October 2006	dd/mm/yy	No, Street Suburb		Benzodiazepines	This person consults multiple prescribers when he fails to take his antipsychotic medication and his psychotic symptoms return. Drugs subject to abuse should not be provided unless through his nominated prescriber, Dr M Gggggg of the RAH (8222 5743) DDU NXXXX
BBBBB Bbbbb  Added 09 November 2006	dd/mm/yy	No, Street Suburb		Benzodiazepines	This person consults multiple prescribers. If any prescriptions are issued, ensure written to minimise fraudulent alteration. Recommend drugs subject to abuse not be provided unless through her nominated prescriber Dr D Bbbbbbb (8443 5777) NXXXX

CONTROLLED SUBSTANCES ACT 1984

CONFIDENTIAL PRIVILEGED CIRCULAR as at January 2007

Name & Alias Used	Date of Birth	Addresses Used	Claimed Condition (s)	Drugs Abused	Recommended Action & Drugs of Dependence Unit Ref.
CCCCC Ccccc  Added 18 <sup>th</sup> October 2006	dd/mm/yy	No, Street Suburb		Endone®	This person consults multiple prescribers. Recommend drugs subject to abuse not be provided and he is referred back to his authorised prescriber Dr D Mmmm (8231 4801) NXXXX
DDDDD Ddddd  Added 18 <sup>th</sup> October 2006	dd/mm/yy	No, Street Suburb	Back pain Head aches Falls	Oxycontin® Buprenorphine Benzodiazepines	This person consults multiple prescribers and may present an old letter from the LMHS. Ms Ddddd does have chronic pain issues but requires treatment within a structured drug dependence treatment model. Recommend drugs subject to abuse not be provided and she is referred to an authorised drug dependence treatment program or Warinilla DDU XXXX
EEEEEEEE Eeeee  Added 5 <sup>th</sup> December 2006	dd/mm/yy	No, Street Suburb	Neck pain from old MVA Lower Back Pain Knee pain	Oxycontin®	This person consults multiple prescribers and is suspected of being involved in drug diversion. Associates with Zzzzz ZZZZZ. Recommend drugs subject to abuse not be provided and she is referred to an authorised drug dependence treatment program or Warinilla. DDU XXXX
FFFFFF Fffff  aka Ggggg GGGGG  Added 01 November 2006	dd/mm/yy	No, Street Suburb No, Street Suburb No, Street Suburb No, Street Suburb	Back pain	Kapanol®	This person consults multiple prescribers. Associate of Zzzzz ZZZZZ (see separate entry) and these two people may use other identities. He may claim to be here from interstate or travelling through SA. Has a history of substance abuse. Recommend drugs subject to abuse not be provided and he is referred to a drug treatment program. DDU NXXXX
GGGGG Ggggg  18 October 2006 15 February 2005	dd/mm/yy	No, Street Suburb	Back pain	MS Contin®	This person consults multiple prescribers. May present a medical letter claiming he has chronic back pain. Should be supervised at all times as there are allegations of stolen prescription forms and presenting forged prescriptions. Recommend drugs subject to abuse not be prescribed or dispensed unless through an approved drug treatment program DH XXXX



CONTROLLED SUBSTANCES ACT 1984

CONFIDENTIAL PRIVILEGED CIRCULAR as at January 2007

Name & Alias Used	Date of Birth	Addresses Used	Claimed Condition (s)	Drugs Abused	Recommended Action & Drugs of Dependence Unit Ref.
HHHH Hhhhh  aka lllll lllll JJJJJ Jlllll  Added 18 October 2006 28 Aug 2006 30 May 2006 03a February 2006 09a August 2005 09a June 2005 01a July 2004	dd/mm/yy  dd/mm/yy dd/mm/yy dd/mm/yy	No, Street Suburb Other various addresses	Knee pain Dental pain	Panadeine Forte®	This person consults multiple medical practitioners and dentists. He may produce identification documents in a false name. He does have unhealthy teeth but has shown no interest in corrective treatment. He often demands to be seen urgently and can be aggressive and threatening. He may become abusive and violent (spit) on staff when refused. He may refuse to leave the surgery and police attendance may be considered. He may present fraudulently altered prescriptions. Recommend drugs subject to abuse not be provided and he be referred to Warinilla. NXXXX
			Migraine Haematoma MVA	Pethidine Morphine Endone®	This person consults multiple prescribers. Specifically requests administration of pethidine and may also ask for a prescription to have pethidine on hand. She has a left eye deformity. May falsely claim to be an old patient of the practice or from interstate. Very experienced and skilful in false presentation. Recommend drugs subject to abuse not be provided and she be referred to a drug dependence treatment program. DDU XXXX
			Lower Back Pain	Oxycontin®	This person consults multiple prescribers. May claim to have recently arrived from interstate. Recommend drugs subject to abuse not be provided unless through her authorised prescriber at Warinilla (8130 7500) DDU NXXX
				Endone®	This person consults multiple prescribers. This person is unstable and may be threatening and potentially violent. Treatment of his drug dependence outside of the prison environment is not recommended. Recommend drugs subject to abuse not be provided or dispensed DDU XXXX

This list is not a complete list of persons believed to be consuming or seeking poisons, therapeutic substances or therapeutic devices by fraudulent or unlawful means or for unlawful purposes. . It is a list of persons identified as being extensive or persistent in their behaviour or at a high risk of harm. If hospitals, practitioners or pharmacists suspect this behaviour by persons not listed here, they are encouraged to telephone the Drugs of Dependence Unit (☎1300 652 584) during business hours for assistance. Access to recent circulars and a current list of persons is also available via a secure website and persons authorised to have this information may contact this Unit to obtain access to this site. This Unit monitors the activities of drug seekers, monitors the prescribing of Drugs of Dependence, issues Authorities for long term treatment with drugs of dependence and treatment of drug dependence.

