A common understanding : guidance on joint working between NHS Scotland and the pharmaceutical industry.

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NHS SCOTLAND

A Common Understanding

GUIDANCE

ON JOINT WORKING BETWEEN NHSSCOTLAND AND THE PHARMACEUTICAL INDUSTRY

SCOTTISH EXECUTIVE

A Common Understanding

GUIDANCE

ON JOINT WORKING BETWEEN NHSSCOTLAND AND THE PHARMACEUTICAL INDUSTRY

Scottish Executive
Edinburgh 2003

Throughout this document:

- 'Employee' refers to all employees of an NHS Board or Trust.
- The Association of the British Pharmaceutical Industry (ABPI) is the trade association representing manufacturers of prescription medicines. Membership is voluntary. The ABPI Code of Practice for the Pharmaceutical Industry sets standards for the promotion of medicines to health professionals. The code applies automatically to members and may be adopted by non-member companies. It is administered by Prescription Medicines Code of Practice Authority.
- 'Pharmaceutical Industry' includes manufacturers and suppliers of pharmaceutical products; high-tech home health care provider's equipment and appliances. This includes ABPI members and non-ABPI members.
- 'Independent contractors' includes general medical practitioners, pharmacists, dentists, opticians, and chiropodists.

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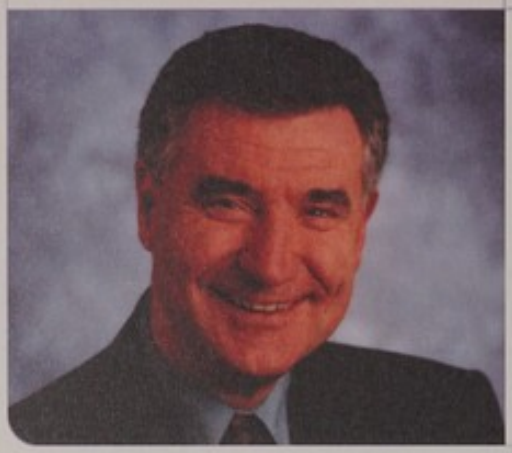
Chief Executive's Foreword



Trevor Jones, Chief Executive, NHSScotland

The Right Medicine: A Strategy for Pharmaceutical Care in Scotland was published in February 2002. As a major action point of the Strategy, an undertaking was made to produce guidance on joint working between NHSScotland and the pharmaceutical industry which will help to ensure common understanding and improve patient care.

The Pharmaceutical Industry is a significant stakeholder in the NHS and is key to developing new and more cost-effective drug therapies. There are many potential benefits to be gained from joint working and NHSScotland is keen to continue to work with the industry both to support existing services and to develop new ones.

The guidance aims to establish a common understanding on joint working by highlighting examples of good practice and a model joint working framework that will help ensure responsibility, transparency and probity in the joint working process. I am confident that we shall achieve our aims and look forward to NHSScotland and the Pharmaceutical Industry continuing to make a significant contribution to the health of the people of Scotland.

Chairman's Foreword

Professor James Barbour OBE, Chairman of Working Group

The issuing of this guidance provides an excellent opportunity to build on existing relationships and to develop uniformity of approach across NHSScotland. I am sure it will complement and help to consolidate existing good practice.

Practitioners in all healthcare settings will, I hope, welcome the model framework. It outlines a pragmatic tool for all the stakeholders engaged in joint working and also helps bring clarity and probity to the process. It is encouraging to have the support of the Association of the British Pharmaceutical Industry whose Director, Jim Eadie, of ABPI Scotland is on record as saying:

"The commitment shown by NHSScotland and the Association of the British Pharmaceutical Industry and its member companies towards the development and implementation of guidance has been a tangible demonstration of the benefits of working together and is itself an example of what can be achieved. I am convinced that as NHSScotland and the Pharmaceutical Industry work more closely in this new spirit there will be real benefits for patient care and improvements in the health of the people of Scotland."

This is an important document which has the support of all parties and I commend it to you.

