The European community and health policy : third report : report together with an appendix, the proceedings of the committee, minutes of evidence and appendices.

HOUSE OF COMMONS Session 1991–92

HEALTH COMMITTEE

Third Report

THE EUROPEAN COMMUNITY AND HEALTH POLICY

Report together with an Appendix, the Proceedings of the Committee, Minutes of Evidence and Appendices

Ordered by The House of Commons *to be printed*
4 March 1992

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The Health Committee is appointed under SO No 130 to examine the expenditure, administration and policy of the Department of Health, associated public bodies and similar matters within the responsibilities of the Secretary of State for Northern Ireland.

The Committee consists of eleven Members, of whom the quorum is three.

The Committee shall have power:

(a) to send for persons, papers and records, to sit notwithstanding any adjournment of the House, to adjourn from place to place, and to report from time to time;

(b) to appoint persons with technical knowledge either to supply information which is not readily available or to elucidate matters of complexity within the Committee's order of reference;

(c) to communicate to any such other Committee, or the Public Accounts Committee, its evidence and other documents relating to matters of common interest; and

(d) to meet concurrently with any such other Committee for the purposes of deliberating, taking evidence, or considering draft reports.

Unless the House otherwise orders, all Members nominated to the Committee continue to be members of the Committee for the remainder of the Parliament.

Monday 21 January 1991

The following were nominated as Members of the Committee:

Mr Tom Clarke
Mr James Couchman
Mr Jerry Hayes
Mr David Hinchliffe
Alice Mahon
Sir David Price
Mr Andrew Rowe
Mr Roger Sims
Rev Martin Smyth
Mr Nicholas Winterton
Audrey Wise

Mr Nicholas Winterton was elected Chairman on Wednesday 30 January 1991.

Mr Jerry Hayes was discharged and Sir Anthony Durant was added on 10 February 1992.

The cost of printing and publishing this Report is estimated by Her Majesty's Stationery Office at £9,316.

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THIRD REPORT

THE EUROPEAN COMMUNITY AND HEALTH POLICY

The Health Committee has agreed to the following Report:

I. INTRODUCTION

1. The Health Committee announced its inquiry into the European Community and Health Policy on 31 January 1991. As a precursor to taking formal oral evidence, we attended briefing sessions at the UK Office of the European Commission and at the Department of Health, before visiting the Commission's Headquarters in Brussels. Because of the Committee's commitments to two other inquiries of major importance, on the maternity services of the National Health Service and on NHS Trusts, we concluded that it would not be possible for us to take oral evidence from all the people we otherwise would have, before the Dissolution of the House for a General Election.

2. We have therefore agreed this short Report, drawing on the oral evidence taken from Baroness Hooper, the Parliamentary Under-Secretary of State for Health and Department of Health officials on 15 January 1992; written memoranda received, (some of it in response to that oral evidence); and the two visits the Committee paid to the Commission, on 24-25 April 1991, and 25-26 February 1992. During the course of our visits we spoke to Commissioner Vasso Papandreou, Commission officials and to UK Government officials of the UK Permanent Representative to the European Community. A list of the Commission officials we met during the visits is appended to this Report.

3. The Committee should like to place on record its thanks to all those at the Department of Health and the European Commission in London and Brussels who gave their time to talk to the Committee, and to the United Kingdom Permanent Representative to the European Community and his staff for organising the two visits. We also had the opportunity to twice meet the Chairman and Members of the European Parliament's Committee on the Environment, Public Health and Consumer Protection. These meetings proved to be most useful, and the Committee hopes that its successor will be able to build on the contact made between the two Committees.

4. This Report does not go into detail on all the relevant Directives and Action Programmes, but concentrates on those areas in which we consider the Government should most seek to exert influence. The Committee has not considered the important new initiatives concerning disabled people or those concerning elderly people, as those proposals are still in their early stages.[1]

II. THE NEW COMMUNITY COMPETENCE IN PUBLIC HEALTH

Introduction

5. At the Maastricht Council last December an agreement was reached which would if ratified give, for the first time, the European Commission defined boundaries within which it could work with respect to public health matters. This new Article, (Article 129), states:

> *(1) The Community shall contribute towards ensuring a high level of human health protection by encouraging co-operation between the Member States and, if necessary, lending support to their action.*
>
> *Community action shall be directed towards the prevention of diseases, in particular the major health scourges, including drug dependence, by promoting research into their causes and their transmission, as well as health information and education.*
>
> *(2) Member States shall, in liaison with the Commission, co-ordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such co-ordination.*
>
> *(3) The Community and the Member States shall foster co-operation with third countries and the competent international organisations in the sphere of public health.*
>
> *(4) In order to contribute to the achievement of the objectives referred to in this Article, the Council shall adopt:*
>
> *—in accordance with the procedure in Article 189b and after consulting the Economic and Social Committee and the Committee of Regions: incentive measures, excluding any harmonization of the laws and regulations of the Member States;*

[1] Ev, p 2, Paras 3.10 and 3.11, and QQ 21-28

—acting by qualified majority on a proposal by the Commission: recommendations.[2]

6. When Baroness Hooper, the Parliamentary Under-Secretary of State, appeared before the Committee on 15 January, she spelt out how the UK Government saw the result of the Treaty:

> "... I believe that it is possible to pursue to some extent the line that we have already taken, that is to look at areas and measures which can best be dealt with at an international, specifically at a European Community, level. We all recognise that health knows no boundaries ... There are areas of public health, ... where action has already taken place, for example the Europe Against Cancer, Europe against AIDS, and the drug prevention campaigns. Of course the drug dependency issue is underlined in the definition of the new chapter on public health".[3]

7. When she was asked if the agreement would benefit the people of the United Kingdom, the answer was an unequivocal "Certainly".[4] Mr Wilfred Aspinall, a member of the EC Economic and Social Committee, takes a more downbeat view of the new Article, stating that it is "very limited in its application and it will only be what the Commission takes as initiatives and the Council of Ministers agrees with."[5] In our discussions with Commissioner Papandreou on 25 February, we gained the impression that she took a similar view that the increase in competence was only marginal. This Committee would rather describe the change in competence so far as limited but sufficiently undefined as to allow for responsive initiatives as may appear appropriate to the Council of Ministers. We believe that the general shift in the Community's role marked by the Maastricht Treaty may represent a movement away from the purely economic and market-oriented focus of the original Community which might have considerable significance in the public health arena in the future. One of the questions we considered was the case for a separate Directorate-General to draw together these issues in the new European context.

A separate Directorate-General?

8. There are a number of Directorate-Generals, (DGs), with an interest in public health, including DG III, (Internal Market and Industrial Affairs), DG V, (Employment, Industrial Relations and Social Affairs), and DG XII, (Science, Research and Development). This does not necessarily mean that there are many staff working on public health. For example, when the Committee visited Brussels in April 1991, we learned that the Commission's Chief Medical Officer had four staff, and the Directorate dealing with pharmaceuticals had twelve officials, (compared to some 2000 in Member States who were involved in work on the Commission's plans for pharmaceuticals). The Committee was also told that the majority of the staff did not have a public health background.

9. Dr Jeremy Metters, the Deputy Chief Medical Officer of the Department of Health, also believed that there is not adequate liaison between the Directorates-General, saying, "At the moment the walls between those DGs are higher than we would like them to be."[6]

10. The Committee put the possibility of the establishment of a separate Directorate-General or a Commissioner for public health to the Minister. She replied:

> "We do not yet know from the Commission what it intends to do, indeed whether it intends to set up a separate DG ... Ms Papandreou ... has always complained that they are not able to do very much on the health front and not able to deliver what the meetings of health ministers within the Council have asked because she simply does not have the staff".[7]

11. It was suggested that new countries joining the Community might provide the opportunity for an extra Commissioner.[8] For example, the Coronary Prevention Group (CPG) states in its submission to the Committee:

> "...CPG believes that there has never been a better time to grasp this nettle as we approach the appointment of new Commissioners and the probability of new Member States joining the Community".[9]

12. The British Medical Association, in its memorandum to the Committee states:

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[2]Treaty on European Union, CONF-UP 1862/91
[3]Ev, Q 1
[4]*ibid*, Q 2
[5]E39, Introduction
[6]Ev, Q 14
[7]*ibid*, Q 6
[8]*ibid*, QQ 7-8
[9]E38, Recommendation 1

"The establishment of a separate Directorate-General does not seem to be a realistic goal at present, but the BMA Council has recently resolved that there should be one focus within the Commission which would be responsible for co-ordinating health-related activities for which executive responsibility is taken by various Directorates-General".[10]

13. Mr Strachan Heppell, a Deputy Secretary in the Department of Health, indicated that the Department seems to be favourably disposed towards a separate DG, although not necessarily a separate Commissioner:

"There is a separate issue about whether we should have a new Directorate-General for health and whether we would have a new Commissioner. The United Kingdom have argued that there should not be a large increase in Commissioners. Indeed the Government have argued in favour of one Commissioner per country, so that might, to some extent, balance out the new members. As to the value of having a Directorate-General, I have no doubt that within the Commission that will be looked at seriously. There is additional work....we would expect to see some strengthening to meet the additional work which undoubtedly will come forward. This is additional work which reflects very much the views of ministers in the health council".[11]

14. It appeared from our discussions with her that Commissioner Papandreou did not personally see the need for a separate DG or Commissioner. She did however say that it would be useful to have a separate unit under the direction of the Commission's Chief Medical Officer. This might come about during reorganisation if it were decided to have just one Commissioner per Member State. We believe that the establishment of a separate Directorate-General for Public Health or a Public Health Unit within the existing structure of the Commission merits further investigation. We suggest that our successors consider the desirability and implications of such a reorganisation.