CONTROLLED SUBSTANCES ACT 1984

CONFIDENTIAL PRIVILEGED CIRCULAR as at January 2007

Medicare Australia operates the Prescription Shopping Information Service to facilitate the proper and efficient use of the medicines attracting a Pharmaceutical Benefit subsidy. Medical practitioners must be registered with that Service and be assigned an Access Number. Information available relates only to medicines dispensed as PBS items and is subject to patients meeting Medicare Australia criteria of having obtained more than a specified number of PBS items and/or obtaining PBS items from six or more prescribers (excluding specialists) in a three month period. Prescribers should contact Medicare Australia (☎1800 631 181) for further information or to access this service. Advice from a drug and alcohol specialist medical officer on clinical aspects of treatment of drug dependent patients may be sought from the Drug and Alcohol Clinical Advisory Service (☎1300 131 340).

Where drug dependence is confirmed, the patient may be referred to an approved drug treatment program. These are located at the Drug & Alcohol Services SA (DASSA) clinics at Warinilla, (92 Osmond Terrace Norwood ☎8130 7500), Northern Clinic (☎8252 4040), Southern Clinic (☎8326 6644) and Western Clinic (☎8243 5715), or a private practice general medical practitioner accredited to prescribe methadone and buprenorphine to treat drug dependence, (names are available from the Drugs of Dependence Unit or Warinilla).

It is an offence for a person to obtain or attempt to obtain a prescription drug by false pretences or have in their possession a forged document to obtain these drugs (*Controlled Substances Act 1984, Section 30*). Medical practitioners may seek police assistance (☎131 444) for police attendance (if the person is on the premises) or report suspected offences for police action.

Pharmacists must not dispense a prescription where there are reasonable grounds to suspect the prescription has been altered, forged or obtained by false pretences (*Controlled Substances (Poisons) Regulations 1996, Regulation 27(5)(b)*) and they must report suspected forgeries to the police (*Controlled Substances Act 1984, Section 30*). Forms for reporting suspected forgeries are available from the Drugs of Dependence Unit.

Persons permitted access to this document may view the most current edition and recent past editions via a restricted internet site at [www.dassa.sa.gov.au](http://www.dassa.sa.gov.au). Please contact Colin Brown (☎8274 3423) to apply to gain access to this resource

Geoff Anderson  
Manager, Drugs of Dependence Unit,  
Delegate of the **MINISTER,**  
**CONTROLLED SUBSTANCES ACT.**



## Appendix 13: Return your unwanted medicines to the pharmacy – the Rum Project

**The Return Unwanted Medicines (RUM) Project**

The RUM Project is run by a not-for-profit company, The National Return and Disposal of Unwanted Medicines Limited (ABN 79 002 171 663).

The project enables consumers to return unwanted or out-of-date medicines to any pharmacy, at any time.

The RUM Project has equipped pharmacies throughout Australia with large yellow containers for collection.

The returned medicines are transported for safe disposal.


The project is supported by pharmacists across Australia and funded by the Commonwealth Government to provide for collection and destruction of returned medicines.


*The project is supported by:*

- Pharmaceutical Society of Australia
- Pharmacy Guild of Australia
- Commonwealth Government of Australia
- Council on the Ageing
- Australian Institute of Environmental Health


*Funded by The Australian Government  
Department of Health and Ageing*

**Return your unwanted medicines to your pharmacy**





**Return Unwanted Medicines**



For further information on the RUM Project please phone 1300 050 825 or visit [www.returnmed.com.au](http://www.returnmed.com.au)

Postal Address: PO Box 2856 CHELTENHAM VIC 3192

Telephone: (03) 9583 8889  
Facsimile: (03) 9583 8533

### Return Unwanted Medicines (RUM): The solution to Medicine Waste

#### Why your medicine cabinet can be a health hazard

Most of the medicines in our medicine cabinet we need, but what about the yellow pills in a jar that's lost its label, and the eye drops with the crystals growing around its seal? And what was so wrong that we were prescribed Quinnox B Sulphonate?

#### Old medicines lying around the home 'just in case' are dangerous...

- ✓ If taken when they're out-of-date
- ✓ If taken when not prescribed for you
- ✓ If in reach of little prying fingers

In an average week, around 50 Aussie kids are admitted to hospital after swallowing medicines not intended for them.

The RUM Project provides the safest and easiest way to dispose of unwanted and out-of-date medicines.