Background

1. *The Right Medicine: A Strategy for Pharmaceutical Care in Scotland* commits the Executive to produce guidance on joint working between NHSScotland and the Pharmaceutical Industry.
2. A governing ethos of NHSScotland is the acceptance and recognition that a modern dependable NHS will be built on effective joint working with others. All joint working, if properly managed, should be of mutual benefit to the organisations concerned and to patients. The relationship between the NHS and the Pharmaceutical Industry should not be any different and should be built on mutual respect and trust.
3. A fundamental principle is that all joint working between NHSScotland and the Pharmaceutical Industry must be for the benefit of patients. Joint working with the Pharmaceutical Industry has many benefits in relation to improvements in service provision, direct patient care and the support and development of NHSemployees/independent contractors. The relationship between NHSScotland and the Pharmaceutical Industry is acknowledged.
4. This guidance aims to establish new thinking on joint working by highlighting examples of good practice and a model joint working framework that will help ensure common understanding, responsibility, transparency and probity in the joint working process – see Appendix A – Joint Working Framework. Examples of potential conflicts of interest can be found in Appendix B.
5. NHS Circular MEL (1994) 48, entitled "Standards of Business Conduct for NHS Staff", specified the general standards which should be maintained by all employees/ independent contractors working in the NHS. This guidance is still extant along with any local standing orders. All health professionals including independent contractors and locum practitioners working under NHS terms and conditions are covered by the circular. The guidance contained in this document should apply equally to charitable sources of funding as well as Local Health Care Co-operatives (LHCC) and initiatives such as NHS24, etc. Community Health Partnerships (CHPs) are intended to evolve from LHCCs and will be responsible for the delivery of a wide range of community health provision, such as GP services, pharmacy and community nursing. This guidance will therefore apply equally to CHPs.
6. All collaborative joint working involving the Pharmaceutical Industry should comply with the relevant codes of conduct for both healthcare professionals and the Pharmaceutical Industry. The ABPI Code of Practice for the Pharmaceutical Industry is administered by the Prescription Medicines Code of Practice Authority (Appendix C). It should also comply with all relevant existing legislation including the Medicines Act 1968, the Medicines (Advertising) Regulations 1994 and the Prevention of Corruption Act 1916 and within the context described in the Scottish Executive publication *Standards of Conduct, Accountability and Openness.*
7. Existing corporate and clinical governance policies and disciplinary procedures relating to commercial joint working should be reviewed to ensure that they cover the need for open declaration and are constructed in such a way as to allow the appropriate action to be undertaken to enable people to comply. Any failing to do so, should be strengthened or amended accordingly and incorporated into local standing orders.

1. Introduction

There are three crucial public service values which must underpin the work of the health service as set out in *Standards of Conduct, Accountability and Openness.*

VALUES

Conduct: There should be an absolute standard of honesty and integrity which should be the hallmark of all personal conduct in decisions affecting patients, employees/independent contractors and suppliers, including the use of information acquired in the course of NHSScotland duties and in dealing with the assets of NHSScotland.

Accountability: Everything done by those who work in NHSScotland must be able to stand the test of parliamentary and public scrutiny, including judgements on propriety and professional codes of conduct.

Openness: NHSScotland should be open about its activities and plans in order to promote confidence between the NHS Boards and Trusts or other health organisations and their employees/independent contractors, patients and the public.

PRINCIPLES

- All joint working between the Pharmaceutical Industry and NHSScotland must be for the benefit of patients.
- Pharmaceutical companies have a desire to improve health and healthcare whilst maintaining probity.
- All patient identification should be removed from data in line with the Data Protection Act to respect and preserve patient confidentiality.
- Clinical aspects of care, including the development of guidelines and protocols, should be under local/national NHSScotland control.
- Work should proceed on a project-by-project basis. This does not preclude a strategic overview to allow effective planning.
- Reports or information pertaining to joint working should not be used or published without explicit permission given by all partners entering the agreement.
- The joint working agreement should not be seen as an endorsement or promotion of a specific medicine or technology.
- The interests of individual patients must be protected, e.g. to guard against the exclusive use of any single product to the exclusion of other brands or products from within the same therapeutic class.
- The joint working should not undermine or conflict with the ethical requirements of any healthcare professional, including the duty of clinicians to provide the treatment they consider clinically appropriate.
- The Pharmaceutical Industry must comply with the relevant Code of Practice at all times.
- All NHSScotland employees/independent contractors involved must comply with NHS (and relevant professional bodies) codes of conduct.
- Pharmaceutical company size (turnover) will not dictate involvement with NHSScotland.
- The Pharmaceutical Industry has to show clear demarcation between research and development interests and marketing operations.
- If joint working involves research then best research practice should be applied and the relevant Local Research Ethics Committee should be consulted.
- All joint working projects must promote and enhance equitable access to evidence-based health care.

Working together to improve patient care

Heart Pack – Coronary Heart Disease Resource Directory

A collaborative project between the Royal College of General Practitioners (RCGP) in Scotland, the Scottish Heart and Arterial Risk Prevention (SHARP) group, Scottish Intercollegiate Guidelines Network (SIGN) and The Pharmaceutical Industry in Scotland.

The main objective of the Heart Pack was to bring together materials to help Primary Care Teams across Scotland implement the recommendations in the SIGN Guidelines. There was a desire to avoid unnecessary duplication of effort, and to offer tools to assist in the management of Heart Disease. Other key objectives were:

- To raise awareness to the SIGN Guidelines on CHD.
- To promote implementation of the key recommendations.
- To assist Primary Care Teams to work together in a co-ordinated and structured approach.
- To identify all post MI patients and ensure they were offered best practice advice.