III. ADVERTISING OF TOBACCO PRODUCTS

Introduction

15. The aim of the draft Directive on the advertising of tobacco products is to:

(i) ban all forms of tobacco advertising in the Community, except that Member States may authorise advertising in tobacco sales outlets which is not visible from the exterior of the premises;

(ii) ban indirect advertising of tobacco;

(iii) ban the use of established trademarks or brand names for new tobacco products;

(iv) ban the free distribution of tobacco products;

(v) require Member States to provide means by which individuals or organisations can take legal action against tobacco advertising or complain to a monitoring body.[12]

16. Few would argue with the sentiments expressed by Dr Jeremy Metters, Deputy Chief Medical Officer, in giving evidence to the Committee on 15 January, that:

"... there is no doubt at all that smoking is the largest single preventable cause of ill health and premature death ..."[13]

17. The differing opinions expressed on the substance of the proposal by the two sides of the argument about the ban on the advertising of tobacco products are well known, and therefore the arguments are not rehearsed at length in this Report. Every memorandum the Committee has received which has commented on the proposed ban on advertising, except that from the Tobacco Advisory Council (TAC), is in favour of such a ban, and as Action on Smoking and Health (ASH) states:

"Support for the proposed ban extends to the whole health community—all NHS regions, all the medical Royal Colleges, every medical body and charity in the least concerned—and to nearly three-quarters of the general public".[14]

18. The TAC states that it is in broad agreement with the views on advertising expressed to the Committee by Baroness Hooper (see paragraph 26). The TAC also states that the tabacco

[10]E32, Para 3
[11]Ev, Q 13
[12]COM (91) 111 final SYN 194
[13]Ev, Q 45
[14]E36, Para 28

industry's advertising campaigns are to persuade existing smokers to change brands, not to encourage people to start smoking, as:

> "Approximately one third of all existing cigarette smokers are . . . either seeking to change their brand or are regularly purchasing more than one brand".[15]

19. Many organisations mention concerns about tobacco sponsorship in sport, for example, the National Pharmaceutical Association:

> "It is totally illogical to link a healthy pastime with a habit which is the single largest preventable cause of ill health and premature death in the United Kingdom. We feel that sport sponsorship is even more likely to encourage young people to smoke than poster and newspaper advertising".[16]

20. Comments are also made in the memoranda the Committee has received on the situation, described for example by the CPG, where:

> ". . . billions of pounds are spent in subsidising . . . agricultural products which are . . . intrinsically bad for health (such as tobacco)".[17]

21. Commissioner Papandreou and her officials themselves expressed concern about this situation, and reported their unsuccessful attempts to remove this glaring contradiction in the Community's policies. She also informed us, however, that in certain areas of Greece, tobacco was the *only* crop which could be grown. We are somewhat sceptical about this claim, and suggest that our successors consider investigating the scientific evidence for this allegation. A further area which we believe merits investigation is the availability of regional funds to assist areas to move away from dependence on cigarette manufacturing.

22. We were also concerned that the harmonisation of duty on tobacco products could have the effect of forcing down the price of these products in the UK. We were pleased to hear from Baroness Hooper that:

> "Price we believe is very important. We would clearly not wish to have anything that would decrease the price . . . of tobacco . . . on health grounds. In anything that we are doing in our negotiations on the harmonisation proposals, which again is not a health department lead, the Treasury is very well aware of the health implications".[18]

The Legal Base

23. The proposal to ban advertising was introduced under Article 100A, concerned with the completion of the internal market , and doubt was expressed in some quarters that it was actually *intra vires*.

24. In June 1991, in a legal opinion for the Confederation of European Community Cigarette Manufacturers Ltd, made available to the Committee by the Tobacco Advisory Council, the legal firm Kemmler, Rapp, Böhlke and Crosby stated:

> "We are of the firm opinion that the proposal is incompatible with the EEC Treaty. We believe that the Council may not adopt the proposal without exceeding its powers and infringing Article 4(1) of the Treaty and that Member States may not implement the directive, if adopted, without infringing Article 5 of the Treaty".[19]

25. The Committee requested a memorandum from the Department of Health regarding the legal position; this takes the contrary view to the suggestion that the proposal is *ultra vires*. It concludes that the legal opinion made available to the Committee was mistaken:

> "Department of Health lawyers . . . consider that the measure is compatible with Article 100A and that a ban on tobacco advertising is not inconsistent with European Community law . . .
>
> There are . . . three main arguments to support the view that the proposal is compatible with the use of Article 100A. First, the proposal can be regarded as equalising the conditions of competition within the Community . . .

[15]E44
[16]E40
[17]E38, Para 2
[18]Ev, Q 52
[19]E31, Para 2.1 (Not printed)

Secondly, having regard to the advertising services, the proposal establishes a Community-wide system for the advertising of tobacco products . . .

Thirdly, the proposal will facilitate trade in goods which carry advertising: for example magazines . . ."[20]

Further progress

26. The United Kingdom Government is still considering its position over the proposal to ban tobacco advertising, "in the light of all the circumstances"[21]. When Baroness Hooper gave evidence to the Committee in January, she stated:

"We are not convinced and have never been convinced that the total ban which we are currently talking about affecting posters and the newspaper advertising, is going to have the sort of impact that some countries believe that it will".[22]

27. In our Fourth Report of last Session, "Maternity Services: Preconception", we drew attention to the evidence from New Zealand and Canada, that, following a ban on tobacco advertising in those countries, tobacco consumption has fallen. In Canada the fall was by 13.8 per cent per adult in the two years since the ban was introduced; in New Zealand there was a 3 per cent fall in the number of people smoking in the six months following the ban.[23]

28. The Government continues to believe that the best way to control tobacco advertising is by means of a voluntary agreement between the Government and the industry,[24] and a new voluntary agreement came into force on 1 January 1992.[25]

29. There has been doubt expressed about the effectiveness of voluntary agreements. In a memorandum submitted by the Association for Community-Based Maternity Care, during the Committee's inquiry into maternity services, it was stated that the Association would recommend a tougher stance on tobacco sales and advertising, as,

"This would probably have a bigger impact on health than any other single action. A voluntary control on tobacco advertised in young women's magazines has not worked".[26]

30. On 11 February 1992 the European Parliament voted to accept the proposal to ban tobacco advertising. The proposal must now go before the meeting of the Health Council in May, where it will have to overcome a blocking minority of the UK, Germany, the Netherlands, Greece and Denmark, who believe the proposal is unnecessary for the completion of the internal market. The UK Government recently confirmed that this is still their position.[27] It has been reported that Denmark and Greece have, or may have, changed their position,[28] although we understand from our discussions with the Commission on 25 February that all five countries are, officially, still against the proposal.

IV. FREE MOVEMENT OF PROFESSIONALS AND MUTUAL RECOGNITION OF QUALIFICATIONS

Introduction

31. One of the basic rights established by the Treaty of Rome was the freedom to work anywhere within the Community. For professionals that right is restricted by Member States only recognising professional qualifications obtained following a period of study of three years or more. There is a proposal for a further Directive to cover qualifications of less than three years study. A common position on this proposal was reached on 25 February 1992. If approved, this will allow the free movement of other professions, such as social workers, who are not presently covered.

32. There are two types of Directives concerning free movement, Sectoral (or Vertical) and General (or Horizontal):

a) Sectoral Directives cover professions such as doctors and nurses, and go into the type and the quality of training. They lay down some 20-30 topics which must be studied before a qualification

[20]Ev, p20
[21]Ev, Q 32
[22]*ibid.*
[23]HC (1990-91) 430-I, Para 53
[24]Ev, Q 32.
[25]Department of Health Press Notice H91/412, 9 September 1991
[26]HC (1991-92) 29-II, p 598, Para 3.5 (a)
[27]*Official Report*, 21 February 1992, col 334 w
[28]eg E32, Para 5 and E36, Para 34

is awarded. Directives benefitting health professionals include those for doctors, nurses responsible for general care, dental practitioners, midwives, pharmacists, general practitioners and vets. These Directives are supported by Advisory Committees and a Committee of Senior Officials. These are constituted as:

i) *Advisory Committees.* There is a Committee for each of the professions, comprising 72 members. Each country nominates 6 representatives, (3 full and 3 alternate), comprising 2 practising members of the profession concerned, 2 teaching and 2 from authorities. The Committees meet as national, independent experts, and their purpose is to give neutral advice to the Commission and Member States.

ii) *The Committee of Senior Officials in Public Health* covers all the health professions. The UK is currently represented by Dr Jeremy Metters, the Deputy CMO. The Committee's aim is to iron out any problems of free movement, although there are now few in this area; any problems now are mainly to do with training.

b) General Directives are much broader, and cover those professions regulated by Statute or common law, such as chiropodists, or a Professional Association, for example psychologists. There is nothing in legislation that can force a Member State to regulate a profession. It was stated by Commission Officials that the UK, Ireland and Denmark are the "least oppressive" in terms of occupations regulated.