It makes possible the return of all household medicines to any pharmacy at anytime - for free and safe collection and disposal.



#### Think before you throw

Unwanted medicines are often dumped into the toilet, tipped down the sink or put out with the garbage, which starts a journey that can seriously harm the environment. More than 200 tonnes of medicines find their way into waterways and landfill every year.

We need to change our behaviours to solve this problem and give the environment a chance.



#### Don't flush medicines down the toilet.

Sewerage plants can't treat all chemicals in waste water, resulting in contamination of waterways.



#### Don't pour medicines down the sink.

Household medicines contain highly soluble chemicals which when entered into water systems can harm aquatic life.



#### Don't throw medicines into the garbage bin.

Household medicines disposed this way end up in exposed landfill sites.

#### RUM provides a far better alternative

By returning out-of-date and unwanted medicines to our local pharmacy, we can make our home a safer place. Help safeguard our community and protect our environment.

#### This is all we need to do... It really is easy



**Step 1:** sort through your medicine cabinet and drawers, putting to one side the out-of-date and unwanted medicines



**Step 2:** take them to your local pharmacy



**Step 3:** give them to your pharmacist for proper disposal, and...



**Step 4:** tell your friends and relatives about the RUM project.



# Appendix 14: Preamble to Medicines Australia Code of Conduct

**MEDICINES**  
*Australia*  
BETTER HEALTH THROUGH RESEARCH AND INNOVATION

## CODE OF CONDUCT

### Preamble

- (a) This Code of Conduct sets out standards of conduct for the activities of companies when engaged in the marketing of prescription products used under medical supervision as permitted by Australian legislation. The Code owes its origin to the determination of Medicines Australia to secure universal acceptance and adoption of high standards in the marketing of prescription medicines for human use.

It is the responsible role of members of the pharmaceutical industry to provide on-going, objective and scientifically valid interpretations of data on prescription medicines to healthcare professionals. The industry also has an obligation to provide appropriate non-promotional information on prescription medicines to members of the general public\*. The Code provides the standard for the provision of this information.

- (b) Acceptance and observance of the Code is a condition of membership of Medicines Australia. In accepting and observing the Code companies must comply with both the letter and the spirit of the Code.

Companies should ensure that all agents acting on their behalf are fully conversant with the provisions of this Code.

Pharmaceutical companies which are not members of Medicines Australia are invited to accept and observe this Code and must comply with its provisions when required by the TGA.

The Code shall be supervised and administered by the Board of Medicines Australia. Medicines Australia may issue determinations from time to time for the purpose of interpretation of certain sections of the Code. Complaints concerning alleged breaches of the Code should be reported to the Chief Executive Officer of Medicines Australia or his or her delegate.

Medicines Australia is also responsible for proposing amendments to the content of the Code of Conduct for adoption by its membership. Medicines Australia consults widely within the pharmaceutical industry and with external stakeholders regarding the Code of Conduct and welcomes comments or suggestions that will improve the Code's content and operation. Comments can be provided to Medicines Australia either by phone on (02) 6282 6888 or email at [secretarycodecommittee@medicinesaustralia.com.au](mailto:secretarycodecommittee@medicinesaustralia.com.au)

A major guiding principle of the Code is that, whenever a promotional claim\* is made for a product, it shall be accompanied by appropriate information based on the Product Information for that product.

The Code also reflects the industry's commitment that all activities with, or materials provided to healthcare professionals and members of the general public must never be such as to bring discredit upon, or reduce confidence in the pharmaceutical industry. Such activities would be seen as a Severe Breach\* of the Code of Conduct.

Failure to comply with the Code will result in sanctions being applied under the provisions of Section 12. Adherence to this Code in no way reduces a company's responsibilities to comply with the Trade Practices Act, Commonwealth and State Therapeutic Goods Acts and other requirements, legislation and Codes, including the IFPMA\* Code. It should be recognised that the Medicines Australia Code is based upon the provisions of the IFPMA Code. Promotion\* of prescription-only products to the general public is prohibited by law.



## Appendix 15: Proper Disposal of Prescription Drugs – U.S. Federal Guidelines (ONDCP)



### Proper Disposal of Prescription Drugs

Office of National Drug Control Policy February 2007

#### *Federal Guidelines:*

- Take unused, unneeded, or expired prescription drugs out of their original containers and throw them in the trash.
- Mixing prescription drugs with an undesirable substance, such as used coffee grounds or kitty litter, and putting them in impermeable, non-descript containers, such as empty cans or sealable bags, will further ensure the drugs are not diverted.
- Flush prescription drugs down the toilet *only* if the label or accompanying patient information specifically instructs doing so (see box).
- Take advantage of community pharmaceutical take-back programs that allow the public to bring unused drugs to a central location for proper disposal. Some communities have pharmaceutical take-back programs or community solid-waste programs that allow the public to bring unused drugs to a central location for proper disposal. Where these exist, they are a good way to dispose of unused pharmaceuticals.