The production of the *Heart Pack* was a good example of joint working which led to the development of the Lothian Primary Care Trust Draft Framework for Partnership Working between the Pharmaceutical Industry and the NHS. Components of this model have been incorporated into this guidance and an adapted model framework can be found in Appendix A.

2. Considerations

When developing a joint working agreement with the Pharmaceutical Industry, NHS Boards and Trusts, Local Health Care Co-operatives/Community Health Partnerships and Primary Care, independent contractors and their employees, should consider carefully issues such as:

2.1 The costs and benefits of any joint working agreement for patients, NHSScotland and the Pharmaceutical Industry;

2.2 Impact of purchasing decisions, including those concerning pharmaceuticals, equipment and appliances. Such decisions must always be taken on the basis of best clinical practice and value for money and with due regard to their impact on other parts of the healthcare system. This should be considered within the context of integration and unification of services;

2.3 Joint working linked to the purchase of particular products, or to supply from particular sources, is not permitted unless as a result of an open and transparent tender for a defined package of goods and services;

2.4 Patient specific information is subject to Data Protection legislation and professional codes of conduct and also include a clear legal duty of the confidentiality requirements (*Caldicott Guidance* is extant). NHS bodies

must assure themselves, taking advice when necessary, that joint working arrangements are both lawful and meet appropriate ethical standards. If in doubt please refer to relevant lead professionals for guidance;

2.5 Where a joint working arrangement permitting access to patient-specific information is agreed, a contract must be drawn up which draws attention to obligations of confidentiality, specifies security standards that should be applied, limits use of the information to purposes specified in the contract and makes it clear that the contract will be terminated if the conditions are not met;

2.6 Where the major incentive to entering into a joint working arrangement is the generation of income for the NHS rather than other benefits, e.g. rental of room or premises, then the scheme must be properly governed by income generation principles rather than joint working arrangements;

2.7 When the joint working arrangement involves the Pharmaceutical Industry employing or seconding employees/ independent contractors to provide services within NHSScotland, this should comply with the relevant employment regulations and an exit strategy and plans for future funding of the post and/or service must be agreed from the outset;

2.8 Joint working arrangements involving NHS Boards and Trusts and LHCCs/CHPs should be at a corporate, rather than individual level. In situations where individual contractors are involved, e.g. single-handed practice, they should be encouraged to register with the LHCC/CHP or Board or Trust to ensure that indemnity insurance covers the proposed work;

2.9 Guidance on joint working between the NHS and the Pharmaceutical Industry relating to Research and Development (R&D) will be published shortly. The Research Governance Framework on Health and Community Care also sets out the respective responsibilities of each party to research trials;

2.10 Products originating from intellectual property from within the NHS or affiliated bodies are covered by NHS MEL (1998) 23 – *Policy Framework for the Management of Intellectual Property within the NHS*;

2.11 Under the Prevention of Corruption Act 1916, any money, gift or consideration received by an employee in public service from a person or organisation holding or seeking to obtain a contract will be deemed by the courts to have been received corruptly unless the employee proves otherwise.

The model framework at Appendix A provides a checklist for all stakeholders, to allow the above considerations and other issues to be raised and clarified from the outset.

Working together to improve patient care

Scottish Diabetes Industry Group (SDIG)

The Scottish Diabetes Industry Group (SDIG) was set up in the Spring of 2002 under the auspices of the Association of the British Pharmaceutical Industry (ABPI) Scotland, as a direct response to requests from the Scottish Diabetes Framework Working Group (SDFWG) for assistance in implementing the Scottish Diabetes Framework.

Fifteen pharmaceutical companies are represented, not all of these are members of the ABPI (although all adhere to the ABPI Code of Practice), but all are interested in improving care to people with diabetes in Scotland.

- The Pharmaceutical Industry was involved through SDIG in the *Diabetes in Scotland 2002 – The Way Forward, Conference*, held in joint working with Diabetes UK Scotland and the Scottish Executive, which was held in Glasgow on 15 November 2002 and was attended by over 600 delegates. SDIG was the main supporting partner of the conference and the "Sharing Practice, Improving Care" Awards in six categories which provided recognition of examples of excellent practice, important research and service innovation in the delivery of diabetes care;
- SDIG provided the IT and technical support for the development of the Diabetes in Scotland website.

In addition to national initiatives there are a number of local initiatives that underline the benefits of effective joint working.