Training

33. The Committee learned with some concern that the training of medical students in some Member States may not be up to a standard that would be acceptable to the British Medical Association or the Royal Colleges. In oral evidence, Dr Metters stated that he had heard "concerns expressed about the qualifications, skills and experience of some doctors coming from Italy"[29], and in its memorandum the BMA states that:

> "As regards basic training, a particular problem in some countries seems to be the lack of practical experience gained by undergraduates. Evidence is largely anecdotal, but the problem seems particularly marked in Germany, where the undergraduate course is largely theoretical".[30]

34. The Association went on to say that so many German students were now seeking to undertake elective periods in the UK, attracted by the high standard of training, that:

> "There is now some concern that this large intake will overburden the system, placing UK students at a disadvantage".[31]

35. The BMA had also had problems with young Spanish doctors brought to its attention:

> "As Spain does not require the equivalent of the pre-registration "house officer" year, many Spanish doctors come to the UK, fully qualified and entitled in law to full registration with the General Medical Council. They then apply for "senior house officer" posts, for which they are often very ill-prepared as far as practical skills are concerned".[32]

36. However, Dr Metters did say that he hoped that appointments committees would not only consider the paper qualifications of an applicant from an EC country, but "also the period of training that was behind them"[33], and that if none of the candidates were appropriately skilled and qualified, then the post should be readvertised.[34]

37. During our meeting on 25 February, it seemed that the Commission's view was that the free movement of professionals meant that harmonisation of training standards would inevitably have to move towards the mean level, rather than the best. **We are not persuaded that the same standards need apply to all professionals as do to doctors and other health professionals. For medical practitioners their level of skill is quite literally a matter of life or death.**

[29] Ev, Q 72
[30] E32, Para 6.2
[31] *ibid*
[32] *ibid*
[33] Ev, Q 69
[34] *ibid*, Q 70

Third Country Diplomas

38. During the evidence session on 15 January, the Committee was not able to get a satisfactory answer from the Department of Health to the question of the acceptability of third country diplomas obtained abroad by medical practitioners who were now working in the UK. The Department were asked to submit a memorandum stating what the position actually was. The resulting paper confirmed our impression that:

> "Some nationals of EC Member States, including naturalised doctors from third countries, hold qualifications obtained in non-EC countries which do not carry the same *automatic right of recognition* in other Member States, notwithstanding that these qualifications may meet the EC standards required by the directives".[35]

39. The submission went on to state that each Member State is free to recognise a particular overseas qualification for registration within its own territory, but this does not bind other Community members[36].

40. According to the Department of Health, the Commission and the European Court of Justice are concerned about this anomaly, which has been perceived as discriminatory, and the Department says that the question of non-EC qualifications in the health sector may be the subject of a draft Directive.[37]

41. The Commission has asked the Committee of Senior Officials in Public Health to consider whether the medical directives should be amended so as to provide for the recognition of third country qualifications held by EC nationals where;

—the qualifications are of a level at least equivalent to that required to satisfy the qualitative and quantitative criteria stipulated by the medical directives; and

—the holder of the qualification has at least 3 years professional experience in the Member State which recognised the qualification.[38]

42. We are most concerned that the provisions relating to all qualified medical practitioners working within the Community should be even-handed, and not be open to accusations of covert racism in their application.[39]

V. PHARMACEUTICALS

General

43. The Commission put forward several proposals designed to facilitate the free movement of pharmaceuticals. These are described below.

i Future system for the free movement of medicinal products in the European Community

44. The current proposals for the free movement of medicinal products apply to products for both human and veterinary use, and include;

(a) The establishment of a new **European Agency for the Evaluation of Medicinal Products (MEA)**, which will be created from the existing Committee for Proprietary Medicinal Products and the Committee for Veterinary Products, with additional logistical and administrative support. It will coordinate the evaluation and supervision of medicinal products, in order to avoid duplication. It will also have to ensure that all the relevant factors are taken into consideration during the authorization process, and the subsequent supervision of medicines through adverse reaction monitoring and inspection and control of manufacturers. The Agency will be funded partly from the Community Budget, and partly by fees for services provided.

(b) A **decentralized procedure**, based on the principle of mutual recognition, which will allow the progressive extension of a marketing authorization from one Member State to the others, with important safeguards to ensure that there is no dilution of standards of quality, safety and efficacy. This procedure will continue to be the most widely used after 1992. The Agency will only become involved if there is a disagreement between Member States about a medicinal product. The Agency would then provide an independent scientific evaluation of the issues involved, and a binding arbitration procedure at Community level will follow. Responsibility for monitoring the product

[35]Ev, p19, Para 1
[36]*ibid*, Para 2
[37]*ibid*, Paras 3-4
[38]Ev, p20, para 7
[39]E42, Annex

will remain with the Member States. By 1996 the decentralised procedure will become the most commonly used for obtaining authorization for products to be used in more than one Member State.

(c) A **centralized procedure**, compulsory for biotechnology products and veterinary medicines used as performance enhancers, and available on an optional basis for other innovatory medicinal products, leading to a Community authorization, valid throughout the Member States. The decision whether or not to grant authorization for applications submitted through this procedure, following evaluation, will be taken by the Commission, in cooperation with the Member States. The Community will then be responsible for monitoring the product and the technical updating of the authorization.

45. During our second visit to Brussels, we learned that the Commission was, until recently, very optimistic about the progress of these measures. There were relatively few technical difficulties, and they were hoping for adoption during the UK Presidency. However, the Commission had just been hit by a "bombshell" from the Council Legal Service. The measures were put forward under Article 100A, which only needs a qualified majority vote. It is now doubted that this Article gives the Commission the required competence. It is argued that the measures should have been put forward under Article 235, and that therefore unanimity is required. We were told that discussions over the problem of the legal base are due to take place in April.

ii Transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems

46. We understand from the Commission that the measures to provide for transparency in regulating pricing have now been fully implemented.

iii The rational use of medicinal products

47. Three measures are being introduced for the completion of the internal market, improvement of the protection of public health, promotion of a rational use of medicinal products, and consumer information. The measures (sometimes referred to as the "Three Pack") are:

(a) *Wholesale distribution of medicinal products for human use*; for the specific authorization for wholesale dealers distributing human medicines.

(b) *Legal status for the supply of medicinal products for human use*; which sets out common criteria to which each Member State should have regard when conducting risk/benefit analysis to determine the appropriate legal status of a medicinal product, and whether it is available with or without a prescription. (The Committee was told on its second visit to the Commission that, eventually, it was planned that there would be a Community-wide standard list of pharmaceuticals that could only be available with a prescription).

(c) *Labelling of medicinal products for human use and on packaging leaflets*; the aim of this proposal is to improve the information available to consumers.

iv Advertising of medicinal products for human use

48. The advertising of medicinal products proposal supplements the above three proposals, and aims to promote the rational use of medicinal products and to harmonize national provisions relating to their advertising in preparation for completion of the internal market.

49. A common position has now been reached on the proposals for the rational use of medicinal products and for the advertising of medicinal products.

Current state of play

50. In evidence, Sir David Price put to Baroness Hooper and Department of Health officials that the area of pharmaceuticals was not so much a level playing field as the Alps, in respect of the research, validation, product launch, initial pricing, follow up pricing, public purchasing policy, patent life and definition of a pharmaceutical product. The Minister responded:

"This is precisely the reason we wanted a definition within the Treaty to give validation to the activities of health ministers in this area. It was very unsatisfactory. Although we on a home basis deal with some of these issues, at the European level we do not".[40]

51. One area in which there seems to be movement is towards a harmonised European validation, as described in paragraph 44.[41]

52. In relation to pricing, it was stated:

"...our policies are aimed to ensure that any pricing system should not be excessively rigid, does not impede the free circulation of goods and does not impinge directly on the organisation of Member States' health care systems..."[42]

53. The Deputy Chief Medical Officer expressed his concern that:

"...any pharmaceutical...in this country should be safe, of good quality and efficacy. The purpose should be to ensure that whether we have a unified system covering the 12, or 12 different equivalents of our Medicines Control Agency, all of which approve or provide product licences, that the provenance of those licences should be the same....it is absolutely essential that this is correct before we move towards a harmonised system because...it will be the patients and ordinary people who will suffer if we have different levels of quality and safety applying to pharmaceuticals that come on to a common market".[43]

54. During our discussions with the Commission on 26 February, we considered the issues surrounding the definition of medicinal products and the applicability of the relevant provisions to such products as food supplements (such as vitamins), traditional herbal products (including infusions) and homeopathic products. For the last mentioned, there was a clear policy that products in a dilution of 10^{-4} or greater would be exempt. In other areas the question would largely be decided on the basis of whether "health claims" were made on behalf of such products by the manufacturers. The definition of a "health claim" and the wider question of which products will fall within the licensing provisions will clearly be an issue of considerable importance in the future.

Proposal for a Supplementary Protection Certificate

55. The aim of the Supplementary Protection Certificate (SPC) is to improve the protection of innovation in the pharmaceutical sector, in particular lessening the effects of interference from the marketing authorization system for medicinal products on the period of protection pharmaceuticals enjoy under the patent system.