The FDA advises that the following drugs be flushed down the toilet instead of thrown in the trash:

**Actiq** (fentanyl citrate)  
**Daytrana Transdermal Patch** (methylphenidate)  
**Duragesic Transdermal System** (fentanyl)  
**OxyContin Tablets** (oxycodone)  
**Avinza Capsules** (morphine sulfate)  
**Baraclude Tablets** (entecavir)  
**Reyataz Capsules** (atazanavir sulfate)  
**Tequin Tablets** (gatifloxacin)  
**Zerit for Oral Solution** (stavudine)  
**Meperidine HCl Tablets**  
**Percocet** (Oxycodone and Acetaminophen)  
**Xyrem** (Sodium Oxybate)  
**Fentora** (fentanyl buccal tablet)

Note: Patients should always refer to printed material accompanying their medication for specific instructions.

Office of National Drug Control Policy  
ONDCP, Washington, D.C. 20503  
p (202) 395-6618 f (202) 395-6730



[www.WhiteHouseDrugPolicy.gov](http://www.WhiteHouseDrugPolicy.gov)

## Appendix 16: Examples of Internet activity pertaining to prescription drug recreational abuse

From:  
Subject: Re: How to get Dr. to upgrade fr Vike ES to Oxycontin?  
Date: 2000-10-01 05:30:05 PST

Thanks to all for your replies. This is kind of a funny story. I work as a drug rep and typically mention this to my Docs as I usually get some small talk out of them and we can BS about the industry, status of the evil HMO's, etc. This usually places them at ease and I feel freer to ask for what I'd like.

In this case, about a month ago I used my patented (actually read about it here) ER technique of, "I fell on my tailbone this morning taking out the trash and am in extreme pain." I have only tried hospitals in nice areas in my work territory (i.e., not big cities, the ER's are so busy you could kill 5 hrs there), I go in there dressed for work (suit & tie) and tell them that I tried to work today and before I could get to my meetings in their area to call on Dr. So-and-So, the pain was too great and I figured I'd go into the ER. I've only done this a half dozen times, and only when all other avenues have failed, but have received Percs or Vike ES every time.

From:  
Subject: Ritalin.. no effect? wtf?  
Date: 1999/06/20

I got some yellow 20mg Ritalin pills the other day, and I snorted 60mg and ate 20mg (never done any type of speed before) and nothing happened except I couldn't sleep for awhile and I was kinda jittery.. I kept grinding my teeth. I got no buzz/high, I hear Ritalin is pretty sh.tty but I expected more than this. I've heard of some types of Ritalin having coatings on them making them unabusable.. could this be the problem or was I just expecting too much?

From:  
Subject: Re: I'd kill for vicodan.  
Date: 2001-01-26 14:01:22 PST

Dave, get some hydro or some codeine and just extract the good stuff from the PAP. Oxy has the stronger side effects, but with hydro/codeine you're almost guaranteed 100% nice floaties.  
>You know, I was thinking the same thing. Hydrocodone is better.. How do you extract the APAP? And what is APAP? heh...  
>>The APAP is like aspirin-sh.t that they toss in, partly to aid the medicine But mostly to discourage abuse. The good thing is, it's highly water soluble while the hydrocodone/codeine isn't.

From:  
To: "Bill" (UC San Diego)  
Subject: Re: Fentanyl Patches and IM  
Date: 2000-09-23 08:30:38 PST

It's awesome to eat. Just tear it open and eat like half (that's plenty), you feel it in like 20 minutes.

"Bill" wrote in message 8qgkoi\$119\$1..

>Would it be safe to inject the substance contained within Fentanyl Patches?

>I know it also contains a small amount of alcohol. Would it need to be diluted with water?



# Appendix 17: Consumer Medicine Information document

## Xanax(R) Tablets

Alprazolam

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about Xanax. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Xanax against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

#### What Xanax is used for

Xanax is used to treat anxiety attacks.

Your doctor may have prescribed Xanax for another purpose. Ask your doctor if you have any questions about why Xanax has been prescribed for you.

Xanax belongs to a group of medicines called benzodiazepines. They are thought to work by their action on brain chemicals.

In general, benzodiazepines such as Xanax should be taken for short periods only (for example 2-4 weeks). Continuous long term use is not recommended unless advised by your doctor. The use of

benzodiazepines may lead to dependence on this medicine. This medicine is available only with a doctor's prescription.

2. you are pregnant or plan to become pregnant.

Your doctor will discuss the risks and benefits of taking Xanax during pregnancy.

3. you are breastfeeding or plan to breastfeed.

Your doctor will discuss the risks and benefits of taking Xanax when breastfeeding.

4. you have or have had any other medical conditions including:

- depression, psychosis or schizophrenia
- liver, kidney or lung disease
- glaucoma (high pressure in the eye)
- myasthenia gravis (nerve muscle weakness)
- You drink alcohol regularly.

Alcohol may increase the effects of Xanax.

#### Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may affect how well Xanax works. These include:

- sedatives (medicines used to produce calmness or to help you sleep)
- medicines to control fits
- antipsychotics (medicines used to treat certain mental and emotional conditions)
- medicines for depression
- muscle relaxants

#### Before you start to take it

You must tell your doctor if:

1. you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

- anticholinergics (medicines used to prevent or relieve the symptoms of allergy such as hay fever)
- pain relievers
- anaesthetics
- cimetidine (a medicine used to treat reflux and ulcers)
- diazepam (a medicine used in the treatment of alcoholism)
- sedatives such as morphine
- anti-epileptics
- HIV protease inhibitors
- medicines used to treat HIV infection.