Working together to improve patient care

An educational grant from a pharmaceutical company supported the printing of 500 training packs, patient information leaflets and patient held records and supports the associated staff training. This joint working initiative is helping to facilitate the rollout of the project in the West of Scotland.

Integrated Care Pathway Held Record	South Glasgow NHS Trust

3. Exit strategies

3.1 NHSScotland is committed to providing a lifetime of care to the people of Scotland. When creating a joint working scheme, the length of time over which the scheme will operate and the implications for the NHS and patients on completion of the scheme need to be considered very carefully. Robust exit strategies must be agreed at the outset to ensure that patient care is not compromised.

4. Monitoring arrangements

Within the principles of openness and transparency and within the terms of NHS Circular MEL (1994)48 Standards of Business Conduct for NHS Staff and local standing orders, the following action should be taken;

4.1 NHS Boards and Trusts should establish monitoring arrangements to ensure that employees/independent contractors register any joint working and are held accountable for it. An official register of interests should be established as part of the monitoring arrangements and all clinicians must subscribe to this. At corporate level, employers should ensure that contract negotiations are conducted according to high ethical standards. Local Standing

Orders should specify who is responsible for keeping and monitoring the register.

4.2 Employers should act to bring the Standards of Business Conduct to the attention of employees and work with them to bring it within their local arrangements.

4.3 The Pharmaceutical Industry, including manufacturers and suppliers of pharmaceutical products, high-tech home healthcare providers equipment and appliances, should adhere to the ABPI's Code of Practice or the equivalent code. The ABPI Code of Practice is a self-regulatory code, which repeats and extends beyond the legal requirements (Appendix C).

5. Action

Employers and independent contractors should review and monitor Local Standing Orders and registers of joint working arrangements in light of this guidance.

5.1 All employees/independent contractors should be made aware of all NHS guidance relating to Standards of Business Conduct, Research Governance, relevant legislation and appropriate professional codes of conduct, e.g. GDC, GMC, RCN, RPSGB, UKCC the ABPI and equivalent relevant code of conduct. The guidance should form a part of training or induction for new prescribers;

5.2 Employers should assume responsibility for ensuring that they and their employees/ independent contractors adhere to their professional code or, for unregulated employees/independent contractors, a code is devised by the organisation;

5.3 All joint working should be documented through the use of a register held by the employer, e.g. NHS Boards or Trusts. In order to demonstrate openness, it is essential that the register should be accessible and made available to the public and to NHS Board and Trust meetings;

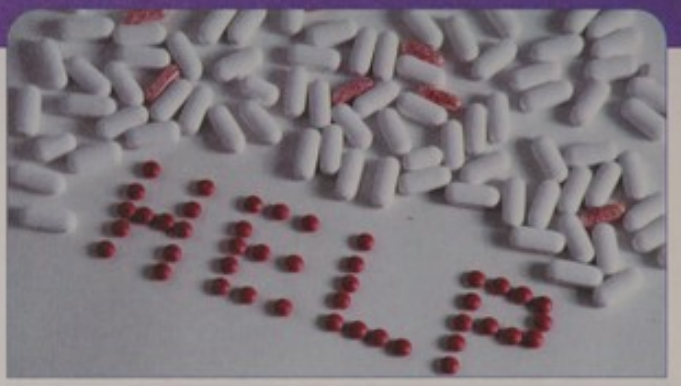
5.4 If clinicians require guidance on any concerns or aspects of a joint working proposal, they should be able to discuss this with the appropriate professional lead. This should be at any time from the outset of the joint working proposal;

5.5 It should be a matter of policy that offers which breach the relevant codes of practice must be reported to the relevant NHS Boards or organisations. Minimum standards for the reporting system should be determined locally, and ideally include an agreed time limit (e.g. two weeks) for the reporting of any such offers;

5.6 Concerns about the conduct of pharmaceutical companies should be sent to the Prescription Code of Practice Authority for consideration under the ABPI Code of Practice for the Pharmaceutical Industry;

5.7 All employees/independent contractors must record with their NHS Board or Trust, or LHCC/CHP any financial interest in organisations (e.g. company shares or research grant), which may impact upon funding, whether through contracts, sales or other arrangements that they may make with non-NHS organisations. The level of recording should be agreed locally;

5.8 Care should be taken to ensure that NHS Boards and Trusts, LHCCs/CHPs and NHS employees do not enter into new joint working arrangements that would conflict with recommendations issued by the Scottish Medicines Consortium or NHS Quality Improvement Scotland.