56. The SPC in effect extends the period of protection initially conferred by a patent partially to compensate for the patent life lost by the time taken to obtain marketing approval. This certificate, which would take effect directly after the expiry of the corresponding patent, would be equal to the patent life lost between the filing date and the date of the first marketing approval within the Community, minus 4 years, subject to a maximum extension of (the Commission proposed) 10 years. The grant of the certificate would avoid the need to amend the European Patent Convention, which specifies a 20 year term.

57. The two branches of the pharmaceutical industry reacted in very different ways to the proposal for an SPC. The Association of the British Pharmaceutical Industry (ABPI), which represents the major research-based pharmaceutical companies, ran a series of advertisements in the national press urging the UK Government fully to support it, whereas the European Generics Forum (now called the European Generics Association), which represents the manufacturers of drugs on which the patents have lapsed, called upon the Commission to withdraw it[44].

58. The Government announced its position on 15 April 1991, in response to a Parliamentary Question:

"....we have concluded that in the United Kingdom, at least, restoration of protection would be achieved by a supplementary certificate of the sort proposed by the Commission but having

[40]Ev, Q 91
[41]*ibid*, Q 92
[42]*ibid*, Q 93
[43]*ibid*, Q 94
[44]E7

the effect that industry would be able to count on 13 years protected life subject to a maximum extension of five years".[45]

59. The Department of Health expressed a certain amount of satisfaction with the compromise proposal put forward by the Dutch Presidency, which gave a maximum of five years' patent term extension, thus giving a maximum of 15 years protection[46]. Although there is now agreement about the proposal for patent term extension, the transitional arrangements have still to be settled. Baroness Hooper said "Obviously we shall seek to get the best possible transitional arrangements for the UK."[47]

60. This comment prompted the ABPI to say in its memorandum, "This can only mean that the UK Government has decided to join the majority of other Member States within the EC who intend to nominate *1 January 1982* as the "start-up" date for the restored patent protection".[48] Earlier in its memorandum the Association stated that its information indicated that

> "Italy, France, Denmark, Holland, Belgium and Luxembourg would all select 1 January 1982 as the date from which products introduced since that date and still in patent by 1 January 1993 will qualify for the restored five years of patent life conferred by the proposed SPC".[49]

61. There was disagreement amongst Member States as to the appropriate transitional arrangements. Germany had very strong objections to the SPC being retrospective at all, and its opposition had threatened the proposed Certificate. However, a compromise has been reached as set out in the table below.

Member State	"Start-up" Date
Belgium	1 January 1982
Italy	1 January 1982
France	1 January 1985
Ireland	1 January 1985
Luxembourg	1 January 1985
Netherlands	1 January 1985
United Kingdom	1 January 1985
Denmark	1 January 1988
Germany	1 January 1988

Greece, Portugal and Spain have no patent protection at present. Once they do, protection will apply for five years, although it will not be retrospective.

62. Both wings of the pharmaceutical industry are disappointed by the amended proposal. The ABPI refer to "...the pharmaceutical industry's disappointment that the UK Government sought to reduce the original SPC provision from ten years to five years",[50] whereas the European Generics Association state that the extra five years market exclusivity will not only damage generic manufacturers, but "UK consumers will have to wait an extra 5 years before being able to buy more affordable medicines."[51] An official of the Commission frankly described the situation as "a mess", but believed that the important victory was the agreement on future arrangements, and that the transitional state of relative chaos will just have to be lived through. The agreement reached therefore seems to be a satisfactory and worthwhile compromise.

VI. ORGANISATION OF WORKING TIME

63. The main provisions of the draft Directive, which was put forward under Article 118(a), concerned with the health and safety of workers, were to lay down:

— *minimum rest periods of 12 hours per day;*

— *1 day off per week calculated over a 40 day period;*

[45] *Official Report*, 16 April 1991, cols. 32-33 w
[46] Ev, Q 83
[47] *ibid*, Q 87
[48] E33
[49] *ibid*
[50] *ibid*
[51] E37, Para 1

— *4 weeks paid leave per annum (on top of statutory holidays);*

— *restrictions on night work to an average of 8 hours per night.*

64. The intention was to set minimum provisions across Europe and to leave as much flexibility as possible to Member States. Derogations would be possible, so that individual States could exclude particular groups of workers from the terms of the Directive.

65. The Directive is currently stuck in the Social Affairs Council, although negotiations are under way. An "orientation debate" took place in the Council in December 1991.[52] There is concern that if implemented it could have major implications for junior doctors and residential care home assistants in the UK. When Baroness Hooper gave evidence to the Committee,it was implied that the UK Government would either "seek derogation or...claim subsidiarity."[53] However, the exclusion of "autonomous" workers from the provisions may well be deemed to cover doctors.

VII. CONCLUSION

66. This year the agreement reached at Maastricht will be implemented. The United Kingdom is in a pivotal position, holding the Presidency of the European Community during the second half of 1992. It thus has a unique opportunity to set an agenda designed to help improve the health of the entire Community. **We recommend that, in its response to this Report, the Government seize the opportunity to lay out its agenda for health during its forthcoming Presidency.** We hope that our successor Committee will thereby be enabled to monitor developments in this field during the second half of this year, and we urge it to do so.

[52]Ev, p 3, Para 4.5
[53]*ibid*, Q 102

Appendix

Commission Officials met by the Committee during its visits to Brussels.

24 April 1991

Mr Antonios Trifyllis	—	Chef de Cabinet of Commissioner Papandreou
Mr Steffen Smidt	—	Deputy Director-General, DG V
Dr William Hunter	—	DG V (Chief Medical Officer)
Mr Hermanus van Zonnenveld	—	DG V

25 April 1991

Mr Sydney Allman	—	DG III
Mr Robert Hankin	—	DG III
Mrs Orlagh O'Farrell-Larkin	—	DG V
Dr Anthony Dickens	—	DG XII
Mr Per Brix Knudsen	—	DG XXI

25 February 1992

Ms Vasso Papandreou	—	Member of the Commission, (Social Affairs & Employment)
Mr Steffen Smidt	—	Deputy DG, DG V
Dr William Hunter	—	Chief Medical Officer
Dr Anthony Dickens	—	DG XII
Mr Fernand Sauer	—	DG III

26 February 1992

Mr Robert Hankin	—	DG III
Mr Jean-Marie Visee	—	DG III
Ms Susanne Jessel	—	DG III

MINUTES OF PROCEEDINGS RELATING TO THE REPORT

WEDNESDAY 4 MARCH 1992

Members present:

Mr Nicholas Winterton, in the Chair

Mr Tom Clarke	Sir David Price
Mr James Couchman	Mr Andrew Rowe
Sir Anthony Durant	Mr Roger Sims
Mr David Hinchliffe	Rev Martin Smyth
Alice Mahon	Audrey Wise

The Committee deliberated.

Draft Report, proposed by the Chairman, (The European Community and Health Policy), brought up and read.

Ordered, That the draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 66 read and agreed to.

Appendix read and agreed to.

Resolved, That the Report be the Third Report of the Committee to the House.

Ordered, That the Chairman do make the Report to the House.

Several papers were ordered to be appended to the Minutes of Evidence.

Ordered, That the Appendices to the Minutes of Evidence taken before the Committee be reported to the House.

The Committee further deliberated.

WEDNESDAY 15 JANUARY 1992

Members present:

Mr Nicholas Winterton, in the Chair

Mr Tom Clarke	Sir David Price
Mr James Couchman	Mr Andrew Rowe
Mr David Hinchliffe	Mr Roger Sims
Alice Mahon	Audrey Wise

Memorandum submitted by the Department of Health

CURRENT EC INITIATIVES/ACTIVITIES AFFECTING THE DEPARTMENT OF HEALTH

I. Health in the EC Treaties

1. The Treaty establishing the EEC contains a number of references to matters which affect health, notably Articles:

48–51 providing for the free movement of people (which is the basis for measures concerning the mutual recognition of qualifications),

100A providing for the free exchange of goods (single market) (which is the basis for measures to harmonise the marketing of health care products including pharmaceuticals and health warnings on products such as tobacco),

118a regarding the health and safety of workers,

130(r) protecting human health as regards the environment.

2. The Community has also launched a number of initiatives relating to health issues based on mixed competence, ie partly within the terms of the Treaty and partly by agreements between Health Ministers as representatives of the member states meeting within the Council. The Ministers of Health have met regularly on this mixed competence basis during each presidency in recent years. They have approved a number of programmes, which are currently under way or at an advanced stage, designed to foster the exchange of information, health promotion, co-operation in research and promotion of pilot projects in certain countries. (For Community competence following the Maastricht agreement of December 1991 see IV. Community Competence below)

II. Department of Health Lead Activities

3. Community programmes under paragraphs 1 and 2 above include:

3.1 *AIDS*

A number of resolutions have been passed in the recent past concerning information and education campaigns. Proposals have recently been approved for a European programme of action against AIDS for 1991 to 1993.

3.2 *Drug abuse*

There is a continuing programme of research and exchange of information on drug demand reduction. It is also proposed to set up a European Drugs Monitoring Centre. This is largely handled in "CELAD", where the Home Office leads. Its remit is likely to be restricted to epidemiology. "Drug dependancy" has been inserted in the new "Public Health" chapter of the Treaty agreed at Maastricht.