These medicines may increase the effects of Xanax.

Xanax may affect some medicines or may affect how well they work.

These include:

- anticholinergics
- medicines for depression
- lithium (a medicine used to treat mood swings and some types of depression)
- aspirin and similar medicines
- You may need different amounts of your medicine as you may need to take different medicines. Your doctor or pharmacist will have more information on medicines to be careful with or avoid while using Xanax.

#### How to take Xanax

##### How much to take

The dose of Xanax will be different for each person. Your doctor will decide the right dose for you.

##### When to take it

Your doctor will tell you how many times a day you should take your Xanax tablets. Xanax can be taken immediately after meals or on an empty stomach. However, this advice such as symptoms or discomfort may be reduced if you take your Xanax tablets immediately after meals.

#### How long to take it

Do not take Xanax for longer than your doctor says.

Usually Xanax should be used for short periods only (for example, 2-4 weeks). Continuous long term use is not recommended unless advised by your doctor. The use of benzodiazepines may lead to dependence on the medicine.

Continue taking Xanax for as long as your doctor recommends it.

#### If you forget to take Xanax

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking Xanax as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are unsure about whether to take your next dose, speak to your doctor or pharmacist.

#### If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Xanax.

Do this even if there are no signs of discomfort or poisoning. Also report any other medicine or alcohol which has been taken. You may need urgent medical attention. Keep original containers for these places handy.

#### While you are taking Xanax

##### Things you must do

Use Xanax exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Xanax.

If you feel that Xanax is not helping your condition, tell your doctor.

If you become pregnant while you are taking Xanax, tell your doctor.

Visit your doctor regularly.

Your doctor needs to check your progress and see whether you need to keep taking Xanax.

Always discuss with your doctor any problems or difficulties during or after taking Xanax.

If you are being treated for anxiety, do not stop taking Xanax with your doctor any problems you may have and how you feel, especially if your anxiety attacks are getting worse or more frequent.

This will help your doctor to determine the best treatment for you.

Tell your doctor if, for any reason, you have not taken Xanax exactly as prescribed.

Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

##### Things you must not do

Do not drive or operate machinery until you know how Xanax affects you.

Xanax may cause drowsiness or dizziness in some people and therefore may affect driving.

Even if you take Xanax at night, you may still be drowsy or dizzy the next day.

Do not take Xanax for a longer time than your doctor has prescribed.

XANAX(R) TABLETS

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XANAX(R) TABLETS

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<p>Xanax should be taken for short periods only (for example 2 to 4 weeks), unless advised otherwise by your doctor.</p> <p>Do not increase your dose of Xanax without first checking with your doctor.</p> <p>Do not stop taking Xanax or lower the dose without first checking with your doctor.</p> <p>Stopping this medicine suddenly may cause some unwanted effects. You and your doctor will slowly reduce your dose of Xanax before you can stop taking it completely.</p> <p>Do not suddenly stop taking Xanax if you suffer from epilepsy.</p> <p>Stopping this medicine suddenly may make your epilepsy worse.</p> <p>Do not take Xanax to treat any other complaint unless your doctor tells you to.</p> <p>Do not give Xanax to anyone else, even if their symptoms seem similar to yours.</p>	<p><b>Side effects</b></p> <p>Tell your doctor or pharmacist as soon as possible if you have any problems while taking Xanax, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.</p> <p>Like other medicines, Xanax can cause some side effects. If they occur, most are likely to be minor and temporary, generally occurring at the beginning of treatment and usually disappearing as treatment is continued or when the dose is reduced. However, some may be serious and need medical attention.</p> <p>Ask your doctor or pharmacist to answer any questions you may have.</p> <p>Tell your doctor if you notice any of the following and they worry you:</p> <ul style="list-style-type: none"> <li>Is patients treated for anxiety and anxiety associated with depression, the most common side effects to Xanax are:</li> <li>• drowsiness</li> <li>• dizziness</li> <li>• light-headedness</li> </ul> <p>Less common side effects are:</p> <ul style="list-style-type: none"> <li>blurred vision, headache, depression, trouble sleeping,</li> <li>• nervousness/anxiety, tremor, change in weight, memory problems, coordination problems,</li> <li>gastrointestinal and nervous system problems, irritation, agitation, concentration difficulties, confusion, hallucinations, irritability, loss of appetite, problems with muscle tone, fatigue, slurred speech, yellowing of the skin and/or eyes, muscle/achalasia, weakness, changes in libido, irregular menstrual periods, incontinence, inability or difficulty passing urine and liver problems.</li> <li>Pressure in the eye is a rare side effect.</li> </ul> <p>In patients treated for panic attacks, the most common side effects to Xanax are:</p> <ul style="list-style-type: none"> <li>• drowsiness</li> <li>• fatigue</li> </ul>	<p><b>After using Xanax</b></p> <p><b>Storage</b></p> <p>Keep your tablets in their blister pack or bottle until it is time to take them.</p> <p>If you take the tablets out of the blister pack or bottle they may not keep well.</p> <p>Keep your Xanax tablets in a cool dry place protected from light where the temperature stays below 30 degrees C (for the bottle) and below 25 degrees C (for the blister).</p> <p>Do not store Xanax, or any other medicines, in a bathroom or near a sink. Do not leave it in the car or on windowsills. Heat and dampness can destroy some medicines.</p> <p>Keep your Xanax tablets where children cannot reach them.</p> <p>A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.</p>	<p><b>Things to be careful of</b></p> <p><b>Be careful when drinking alcohol while taking Xanax.</b></p> <p>Combining Xanax and alcohol can make you more sleepy, dizzy or light-headed.</p> <p>Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are taking Xanax.</p> <p><b>Be careful if you are elderly, unwell or taking other medicines.</b></p> <p>Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.</p>
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XANAX(R) TABLETS