6. Risk management

Before entering into any joint working agreement, NHS Boards' and Trusts' employees/independent contractors should ensure:

6.1 there are no potential irregularities which may affect a pharmaceutical company's ability to meet the conditions of a joint working agreement or impact on it in any way, e.g. checking financial standing by reference to company accounts. (For independent contractors this can be delegated to the local organisation offering indemnity cover);

6.2 costs and benefits are assessed bearing in mind alternative options where applicable, and ensure that the decision-making process is transparent and defensible;

6.3 legal and ethical restrictions on the disclosure of confidential patient specific information, or data derived from such information, are complied with. Additionally, disclosure for research purposes should not take place without the approval of the appropriate research ethics committee. Refer to legal framework covered by the Data Protection Act, Patient Confidentiality and R&D;

6.4 the way that clinical and financial outcomes are to be monitored must be determined;

6.5 the joint working agreement includes break clauses to enable an NHS Board or Trust, LHCC/CHP, independent contractor and pharmaceutical company to terminate the agreement if it becomes clear that it is not providing expected value for money/clinical outcomes. Individuals responsibile for terminating an agreement should be agreed at the outset and they should be identified in the joint working agreement;

6.6 the onus should be on the individual to declare and record financial or personal interest, e.g. all company shares (in both the joint working company and any competitor) research grant in any organisation with which they have to deal, and be prepared to withdraw from those dealings if required, thereby ensuring that their professional judgement is not influenced by such considerations. If in doubt refer to NHS Circular MEL (1994)48 *Standards of Business Conduct for NHS Staff* and *Standards of Conduct, Accountability and Openness*, or seek guidance from the professional lead at the appropriate board level.

APPENDIX A

MODEL FRAMEWORK BASED ON LOTHIAN PILOT

FRAMEWORK FOR JOINT WORKING BETWEEN NHSSCOTLAND AND THE PHARMACEUTICAL INDUSTRY

CONTENTS:

i. Introduction:

The concept of designing a practical tool to enable joint working between the Pharmaceutical Industry and NHSScotland emerged after the positive experience of a collaborative project between the Royal College of General Practitioners (RCGP) in Scotland, the Scottish Heart and Arterial Risk Prevention (SHARP) group, Scottish Intercollegiate Guidelines Network (SIGN) and the Pharmaceutical Industry in designing the *Heart Pack* for use across Scotland.

This framework is intended to act as a practical and flexible guide that can be applied when collaborative joint working between NHSScotland and the Pharmaceutical Industry is the desired outcome. A fundamental principle of all joint working between the Pharmaceutical Industry and NHSScotland is that it must be for the benefit of patients. In addition, the use of the framework is to ensure that any interaction between NHSScotland and the Pharmaceutical Industry is conducted in an open and transparent manner.

ii. Values:

The following values should underpin joint working and all parties involved are asked to confirm and adhere to these values.

- Mutual trust, honesty and respect.
- Openness and transparency in all communications.
- Recognising and valuing the contribution of all partners.
- Access and sharing of information pertaining to the joint working project.
- Consensus, collaboration and inclusion as the "best way" in decision making.
- Responsibility and accountability.
- Acknowledgement of the interdependent relationship between NHSScotland and the Pharmaceutical Industry.
- Full commitment to the framework.

iii. Principles:

- All joint working between the Pharmaceutical Industry and NHSScotland must be for the benefit of patients.
- All joint working projects must promote and enhance equitable access to evidence-based health care.
- Clinical aspects of care, including the development of guidelines and protocols, should be under local/national NHSScotland control.
- Work should proceed on a project-by-project basis.
- All patient identification should be removed from data in line with the Data Protection Act to respect and preserve patient confidentiality.
- Reports or information pertaining to joint working should not be used or published without explicit permission given by all partners entering into the agreement.
- The joint working agreement should not be seen as an endorsement or promotion of a specific medicine or technology.
- The interests of individual patients must be protected, e.g. guard against the exclusive use of any single product to the exclusion of other reputable brands on the market.
- The joint working should not undermine or conflict with the ethical requirements of any healthcare professional, including the duty of clinicians to provide whatever treatment they consider clinically appropriate.
- The Pharmaceutical Industry must comply with the ABPI Code of Practice at all times.
- All NHSScotland employees/independent contractors involved must comply with NHS (and relevant professional bodies'), codes of conduct.
- The NHS recognises that ethical pharmaceutical companies hold a clear desire to improve health and healthcare whilst maintaining probity.