3.3 *Cancer*

A second "Europe against Cancer" Action Programme for 1991 to 1994 was approved at the May 1990 Health Council and is currently under way.

3.4 *Tobacco*

3.4.1 Directives on cigarette labelling and tar yield have been adopted under the Europe against Cancer programme. A proposal to extend the scope of the labelling directive to cover tobacco products other than cigarettes was approved at the June Health Council. This proposal also includes a ban on the marketing of oral snuff.

3.4.2 A directive on the partial harmonisation of tobacco advertising in the press and by means of bills and posters was withdrawn following the Health Council meeting of 3 December 1990. The Commission have

now brought forward a revised proposal for a total ban and this is currently under negotiation in the Council working group. The Council did not debate the subject in November 1991 since the opinion of the European Parliament had not been received but it is known that view diverge on this proposal.

3.5 *Acute human poisoning*

A proposal for co-operation and exchange of information among European poison centres was adopted at the December 1990 Health Council.

3.6 *Nutrition*

A Resolution for action on nutrition and health was approved at the December 1990 Health Council. The Commission are currently consulting member states on the programme of action to be adopted. The Commission propose that 1995 be declared European Year of Nutrition.

3.7 *Medicines*

3.7.1 A number of proposals have been put forward in this area as part of the programme of legislation in preparation for the Single European Market. One group is connected with the harmonisation of national laws on trade in pharmaceutical products. The main recent proposal has been the extension of patent life protection by a maximum of 10 years to a maximum life of 16 years. In response to the objections of some member states including the United Kingdom a Dutch Presidency compromise of 15 years maximum life with extension certificates of up to five years was adopted as a common position by the Council on 19 December 1991 with transitional provisions and a permitted deviation of three years either way from the 1 January 1985 baseline for individual member states.

Another current issue is the requirement for the Commission to report back to the Council (by December 1991) on further appropriate measures to regulate the pricing of medicines for human use. Member states have suggested that attention should focus on product substitution (generic or otherwise), product identification and pack sizes. The industry has also been consulted. The Consultative Committee meets again in February 1992.

3.7.2 A common position was reached in October 1991 on the proposals for the advertising of medicinal products, and the so called "Three Pack" proposals which include measures on wholesale dealing, the legal status of medicines and information for patients (labelling of pharmaceutical products). A common position was also reached on the draft directive on alternative medicines (homeopathic medicines) on 19 December. The creation of a European Medicines Evaluation Agency for the licensing of new high technology medicinal products is still under discussion in the working group.

3.8 *Medical Devices*

A directive regulating the marketing of implantable devices (eg heart pacemakers) has recently been agreed by the Internal Market Council. A proposed directive to regulate other devices is currently under discussion.

3.9 *Health Professional Qualifications*

A number of directives ensure mutual recognition of professional qualifications throughout the EC (doctors, nurses, dentists etc). A draft Directive covering psychiatric and paediatric nurses has recently been put forward. Other staff and qualifications are covered in a general directive affording mutual recognition to qualifications and training requiring at least three years study. A second general directive covering qualifications requiring less than three years study is under discussion.

3.10 *Elderly People*

An EC action programme agreed by the Social Affairs Council in November 1990 includes exchanges of information, co-operation in research and promotion of pilot projects. 1993 will be European Year of the Elderly and of Solidarity between Generations.

3.11 *Disabled People*

The second EC action programme (HELIOS) runs until December 1991. This includes pilot projects and the EC HANDYNET and HANDYAIDS initiatives. Proposals for a third programme have recently been adopted by the Commission and will shortly be passed to the Council for negotiation in the working group.

3.12 *Research*

The Department of Health, together with the MRC, provides the United Kingdom input to the Medical and Health research element with the EC Research Framework Programme. The main areas of research concern Cancer, AIDS, age related health problems, Environmental and Lifestyle problems, Medical technology and Health Services research. The Department also contributes to radiation protection and human genome analysis elements and AIM (computers in medicine) within the Framework programme.

3.13 *Infant milk and follow up formulae*

MAFF leads on this proposal but Department of Health officials are involved in the negotiation of the draft directive which aims to regulate the composition and marketing of infant and follow up formulae. The proposal was agreed in July 1991 and Departmental officials are currently liaising with MAFF on its implementation.

3.14 *Food with Particular Nutritional Uses*

MAFF lead on this framework directive under which two draft directives with specific health involvement have emerged.

These are:

(a) draft directive on Weaning Foods which is currently being negotiated in the Council working group,

(b) draft directive on Weight-loss Foods which has recently been passed by the Commission to the Council.

III. Other Health Related Activities

4. The Department also has an interest in a number of other EC activities on which other Departments lead. DH keeps in close contact with other Government departments on these issues.

4.1 *Liability of Suppliers of Services*

A draft directive has been proposed by the Commission affecting negligence claims against providers of services including health and personal social services. The proposal reverses the burden of proof for allegations of negligence. Emergency services are excluded from the scope of the proposed directive but it is not yet clear whether this includes ambulance services. In its present form the proposal would include health and personal social services but the Commission have indicated that they will be introducing an amendment to exclude "medical services" and that a separate directive on the subject may be put forward at a later date. Negotiations by officials in the Council working group are under way with DTI taking the lead for the UK.

4.2 *Convergence of Social Protection Policies*

The Commission have proposed a Council recommendation including references to health care provision for those in receipt of social benefits. Social Security lead on this issue which is currently under negotiation in the Social Affairs Council.

4.3 *Environment and Health*

Department of the Environment normally lead on the many existing and proposed directives in this area. DH offers scientific input on human health aspects and on interaction with WHO activities in this area. The Dutch Presidency are currently attempting to give the health impact of environmental issues a higher profile within the Health Council.

4.4 *Food Safety*

MAFF take the lead on existing and new directives but DH has a substantial interest and provides a major policy and scientific input. A large number of directives are under consideration and a proposal on Food Hygiene is expected shortly. A proposal for a zoonoses regulation is currently being considered by the Commission. A controversial Commission Decision concerning the importation of fresh fruit and vegetables from Peru following the outbreak of Cholera there, is being challenged in the European Court by the UK but the Commission seem to be willing to compromise over the legal base.

4.5 *Organisation of working time and other Social Action programme proposals*

The Department of Employment leads on these proposals for directives governing the time worked by shift workers, proof of an employment contract and others. Negotiations on the Directive are under way and an "orientation debate" took place in the Council in December 1991. The proposals could affect the employment of staff in NHS and local authority care establishments.

4.6 *Public procurement, Health and safety at work and Alcohol*

The Department liaises closely with other Government Departments which lead on these issues on matters affecting health and the NHS.

In particular, there is a draft Directive on the public procurement of services which might have significant effects in the healthcare sector. The draft Directive lays down specific procedures to be followed for awarding contracts in many sectors such as cleaning, laundry, maintenance management consultancy and architecture. These provisions include publication of the tender and procedures to be followed for applications and selection. For other sectors, including healthcare, the less stringent provision of notifying what contracts have been awarded is required. Many of the more stringent publication provisions will apply to health authorities when contracting with private sector bodies for their services eg architects etc. The less stringent provisions may apply to "NHS internal market" contracts and "contracts" awarded to independent practitioners such as General Practitioners.

4.7 *Transfer of Corpses*

This proposal for a Directive has not yet reached the stage of being formally put forward to the Council of Ministers and is still being discussed in meetings of experts. The document calls for the harmonisation of rules for the transfer of corpses so that there will be no need for checks at frontiers. The removal of frontier checks is necessary for the completion of the internal market, and this measure is therefore being brought under Article 100A which will require Qualified Majority Voting. The proposal concerns questions of public health, death registration procedures, investigation of suspicious deaths, and border checks on goods by customs and excise. The UK lead has not yet been established, although it is clear that DH does have an important contribution to make.

4.8 *Data Protection*

A draft general directive has been put forward by the Commission on which the HO leads. The directive grants individuals a general right of privacy. This right to privacy translates in the healthcare sphere to the requirement to gain the written consent of a patient before written or electronically held data on that person can be processed. DH is arguing that the provisions of the directive will need to be revised to ensure that the creation of a large bureaucracy which would divert resources away from patient care is avoided.

IV. Community Competence

The recent Maastricht Agreement, due to become effective at the beginning of 1993 includes a chapter on public health. This would give the EC competence in the areas of preventive medicine, for example in coordinating health information campaigns or research into major public health diseases.

January 1992

Examination of Witnesses

Baroness Hooper, a Member of the House of Lords, Parliamentary Under-Secretary of State, Mr Strachan Heppell CB, Deputy Secretary, Dr Jeremy Metters, Deputy Chief Medical Officer and Mr Paul Allen, Assistant Secretary, Head of International Relations Unit, Department of Health, examined.

Chairman

1. Lady Hooper, can I welcome you as a Minister from the Department of Health to our deliberations this afternoon. I thank you very much for finding the time to come before us in what is, I know, a very busy schedule and programme for you, to help us in our ongoing inquiry and with our ongoing interest in the European Community and health policy. You will appreciate that this is particularly relevant following the Maastricht conference and the agreements which were entered into on that occasion. I therefore put one very general opening question to you. In answering it, if you would like to make any opening statement on behalf of your Department, I am very happy and so is the Committee for you to do that. Following Maastricht, the European Commission, as we understand it, now has a defined role in the area of public health and preventive medicine. How do you see this particular position benefiting the people of the United Kingdom? Along with that question, will the co-ordination of health information campaigns and research into public health diseases now be more effectively managed? A new framework will clearly need to be set up. How do you envisage that operating?