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<p><b>Disposal</b></p> <p>If your doctor tells you to stop taking Xanax or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.</p>	<p><b>Product description</b></p> <p><b>What it looks like</b></p> <p>Xanax tablets are available in 250 microgram, 500 microgram and 1 mg and 2 mg strengths.</p> <p>Xanax 250 microgram tablets are white, scored, oval-shaped tablets marked "Upjohn 25". They are available blister packs of 50 tablets.</p> <p>Xanax 500 microgram tablets are pink, scored, oval-shaped tablets marked "Upjohn 55". They are available in blister packs of 50 tablets.</p> <p>Xanax 1 mg tablets are lilac, scored, oval-shaped tablets marked "Upjohn 90". They are available in blister packs of 50 tablets.</p> <p>Xanax 2 mg tablets are white, un-scored, capsule-shaped tablets marked with "U" and "94" on one side. They are available in bottles of 50 tablets.</p>	<p><b>Ingredients</b></p> <p>The active ingredient in Xanax tablets is alprazolam.</p> <p>Xanax tablets also contain lactose, microcrystalline cellulose, colloidal silica anhydrous, maize starch, croscarmellose sodium with sodium benzoate, magnesium stearate, erythrosine CI 45430 (500 microgram and 1 mg tablet only) and indigo carmine CI 73015 (1 mg tablet only).</p>	<p><b>Identification</b></p> <p>Xanax tablets can be identified by the Australian Register Number on the box:</p> <ul style="list-style-type: none"> <li>250 microgram Blister: AUST R 62558</li> <li>500 microgram Blister: AUST R 12352</li> <li>1 mg Blister: AUST R 12353</li> <li>2 mg bottle: AUST R 31931</li> </ul> <p><b>Supplier</b></p> <p>Xanax tablets are supplied in Australia by:</p> <ul style="list-style-type: none"> <li>Pfizer Australia Pty Ltd ABN 59 008 422 348 38-42 Wharf Road West Ryde NSW 2114 Australia</li> </ul> <p>Toll Free number: 1800 675 229</p> <p>This leaflet was revised in June 2007</p>
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# Appendix 18: Drug Addiction in Health Care Professionals – U.S. Drug Enforcement Administration



## Drug Addiction in Health Care Professionals

The abuse of prescription drugs—especially controlled substances—is a serious social and health problem in the United States today. People addicted to prescription medication come from all walks of life. However, the last people we would suspect of drug addiction are health care professionals—those people trusted with our well-being. Yet health care workers are as likely as anyone else to abuse drugs.

Even though the vast majority of DEA registered practitioners comply with the controlled substances law and regulations in a responsible and law abiding manner, you should be cognizant of the fact that drug impaired health professionals are one source of controlled substances diversion. Many have easy access to controlled substance medications; and some will divert and abuse these drugs for reasons such as relief from stress, self-medication, or to improve work performance and alertness.

This guide will help you recognize the signs that may indicate that a colleague or co-worker is diverting controlled substances to support a substance abuse problem.

- [What Are My Responsibilities?](#)
- [How Do I Recognize a Drug Impaired Co-Worker?](#)
- [Should I Become Involved?](#)
- [What If I Know That Drugs Are Being Sold or Stolen?](#)
- [What Can I Do to Help?](#)

### What are My Responsibilities?

You have a legal and ethical responsibility to uphold the law and to help protect society from drug abuse.

You have a professional responsibility to prescribe and dispense controlled substances appropriately, guarding against abuse while ensuring that patients have medication available when they need it.

You have a personal responsibility to protect your practice from becoming an easy target for drug diversion. You must become aware of the potential situations where drug diversion can occur and safeguards that can be enacted to prevent this diversion.

### How Do I Recognize a Drug Impaired Co-Worker?

- Drug abusers often exhibit similar aberrant behavior. Certain signs and symptoms may indicate a drug addiction problem in a health care professional. Have you observed some of the following signs?
- Work absenteeism –absences without notification and an excessive number of sick days used;
- Frequent disappearances from the work site, having long unexplained absences, making improbable excuses and taking frequent or long trips to the bathroom or to the stockroom where drugs are kept;

### Should I Become Involved?

Health care professionals often avoid dealing with drug impairment in their colleagues. There is a natural reluctance to approach a co-worker suspected of drug addiction. There is the fear that speaking out could anger the co-worker, resulting in retribution, or could result in a colleague's loss of professional practice.