- Pharmaceutical company size (turnover) will not dictate involvement with NHSScotland.
- The Pharmaceutical Industry has to show clear demarcation between research and development interests and marketing operations.
- If the joint working project involves research, best research practice in line with the Research Governance Framework should be applied and consultation with the relevant Local Research Ethics Committee should be sought.

iv. Joint working project summary

1. NAMES OF THE PARTNERS ENTERING THE JOINT WORKING AGREEMENT	
2. NAMES OF THE LEAD REPRESENTATIVE OF EACH PARTNER	
3. SUMMARY OF INTENDED AIMS/OBJECTIVES	
4. SUMMARY OF EXPECTED OUTCOMES	
5. EXACT NATURE OF THE JOINT WORKING PROPOSAL	
6. START DATE	
7. FINISH DATE	
8. EXIT STRATEGY	

v. Resources and costs:

1. OVERALL COST OF THE JOINT WORKING PROJECT	
2. WHAT ARE THE DIRECT AND INDIRECT RESOURCE / COST COMMITMENTS BY EACH PARTNER?	
3. HOW WILL THE RESOURCES/COSTS BE MONITORED AND RECORDED?	
4. LIST VALID AND RELEVANT INFORMATION ON COST EFFECTIVENESS (has value for money been shown?)	

vi. Governance arrangements:

1. WHO HAS BEEN CONSULTED PRIOR TO THE JOINT WORKING PROJECT AND HOW WAS THIS DONE?	
2. HOW WILL PATIENTS BE INFORMED OF THE JOINT WORKING?	
3. DECISION-MAKING PROCESS OF THE PROJECT	

4. OPERATIONAL AND MANAGEMENT ARRANGEMENTS	
5. HOW DOES THE PROJECT RELATE TO, AND MESH WITH, EXISTING SYSTEMS OF CARE IN THE PRIMARY AND SECONDARY CARE SECTORS?	
6. HAS THE PROJECT BEEN PILOTED OR ARE THERE PLANS TO DO THIS? HOW WOULD THIS BE DONE?	
7. HAS THE PROPOSAL BEEN COMPARED WITH OTHER JOINT WORKING PROPOSALS CURRENTLY ON OFFER?	

vii. Monitoring and evaluation:

1. MANAGEMENT OF THE PROJECT FORMAT/ PROCESS	
2. WHO HAS DESIGNATED RESPONSIBILITY AT EACH STAGE OF THE PROPOSAL? – PLEASE LIST	
3. ON COMPLETION OF THE PROJECT HOW WILL IT BE EVALUATED IN TERMS OF PATIENT BENEFITS?	
4. WHAT HAVE BEEN THE LEARNING OUTCOMES/OPPORTUNITIES?	
5. AUDIT ARRANGEMENTS	

viii. Data and patient protection:

1. WHAT INTERESTS DO THE COMPANY AND THE NHS HAVE IN RELATION TO THE JOINT WORKING PROPOSAL – WHERE DO THESE INTERESTS COINCIDE?	
2. WHAT ARE THE POTENTIAL CONFLICTS OF INTEREST?	
3. WHO 'OWNS' THE DATA GENERATED BY AUDIT AND MONITORING OF THE JOINT WORKING?	

4. WHO HAS ACCESS TO THE DATA AND IN WHAT FORM, I.E. AGGREGATION AND ANONYMISATION CRITERIA? (Bearing in mind the Data Protection Act)	
5. HOW WILL THE DATA BE USED?	
6. WHAT ARE THE RESEARCH AND DEVELOPMENT ISSUES?	
7. WRITTEN CONTRACT BETWEEN PARTIES CLEARLY STATING OBLIGATIONS OF CONFIDENTIALITY, SECURITY STANDARDS AND LIMITS USE OF INFORMATION TO PURPOSE SPECIFIED IN CONTRACT	
8. FOR CLINICAL SERVICES, WHAT ARE THE PROFESSIONAL INDEMNITY AND LIABILITY ARRANGEMENTS THAT THE PROVIDER HAS IN PLACE?	

ix. Declaration of interests (see below) YES ☐ NO ☐

If YES, Please tick one box in (A) and in one box in (B)

(A)		(B)	
Personal	☐	Specific	☐
Non-Personal	☐	Non-Specific	☐

Signature: ..... Date: .....

'PERSONAL' implies that you (or your spouse) receive direct payment for services or hold shares in the relevant company concerned or a competitor.

'NON-PERSONAL' implies that your Unit benefits by receiving funding from the company.

'SPECIFIC' implies that you have undertaken work or given advice on other products made by the relevant manufacturer.

This system is used by the Medicines Commission and other national drug regulatory bodies.

APPENDIX B: EXAMPLES OF POTENTIAL CONFLICTS

It may be helpful to give employees/independent contractors some examples of instances giving rise to potential conflicts of interest and how these could be managed. Examples are given below:

A. *A clinician wishes to include in the Formulary a new medicine, manufactured by a company with which he has links, e.g. company shares, research grant.* The committee (e.g. Drug and Therapeutics Committee) should require declarations of interest from clinicians submitting proposals for new products to be added to formularies and ensure the decision is based on clinical and cost-effectiveness information.