(*Baroness Hooper*) Thank you, Chairman, and thank you for inviting me to be here and to have the opportunity to make a brief general statement as well as responding to your question. Perhaps I should start by saying that—very much from a personal point of view, apart from a departmental point of view—I have always recognised the importance of taking a constructive and positive approach to our activities on the European Community level. As you will appreciate, as a former Member of the European Parliament, I have some background in that institution. That is a role that we have pursued along the lines of inter-Governmental co-operation in the Department of Health in the various programmes

[**Chairman** *Cont*]
that already exist in the European Community. Clearly the new definition of public health as a result of the Maastricht treaty helps us in giving us a very clear definition of the boundaries within which we can work. We are clearly limited to issues of public health and we are clearly limited to non-harmonisation measures in terms of our activities as health Ministers. So we remain as before on the wider front of internal market measures still being dealt with by other councils. We also are at an important moment for the UK being at the beginning of a year which we will terminate in the presidency of the European Community. As that will be leading into the implementation of the Maastricht treaty, of course, we will hope to be able to use our ability to formulate the agenda of health council ministers' meetings in order to ensure that we move in what we believe to be the right and positive direction. To answer more specifically your question as to how we see the result of the treaty, the Commission's and the European Parliament's new powers in relation to public health, I believe that it is possible to pursue to some extent the line that we have already taken, that is to look at areas and measures which can best be dealt with at an international, specifically at a European Community, level. We all recognise that health knows no boundaries and in that respect it is rather like environment. There are areas of public health, areas which already are on the agenda, where action has already taken place, for example the Europe Against Cancer, Europe Against AIDS, and the drug prevention campaigns. Of course the drug dependency issue is underlined in the definition of the new chapter on public health. There are also other areas, and while nothing has finally been decided in terms of presidency initiatives, clearly the whole area of research is important to us. It will still be dealt with under the research heading, but in order to have effective research we need equal bases of information, epidemiological information and statistics. We will be looking at areas of common database possibilities and also perhaps increased collaboration in an area such as the passing of information on communicable disease. We have, as many of you probably know, at Colindale a very efficient and effective centre. I am told by the people at Colindale that they have been able to inform the Spanish Government when they had a typhoid outbreak in Spain, as a result of the methods that we have in investigating the source of any problem on this front. This is clearly something that it would be useful to deal with at an international level. We shall be looking at those sorts of areas as a way forward.

2. So you think that the agreement that has been entered into at Maastricht under the new treaty will benefit the people of the United Kingdom?

(*Baroness Hooper*) Certainly. I do not confine all our activities on an international front to the European Community because one of our jobs must be to continue within the European Community to ensure that there is co-ordination and non-duplication with other international organisations such as WHO Europe, the Council of Europe and so on. Obviously the reason why we have this kind of co-operation is to ensure that those issues which are best dealt with on an international level are effective. Indeed in some cases they must be dealt with on an international level.

3. Before I pass over to Sir David Price, I was remiss not to request, Minister, that you introduce your team so that those who are taking down the details of what is being said today are aware of who is speaking as and when they intervene to make a contribution.

(*Baroness Hooper*) I am delighted to do so. I asked in advance whether it was proper for me to do so and I was told that I should wait to be asked.

4. I should have asked you to introduce your team at the beginning.

(*Baroness Hooper*) Strachan Heppell, is a Deputy Secretary in the Department and is probably well known to you. He is the UK representative on the high level official committee which has just been set up by the Commission and has had just one meeting. Paul Allen currently heads our International Division. In introducing Paul, I should say that in the Department, because we recognise the importance of our future work in the European Community, the whole International Division has been reorganised with much more emphasis on the European Community work and some additional officials have been recruited. Dr Jeremy Metters is Deputy Chief Medical Officer and also represents us on a variety of committees both within the European Community and other international organisations.

5. There is one other matter before we proceed any further. Obviously we are talking about a whole range of issues this afternoon and clearly it is inevitable that Members may have a vested interest. I know my colleague Mr Couchman would like to declare an interest at this stage of our proceedings.

Mr Couchman: I have little doubt that we shall be talking about sensible drinking and alcohol and I have an interest to declare in that matter in that I run eight London pubs. I believe there should not be any misunderstanding. I also advise certain interests within the alcohol trade. I also have an interest in pharmaceuticals and I cannot believe that we will get through the afternoon without talking about pharmaceutical products in a European context. Perhaps I had better make that clear at the outset.

Chairman: Thank you very much indeed. I now pass the questioning, which will be fierce, to Sir David Price.

Sir David Price

6. It will be very gentle, Chairman! I start simply on constitutional matters. It seems to me that Title XV of the Maastricht agreement changes the position of public health within the responsibilities of the Commission from having come in, as it were, by its tail through research, through social affairs, through health and safety at work and also on the trade side, because this is pharmaceuticals, level playing fields. It seems to me—and would I be right—that if they take the management consequences there should be a direct remit now within the Commission to set up a public health department, whether it should be a DG of its own or should come under one of the existing ones? I wonder, Minister, whether you, the Department or the Government have any views on this?

[**Sir David Price** *Cont*]

(*Baroness Hooper*) Yes, it is of course early days in terms of the agreement only having just been achieved and its implementation not becoming complete until the beginning of January next year. We do not yet know from the Commission what it intends to do, indeed whether it intends to set up a separate DG. All I can say with some assurance is that the Commissioner, Ms Papandreou, who has been dealing with social affairs and employment as well as health and other related matters, has always complained that they are not able to do very much on the health front and not able to deliver what the meetings of health ministers within the Council have asked because she simply does not have the staff. I am quite convinced that there will be a—

7. That was the impression we got when we visited Brussels last spring, but it also raises the question that if we are to have new members it might be convenient to have a new directorate general in the normal politics of it. It would seem to me that unless this new Title XV is not reflected administratively it will continue to be slightly bits and pieces round other directorates general and will not be handled directly, as I think all of us here would like it to be.

(*Baroness Hooper*) When you say "new members", you mean new members of the Community, new countries joining?

8. Yes, therefore unless we change the ground rules there have to be new commissioners and you have to find something for them to do.

(*Baroness Hooper*) Not only that, I might go so far as to say that if we have additional appointments being made to the Commission to reflect this, I would very much hope that there might be a UK representative among those people. The effect of the new chapter is fairly limited. As I said, it excludes direct harmonisation measures and leaves with other councils and other directorate generals some of the really bulky stuff that affects health.

Sir David Price: But with respect—if I may remind you what the first sentence of the Title says—"The Community shall contribute towards ensuring a high level of human health protection". Nobody at present has a direct remit in any of the DGs to ensure a high level of human health protection. It comes in indirectly.

Chairman

9. Would Mr Heppell, as an official and member of this new high powered committee that I gather has been set up, like to add to the Minister's reply in answer to Sir David's question about whether there should be a new DG, whether, because none of these things comes under one particular department, a new DG should be set up to deal specifically with public health?

(*Baroness Hooper*) Perhaps before Mr Heppell answers, I might say that I do not think Sir David specifically asked if we considered there should be a new DG. Therefore I did not answer that issue directly. My feeling on it is that we ought to wait and see. I do not believe that we should set up a new DG in advance of the implementation of this Title.

Sir David Price

10. But reflecting the Chairman's question to either you or Mr Heppell, who actually will be responsible to the Council of Ministers for fulfilling Article 1 of Title XV of the Maastricht treaty?

(*Baroness Hooper*) At present it will be the current DG.

11. In Social Affairs?

(*Baroness Hooper*) Yes.

12. But in answering that you have already talked about research. Research has a different directorate general and level playing fields, to which I shall come much later. On pharmaceuticals it is not actually a level playing field but the Alps as you know. Who is going to sort that lot out?

(*Baroness Hooper*) It will still be the internal market.

Chairman

13. Mr Heppell, come in briefly.

(*Mr Heppell*) The compliment that the committee I have joined is to be high powered remains to be proven. It is called a high level committee, but no promises are made. On the question concerning where the work will be done, at present the work is done within Directorate General V which comes under Ms Papandreou. There is a separate issue about whether we should have a new directorate general for health and whether we would have a new commissioner. The United Kingdom have argued that there should not be a large increase in commissioners. Indeed the Government have argued in favour of one commissioner per country, so that might, to some extent, balance out the new members. As to the value of having a directorate general, I have no doubt that within the Commission that will be looked at seriously. There is additional work. They certainly have a relatively small staff. The chairman of the new committee, of which I am a member, is the Deputy Director of that DG, Mr. Steffen Smidt, whom you met at your meeting in Brussels. They would certainly be looking very seriously at that and we would expect to see some strengthening to meet the additional work which undoubtedly will come forward. This is additional work which reflects very much the views of ministers in the health Council.