Many employers or co-workers end up being "enablers" of health care practitioners whose professional competence has been impaired by drug abuse. Addicted colleagues are often given lighter work schedules, and excuses are made for their poor job performance. Excessive absences from the work site are often overlooked. Drug impaired co-workers are protected from the consequences of their behavior. This allows them to rationalize their addictive behavior or continue their denial that a problem even exists.

If you recognize the aforementioned signs or symptoms in a co-worker, it's time to demonstrate concern. You may jeopardize a person's future if you cover up or don't report your concerns. Many well-educated, highly trained, and experienced health care practitioners lose their families, careers, and futures to substance abuse. Tragically, some health care workers have even lost their lives to their drug addiction because the people who saw the signs and symptoms of their drug use refused to get involved.

By becoming involved, you can not only help someone who may be doing something illegal, but more importantly, your action could affect the safety and welfare of your addicted employee or coworker AND those patients or the public who may come in contact with him or her.

### What If I Know That Drugs Are Being Sold or Stolen?

Drug abuse and drug dealing are serious problems that should be handled by qualified professionals. If you suspect that a drug deal is in progress, do not intervene on your own. Contact security or notify the police.

If you are a DEA registrant and become aware of a theft or significant loss involving controlled substances, you must immediately report the theft or loss to the nearest DEA office as well as your local police department.

### What Can I Do to Help?

For some employees, the mere fact that their supervisor talks to them about their poor work performance is enough to help them change. For others, however, the problem may be more severe and require more drastic measures. The threat of losing a job may have more influence on a drug abuser than a spouse's threat to leave or a friend's decision to end a relationship. Many drug abusers will seek help for their problem if they believe their job is at stake, even though they have ignored such pleas from other people important in their life.

Drug addicts can recover, and effective help is available. Encourage your co-worker or employee to seek drug treatment assistance. Treatment programs range from self-help to formal recovery programs. A number of state licensing boards, employee assistance programs, state diversion programs, and peer assistance organizations will refer individuals and their families to appropriate counseling and treatment services. These services will maintain the confidentiality of those seeking assistance to the greatest extent possible.

Department of Justice  
Drug Enforcement Administration  
Office of Diversion Control  
Liaison and Policy Section  
Washington, D.C. 20537

- Excessive amounts of time spent near a drug supply. They volunteer for overtime and are at work when not scheduled to be there;
- Unreliability in keeping appointments and meeting deadlines;
- Work performance which alternates between periods of high and low productivity and may suffer from mistakes made due to inattention, poor judgment and bad decisions;
- Confusion, memory loss, and difficulty concentrating or recalling details and instructions. Ordinary tasks require greater effort and consume more time;
- Interpersonal relations with colleagues, staff and patients suffer. Rarely admits errors or accepts blame for errors or oversights;
- Heavy "wastage" of drugs;
- Sloppy recordkeeping, suspect ledger entries and drug shortages;
- Inappropriate prescriptions for large narcotic doses;
- Insistence on personal administration of injected narcotics to patients;
- Progressive deterioration in personal appearance and hygiene;
- Uncharacteristic deterioration of handwriting and charting;
- Wearing long sleeves when inappropriate;
- Personality change - mood swings, anxiety, depression, lack of impulse control, suicidal thoughts or gestures;
- Patient and staff complaints about health care provider's changing attitude/behavior;
- Increasing personal and professional isolation.



## Appendix 19: Brochures supplied by Mundipharma

### HOW TO STOP DRUG DIVERSION & PROTECT YOUR PRACTICE

#### 1. Be Wary of a Patient New to the Practice

The Drug diverter may be another practitioner, friend, or relative, but more likely he/she claims to be travelling through town, or visiting friends/relatives. Many tell elaborate stories, "Doctor, you're not going to believe this, but..."



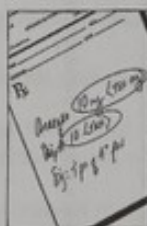
Drug Diversers don't look alike, but they often exhibit similar behaviour in order to obtain prescriptions that they can alter or photocopy. Look for any of the following clues:

- Usually presents alone
- Wants an appointment towards end of office hours, or telephones/arrives after regular hours.
- Insists on being seen immediately and/or demands immediate action. Says he/she is in a hurry to catch a plane, keep an important appointment, etc.
- Not interested in having a physical examination, giving permission to obtain past records, or undergoing diagnostic tests.

#### 2. Adhere to Your Professional Standards

- Always obtain a complete history, examine the patient and order appropriate diagnostic tests.
- Look for signs of drug abuse: inflamed nostrils, perforated nasal septum, skin tracks (often multiple, linear, occasionally hyperpigmented lesions on arms, wrists, axillae, neck, between toes, ankles, groin). Subcutaneous route of abuse often leaves larger round or irregular scars.
- Document results of exam and the questions you asked.
- Request photo (or other) I.D. and Medicare number; photocopy documents and file them in patient's record.
- Call previous practitioners, pharmacists, hospitals or Pharmaceutical Services Branches (or equivalent) in each State or Territory to confirm patient's history; **get the telephone numbers from directory assistance, not from the patient.**
- Schedule diagnostic tests appropriate to the complaint.
- Stick to your own principles about prescribing medication in the absence of a formal doctor-patient relationship.
- Obtain photo I.D. from anyone picking up a prescription for someone else.
- If you suspect an attempt to divert prescription medications, call your local police station and/or the Drugs of Dependence Unit/Pharmacy Branch in your State.