B. *A pharmaceutical company representative wishes to present the case for a new product to be included in a Formulary.* The Board or Trust should establish and adopt a reasonable policy on approaches from industry representatives.

C. *Offer from a company to provide training of employees/independent contractors.* Employers should be careful to ensure that employees/independent contractors are not pressurised by sponsors of training, to alter their own activity to accord with sponsors' wishes, where these are not backed up by appropriate evidence. Training provided by industry is acceptable if it is unbiased, has mutual benefit for both the NHS and the sponsoring company, is evidence-based and the hospitality is appropriate. However, participants should assess whether they may be unduly influenced.

D. *A pharmaceutical company offers to sponsor a clinical employee/independent contractor in an NHS Board or Trust.* The Board or Trust should not accept the joint working if it would require the employee/independent contractor to recommend the sponsor's product, including equipment, in preference to other clinically-appropriate products, nor if it requires the Board or Trust to recommend patients to use a particular dispensing service or withhold information about other products.

E. *High-tech home healthcare provider offers to supply equipment at a reduced rate in return for business linked to a specific product.* NHS contract negotiators should advise the company that any contract will not prejudice the provision of the most appropriate service to patients, and will not bear any relation to other contracts.

F. *Sponsored attendance at conferences and symposia, should be agreed and registered by the employer and a report on the benefits to patient care and/or service provision shared with colleagues.* Attendance of more than one member of any clinical team must be considered carefully to ensure that patient care is not compromised.

APPENDIX C: PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY

The Association of the British Pharmaceutical Industry (ABPI) established the Prescription Medicines Code of Practice Authority in 1993 to operate the Code of Practice for the Pharmaceutical Industry at arm's length from the ABPI itself.

The Code of Practice for the Industry was introduced in 1958. Copies of the code are available from the PMCPA, **www.abpi.org.uk** or **www.emc.vhn.net**. It covers and extends beyond legal requirements in the UK.

Compliance with the code is obligatory for ABPI member companies and, in addition, about 70 non-member companies have voluntarily agreed to comply with the Code and to accept the jurisdiction of the Authority.

The Code covers the advertising of medicines to health professionals and administrative employees/independent contractors and also covers information about such medicines made available to the general public.

It covers:

- journal and direct mail advertising;
- the activities of representatives including detail aids and other printed material used by representatives;
- the supply of samples;
- the provision of inducements to prescribe, supply, administer, recommend or buy medicines by the gift, offer or promise of any benefit or bonus, whether in money or in kind;
- the provision of hospitality;
- the organisation of promotional meetings;
- the sponsorship of scientific and other meetings including payment of travelling and accommodation expenses;
- the provision of medical and educational goods and services;
- the provision of information to the general public either directly or indirectly, including by means of the Internet;
- all other sales promotion in whatever form, such as participation in exhibitions, the use of audio-cassettes, films, records, tapes, video recordings, electronic media interactive data systems and the like.

Complaints submitted under the Code are considered by the Code of Practice Panel, which consists of the three members of the Code of Practice Authority acting with the assistance of independent expert advisers where appropriate. Both complainants and respondents may appeal to the Code of Practice Appeal Board against rulings made by the Panel. The Code of Practice Appeal Board is chaired by an independent legally qualified Chairman and includes independent members from outside the industry.

In each case, where a breach of the Code is ruled, the company concerned must give an undertaking that the practice in question has ceased forthwith and that all possible steps have been taken to avoid a similar breach in the future. An

undertaking must be accompanied by details of the action taken to implement the ruling. Additional sanctions are imposed in serious cases.

Complaints about the promotion of medicines should be sent to the Director of the Prescription Medicines Code of Practice Authority, 12 Whitehall, London SW1A 2DY (telephone 020 7930 9677, facsimilie 020 7930 4554). The Authority can also be contacted for informal advice.

Extract from The Medicines (Advertising) Regulations 1994

Inducements and hospitality

21. (1) Subject to paragraphs (2) and (4), where relevant medicinal products are being promoted to persons qualified to prescribe or supply relevant medicinal products, no person shall supply, offer or promise to such persons any gift, pecuniary advantage or benefit in kind, unless it is inexpensive and relevant to the practice of medicine or pharmacy.

(2) The provisions of paragraph (1) shall not prevent any person offering hospitality (including the payment of travelling or accommodation expenses) at events for purely professional or scientific purposes to persons qualified to prescribe or supply relevant medicinal products, provided that –

(a) such hospitality is at a reasonable level,

(b) it is subordinate to the main scientific objective of the meeting, and

(c) it is offered only to health professionals.

(3) Subject to paragraph (4), no person shall offer hospitality (including the payment of travelling or accommodation expenses) at a meeting or event held for the promotion of relevant medicinal products unless –

(a) such hospitality is reasonable in level,

(b) it is subordinate to the main purpose of the meeting or event, and

(c) the person to whom it is offered is a health professional.