Sir David Price: In general how do you interpret this? I am still sticking to the first sentence of the new remit. "... encouraging co-operation between the Member States and, if necessary, lending support to their action". Do either of them involve funds? Or is it just words? It says here: "encouraging co-operation between the Member States and, if necessary"—obviously I can see the Treasury coming in there—"if necessary, lending support to their action". But how is "lending support" other than putting money behind it, using Community funds?

Chairman

14. Dr Metters, you are pregnant with words!

(*Dr Metters*) We notice the problems that Sir David has referred to in that we have DG III, DG V, DG XII, DG XIII—I will not go on—all with a finger in the health pie. At the moment the walls between those DGs are higher than we would like them to be.

[**Chairman** *Cont*]
If one is to achieve this encouraging of co-operation in the public health field there has to be a coming together. Whether it is under a new commissioner or whether it is under a regrouping within directorates general, certainly the officials in Commission when I was there shortly after Maastricht had not got round to thinking about it, but they were saying that a number of jobs that were then currently vacant they were holding vacant with a view to dividing them because of the added responsibilities that were incumbent on them following the Maastricht treaty. What they were not saying was how they were going to bring these areas of interest together.

Sir David Price

15. Following that up, Dr Metters—this is a totally unfair question and is why I am going to ask it of you—when we went there last year we got the impression that in public health co-operation in Europe WHO Europe at Copenhagen had the technical competence, but they did not have the funds. Brussels had the funds but did not have the technical competence. That is a sweeping generalisation of course, but would we be right in that kind of broad brush approach that the common man, the gentleman on the top of the Clapham omnibus would have in looking at it?

(*Dr Metters*) I am sure that must be right, but they have not yet achieved the technical competence.

16. Is there therefore a need—and possibly looking to the second half of the year when we have the presidency—of strengthening the technical base of Brussels in public health matters?

(*Dr Metters*) I would say that the question is whether one wants to see duplication between the technical work that is already well developed in Copenhagen and also, to a lesser extent, in Strasbourg with the Council of Europe in other areas and in Geneva, WHO headquarters, and have that duplicated or triplicated at Brussels because they now have public health responsibilities, or whether one wants to see a coming together of these different interests so that one does not have two or three separate international Civil Service bureaucracies doing the same thing.

Chairman

17. That is what you, Dr Metters, and perhaps the Minister on behalf of the Government, would wish to see happen, a coming together of these organisations, rather than having these two, three or four levels or areas of bureaucracy?

(*Baroness Hooper*) Perhaps I may respond on that because this is an interesting area that has been underlined as a first topic. It is, I think, an area that we might look to in the course of our presidency, bringing these various groups together in order to ensure that we get the right kind of co-ordination and avoid unnecessary duplication.

18. Minister you said just now that you "think" that we should look at it. Are you saying to this Committee that this will be the policy of Her Majesty's Government during our term of presidency?

(*Baroness Hooper*) I am not in a position to say that categorically because we are still in the process of preparing our programme, but I am finding our discussion in this Committee very useful in helping to formulate ideas, which I think is your intention.

Mr Couchman

19. You mentioned the Europe against AIDS and the Europe against Cancer programmes. How successful do you feel they have been? I noticed that you also said that research came under the bailiwick of a different commissioner to social affairs. What is the state of play with regard to the other research programmes? You mention a number of them in your paragraph 3.12 ranging from cancer and AIDS to age related problems, medical technology, even computers and goodness knows what. How far have these programmes got?

(*Baroness Hooper*) Perhaps I might ask Dr Metters to reply.

(*Dr Metters*) I think I should explain that until two years ago I was one of the two UK representatives on what was the Medical and Health Co-Ordinating Committee for Research. As such that committee brought together two representatives of each country and one looked at the six different programmes that were then within the second framework programme. The cancer and AIDS programmes were two of these, epidemiology was the third, health technology assessment a fourth, health services research a fifth and biology the sixth. The difficulty was that as health was then outside the Treaty of Rome, the legal services advised that we could not give direct support for bench work research. This had to be research that would bring together interests from the various countries in collaborative research, the bench work done and funded in individual states, but the bringing together of bench work from individual states funded by that committee. There was a little bit of sleight of hand and in the AIDS and cancer fields the strict requirement that this was research co-ordination was not universally observed, so there were some fellowships that were supported in the cancer programme. The AIDS programme and cancer programme undoubtedly were the flagships of the work, but there was this restriction against funding the basic bench work or epidemiological studies. We could only support it as a co-operation procedure. With Maastricht that restriction has disappeared and it will be possible for direct funding on any of the issues already in the programme or other new ones that will come in with the new BioMed II.

20. Would you like to say a word on the difficulties of having research outside the major commissioner's responsibilities, the social affairs commissioner?

(*Dr Metters*) I think Commissioner Pandolfi would say that the research programme was his major responsibility. Where I see the problem with Community research is to ensure that one is getting a Community added value in that there is no purpose doing research in the Community simply because it is good to have it in the Community. There has to be something over and above what 12 countries doing their individual studies can achieve on their own. I am not sure that in the health field, with the exception of the cancer and AIDS programmes where this has gone the furthest, that we have entirely cracked that problem yet. Undoubtedly in the new BioMed programme there are many opportunities.

[**Mr Couchman** *Cont*]

(*Baroness Hooper*) On the research front, of course Commissioner Pandolfi is the research commissioner, but he is not only a health research commissioner. There are many other areas where his activities are far more extended than on the health front. But as far as our national programme co-ordinating with the European Community programme is concerned, not only do we have the benefit of Dr Metters' involvement in the various committees, but our new director of research and development in the Department of Health, who is primarily concerned with health service research as a result of a House of Lords Select Committee recommendation, has taken great care to ensure, by visits to Brussels, that he co-ordinates what he is doing and is involved with the thought processes in Brussels. I think that is important.

Chairman: Thank you very much. We have a lot of ground to cover and I now pass on to Mrs Alice Mahon.

Alice Mahon

21. What is planned for the European Year of the Elderly and solidarity between generations in 1993? You mentioned something about pilot projects. Have any been worked up yet and can you give us some details?

(*Baroness Hooper*) No, I am not in a position to give you any details about it, but a number of Departments are involved with the programme for elderly people and the programme for 1993. The Department of Health as the lead department has set up a committee to consider it which is fortunate in that Age Concern UK, which has been very active in forming Eurolink Age, which is the European development of it, has been able to help us in the administration of the committee. We are still in the process of gathering ideas and we have not formulated a final programme as yet.

22. You do not know when that committee will report back? Is it imminent?

(*Baroness Hooper*) I am due to have a meeting with them within the next couple of months and I would hope that we have some ideas of the programme to offer for consultation by the time our presidency starts.

23. What about the funding of the European Year of the Elderly? Can you give us any detail about funding? I do not want to sound cynical, but will it just be cosmetic? Shall we have any meat on the funding projects? Is there a separate budget?

(*Baroness Hooper*) Yes, as with all the programmes that we have been involved in, we have had to look at a separate budget on the European Community level and in national terms obviously we shall be looking at the various projects that arise to see how they will fit into our existing funding arrangements. Obviously, again, we have made no final decisions on funding as yet.

(*Mr Heppell*) To supplement that, we have, as you would expect, been consulting widely with the voluntary bodies. Those voluntary bodies who will be taking an active part will receive financial support from the Department.

(*Baroness Hooper*) I am sure you may be aware that the aim of the European year is to raise awareness of aging, to promote positive images of older people and to facilitate exchange of experience and practice across Europe. Those obviously are the areas at which we are looking to formulate a programme.

Chairman

24. Do you think that you might be prepared to increase the funding of the work being carried out at St Mary's Hospital into Alzheimer's disease, bearing in mind that that team has announced that it is upping and emigrating to the United States for lack of funds?

(*Baroness Hooper*) My understanding is that that particular research comes within the MRC's research programme. It is not directly financed by the Department.

25. Is it not to do with aging?

(*Baroness Hooper*) Certainly, yes.

26. And therefore could it not qualify for some form of assistance from this great organisation, the European Community, with its extended responsibilities?

(*Baroness Hooper*) I am not sure that the research issues would come under this heading. The sort of funding we are talking about is funding of projects—

27. Dr Metters, you look as if you are about to burst.

(*Dr Metters*) I was going to say that the sort of research that St Mary's was doing would have been ultra vires under the prohibition that existed up until Maastricht, in that this is bench work research and as such there would not have been any way in which it could have been funded from the medical and health programme. The situation since December has changed.

28. So what is the expectation for funding for St Mary's?

(*Dr Metters*) I would be very unwise to predict how the EC might respond.

(*Baroness Hooper*) But in any event I understand that the team is not being entirely broken up at St Mary's. There have been developments on that front.

Chairman: We are making further inquiries quite separately, but I am very grateful for that contribution.

Mr Rowe

29. I think the Minister knows that I have great interest in voluntary and non-Governmental organisations and it is my perception that NGOs have made a lot of the running in the whole matter of aging and raising public awareness. I just wondered whether the Department is doing its utmost to strengthen the NGO co-operation across Europe. Age Concern can do so much and Help the Aged likewise, but there is, I would guess, a very uneven pattern of NGO interest and involvement. I wondered whether the Minister would care to say something very briefly about that.