#### 3. Protect Your Prescription Pads

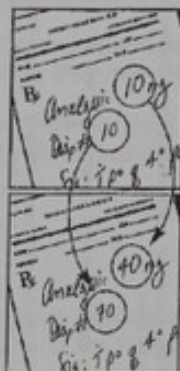


- Keep tight control all prescription pads consider keeping locked up. Guard like your credit card. Keep them in your pocket, not in the examination room.
- Never sign an inco prescription blank don't leave space

between the last item written and your signature items can be added by a forger.

- Write the quantity and strength of drugs as prescriptions in both numbers and letters like the way you write your cheques. (The 10 can easily be altered to 40, 70 or 100)
- Do not print your prescriber number on it - write it when you write a prescription.

- Unwilling/unable to give name of regular doctor; often claims to have no health insurance. Often suggests it will be difficult to contact the doctor - strategy, say you can't prescribe the drug without contacting the previous doctor, to ask them to get their usual doctor to contact you. A patient with pain severe enough to require opioids will usually have made arrangements about circumstances such as travel.
- Unable to recall the hospital or clinic where past records are kept or states it closed down or burned down.
- Claims to have lost prescription or forgotten to pick medication, or says that it was stolen.
- Appearance of patient is not consistent with their claim of severe pain requiring opioids - doesn't appear to be in pain (restless, sweating, tachycardia etc)
- Patient rejects or dismisses offered alternative medication or non-drug treatment.
- Recites textbook symptoms or gives vague medical history.
- Has no interest in diagnosis or a referral; wants a prescription now.
- Shows an unusual knowledge of controlled substances.
- Requests a specific controlled drug and is unwilling to try another medication.
- States that specific nonopioid analgesics do not work or that he/she is allergic to them.



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## Helpful Information for patients who require an opioid analgesic for pain management



### HELPFUL INFORMATION FOR PATIENTS WHO REQUIRE AN OPIOID ANALGESIC FOR PAIN MANAGEMENT

#### Collect the Information You Need from the Patient

##### Ask the patient:

- What other conditions they are being treated for?
- What other health professionals are they seeing, including medical practitioners, naturopaths, homeopaths and herbalists?
- Whether they smoke, how much alcohol they drink and whether they use, or have used, illicit drugs?
- Whether they have had any allergies to medications, food or other substances?
- What medications they are taking including "Over The Counter" products, vitamins and herbal medicines?

#### Communicate Clearly

##### Make it easy for your patient to remember what you say:

- Organise the information you plan to cover
- Use simple lay terms not medical terminology
- Provide written information to reinforce what you have said
- Encourage questions about any concerns
- At the end of the discussion ask the patient to give a summary of what you have told them.

#### Give your Patient the Information He/She Needs

##### Your patient should be told:

- The name of the medication

- The purpose for which it is being prescribed
- How often it should be taken
- Whether to take it before, with or after food
- Whether it should be taken with water or any other liquid
- Whether there are interactions with other medication or with particular foods or alcohol
- About known, expected side effects and their management
- To whom they should speak about medication problems eg. Nurse, doctor, pharmacist
- How to avoid 'running out' of medication

#### Emphasise the Most Important Messages

##### Remind your patient to:

- Keep their medication out of the sight and reach of children.
- Avoid taking medications in front of children, since they tend to mimic adults. Note: Child-resistant caps are not child-proof. However, they may deter or delay a child long enough for someone to intervene.
- Never give their medications to anyone else.
- Never just add on new medication to a previously prescribed one without asking their doctor.
- Never take someone else's medication.
- Never break, crush or chew controlled release opioid analgesics
- Destroy unused and out-of-date medications, or return them to their pharmacist for destruction.



**Provide Clear Messages for Patients Taking Opioid Analgesics for Chronic Pain**

- Obtain the patients' consent in writing. Give one copy to the patient and keep one copy with the patients' record.
- Advise the patient that, by law, they must meet the requirements of the Drug and Poisons Regulations in the state. Emphasise that this protects patients and the prescribing doctors.
- Ask the patient to keep a pain diary explaining how they can make it a useful record and a helpful way of monitoring their pain relief.
- Arrange regular review to ensure that the pain is opioid responsive and to assess whether or not the dose can be reduced.
- Patients taking opioid analgesics need to understand that there is a total safe dose per day.

**Offer Information to Relieve Your Patients' Concerns**

Explain, in simple lay terms, the difference between tolerance, physical dependence and psychological dependence. Avoid the use of the terms addict or addiction. Reassure the patient that the use of opioid medication is supported by the Australian Pain Society, and the Faculty of Pain Medicine, provided the guidelines are met and the patient takes the medication as prescribed.



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