(4) Nothing in this regulation shall affect measures or trade practices relating to prices, margins or discounts, which were in existence on 1 January 1993.

(5) No person qualified to prescribe or supply relevant medicinal products shall solicit or accept any gift, pecuniary advantage, benefit in kind, hospitality or sponsorship prohibited by this regulation.

Any person who contravenes regulation 21(1) is guilty of an offence, and liable, on summary conviction to a fine not exceeding £5000, and on conviction on indictment to a fine, or to imprisonment for a term not exceeding two years, or both. Anyone contravening 21(5) is also guilty of an offence and liable, on summary conviction to a fine not exceeding £5000.

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James Barbour

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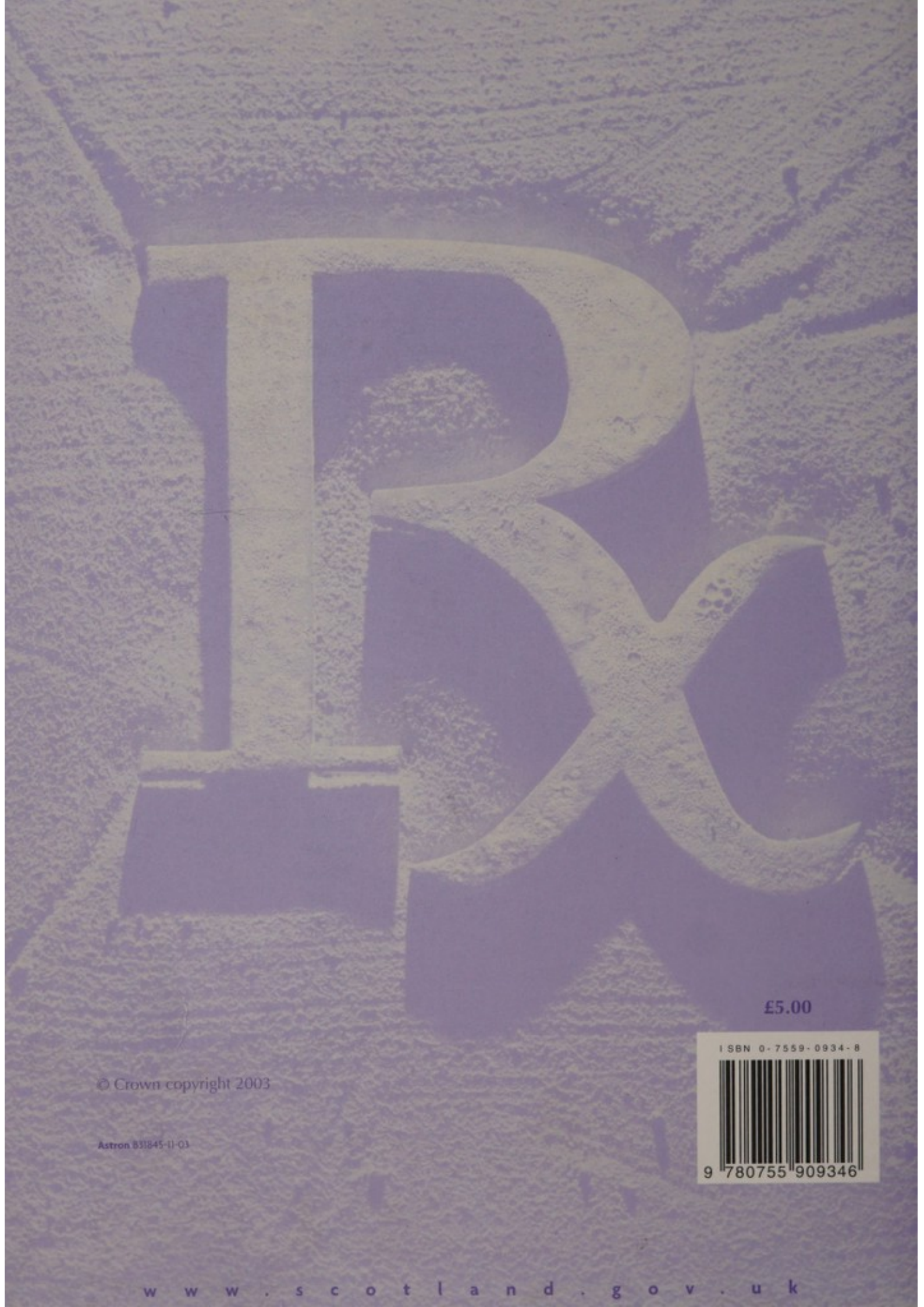

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