(*Baroness Hooper*) Yes, thank you. It is true. We can quite justifiably say that in the United Kingdom we have a far more highly developed voluntary sector than any other European country. You obviously, advisedly, used the expression "NGO" because the

[**Mr Rowe** *Cont*]
counterparts to our voluntary sector in other European countries are principally just that. The concept of and the attitude to them is very different. On the wider front there has been interest within the European Community in tackling the issue of NGOs and doing things which might not be beneficial to the way in which our voluntary sector operates, affecting their tax liability and removing the charitable status that is so important to them. We are keeping an eye on that and ensuring that they are not disadvantaged as a result. The best form of influence than can be exercised in this area is probably by example and the sort of example that our voluntary organisations give, especially in this area that we have been discussing of elderly people—primarily the work of Age Concern and Help the Aged, who are very active on a European level—is what is most needed. It is not something that can be imposed down. It is something that has to be done from the ground roots up so that by the voluntary organisations developing their own contacts overseas—and more and more they are doing that on a bilateral basis as well as on a European Community basis—the more evenly balanced the contribution of the voluntary sector can be.

Alice Mahon

30. I should like to ask about the proposals that are being put forward for the third HELIOS programme for disabled people. I just wondered whether you could tell us a little bit about that and also a little about the pilot projects as well, the HANDINET and HANDYAIDS initiatives?

(*Baroness Hooper*) We have just carried out an evaluation of our involvement in the second HELIOS programme. A team from Southampton University has carried it out and have just produced an interim report which is obviously known by the Committee. We are still looking at it, but the initial impressions suggest that all the UK participants who have been involved have found the experience very rewarding. Obviously in a more general sense the European Community's objective in relation to disabled people is to promote economic and social integration, so this affects employment and other areas of activity as well as the directly health- related one. It is a more general point perhaps, but the result of the Maastricht treaty will be in part to ensure that health ministers have much more information and input into what is happening in the other Councils in health related matters. I would expect that, for example, the needs of disabled people in relation to employment would be something that would benefit.

Sir David Price

31. As you mentioned Southampton, I should declare an interest and involvement in the medical school there. As you know we have the only European Chair of Rehabilitation in this country. Taking our six months of leadership in Europe, is the whole area of rehabilitation an area on which we might take an initiative? The whole area is still really the Cinderella side of health care, but the work that some of us have been involved in has enormous potential, just taking stroke victims alone. I declare an interest in being involved in it in Wessex. There is every sign that we are making good progress, but the resources at present going into it are minuscule. It is one area where a not very great increase in resources could make an enormous impact. It is a common problem throughout Europe, just taking stroke victims. It is something that the Treasury will not do their nut on.

(*Baroness Hooper*) I accept that. Whether we call it an initiative or not, we are intending to have an event which will focus on the needs of disabled people and the progress in this area.

Chairman: Perhaps we can now pass to one of the more controversial areas of the discussions that we are having and the evidence that we are taking this afternoon, the directive on the advertising of tobacco products, alcohol and so on. I put the questioning into the hands of David Hinchliffe.

Mr Hinchliffe

32. The Chairman may regard this as controversial, but I do not. I think it is fairly straightforward and I know that there is agreement across the Committee on this. We had a fair amount of press coverage last week on a leaked document between your Department, Minister, and the Treasury, indicating that the Department of Health now had fairly strong evidence of the impact of advertising on the take up of smoking, based, I believe, on the New Zealand studies. I am sure you are probably aware and your colleagues will be aware of the coverage I am referring to. In paragraph 3.42 of your memorandum you say: "It is known that views diverge on this proposal". In the light of last week's publicity and these comments in the memorandum, can you clarify what is the UK Government's present position with regard to the directive and the overall question of advertising of tobacco and alcohol?

(*Baroness Hooper*) I agree with you, Chairman, that this is a highly controversial issue. Even now I understand the European Parliament is debating the latest Commission proposals on the total ban on advertising and will be voting on it tomorrow. No doubt there will be even more press interest in the subject as a result of that. Our present position on the proposals—which were not really discussed at the last Council meeting because the debate had not taken place in the European Parliament and opinion had not been received—is that we are still considering our position, in the light of all the circumstances. We are not convinced and have never been convinced that the total ban which we are currently talking about affecting posters and the newspaper advertising, is going to have the sort of impact that some countries believe that it will. We were in the lead in banning television advertising. This is something which has much more effect than posters and newspaper advertising. Clearly in other countries, such as New Zealand and Canada, all the evidence is that the ban on advertising has been accompanied by other measures including price rises. My own view, certainly in the European Community context, is that price affects tobacco consumption far more than advertising, given that we no longer have television advertising. Those countries within the European Community which have a total ban, and despite of it, are not showing as good results on reduction of

[**Mr Hinchliffe** *Cont*]
tobacco consumption as we are with our current system of very strict voluntary agreements on the way that tobacco is advertised in those last two remaining ways—posters and newspapers and the other measures that we take, which include price restraint and educational means.

Chairman

33. On a point of clarification, Minister, so that we are aware of exactly how the situation is within the European Community, we are not the only country that is opposing a total ban, are we?
(*Baroness Hooper*) No.

34. I believe we share this view with Germany, Holland, Denmark and Greece, so there are five countries within Europe that oppose the total ban.
(*Baroness Hooper*) Yes.

Mr Hinchliffe

35. I referred to this information which was, I believe, a leaked memorandum—you may not wish to comment on that for obvious reasons. You will, presumably, be familiar with the research carried out in New Zealand that indicated a significant reduction in smoking during this period when the advertising was stopped. Do you feel that that alters the Government's position? Does it have a bearing on the present position?
(*Baroness Hooper*) Obviously it is something that we take into account. We are talking here in the Committee about the European Community context, but also a White Paper has been issued which concerns the health of the nation. There has been a lot of comment on advertising. Our current position is still that we are not fully convinced that the effect of advertising alone would have any more effect than the package of measures which we are currently operating and others which we intend to bring forward.

36. Can I briefly press you further on the issue of the current voluntary agreements? As the Chairman is aware, one of the few positions of influence and importance that I hold in this place is as joint secretary of the All Party Parliamentary Rugby League Group—a very august body.
(*Baroness Hooper*) What is that?

37. The rugby league group.
Chairman: They play 13 instead of 15!

Mr Hinchliffe

38. You have spent some time in the North so you should know what rugby league is, not too far from Widnes!
(*Baroness Hooper*) I am afraid I did not quite hear what you said.

39. At our last meeting we specifically targeted the issue of tobacco sponsorship of sport because, as you may be aware, along with a number of sports in this country, rugby league is heavily dependent on sponsorship, for example, the recent Regal Trophy and the Silk Cut Challenge Cup at Wembley. Huge amounts of money come into the game through tobacco sponsorship. Certainly I, along with a number of members of the group, are rather uneasy about that. We had speakers last month from the BMA and Action on Smoking and Health, and quite clearly their evidence indicated that the present voluntary agreements with the industry are totally ineffective. Have you had any research into the operation of the voluntary agreement as it relates, for example, to the association with sport where one might say there is a complete contradiction between good health, athleticism in games such as rugby league and other sports, and the activity of smoking?
(*Baroness Hooper*) Obviously the responsibility of the Department of Health in this relates to the voluntary agreement on advertising which was revamped towards the end of last year. It was revamped as a much more strictly drawn document particularly targeting children. In my view one of the most important aspects of all this is to stop children from starting to smoke. We were able to be extremely tough in our negotiations with the industry. We feel that we came out with an extremely good and effective agreement. The sports sponsorship voluntary agreement is a matter for the Department of Education. We co-operate with them as much as possible, but obviously ultimately it is their responsibility. My understanding is that that too is for revision and it may be that some of the anxieties and worries that have been raised about the way that the current sponsorship arrangements are working will be taken into account in reviewing that.

Chairman

40. Just to balance up what David Hinchliffe has said, am I not correct that the consumption of cigarettes and tobacco smoking in this country, where we permit advertising, although strictly regulated, has declined by some 20 per cent in the last 10 years?
(*Baroness Hooper*) I think that is the correct figure.

41. I say that because the BMA was quoted as saying the situation was not working. Is that not an indication that it is working?
(*Baroness Hooper*) Yes, in the context of the European Community we are second only to the Netherlands which also combines a system of legislation and voluntary agreements in controlling advertising.

Mr Hinchliffe

42. I feel that the figures you have thrown out, Mr Chairman, need to be qualified, because it is my understanding from the information that I have read recently that the decline is in older age groups and the take up of young smokers is higher than ever, particularly young women smokers, which is a worrying aspect. I would welcome you, Minister, pressing your colleagues in the Department of Education and Science on this issue of sponsorship of sport, in relation to the comments you made about the involvement of children. The evidence we received last month at the meeting I have referred to was very clear in suggesting that sports are being used to recruit new young smokers. The glamorisation of success through sporting sponsorship and the association with smoking is a means of recruiting new young smokers. That is a worrying aspect that I am sure you share my concern about. I would

[Mr Hinchliffe *Cont*]
welcome your having dialogue with your colleagues in the Department of Education and Science on this issue and perhaps possibly dropping us a line when you have had a chance to do that.

(*Baroness Hooper*) We are certainly very concerned about this issue because we spend a certain amount of money on an advertising campaign directed at young people in order to impress the dangers upon them.

Chairman

43. That is through the Health Education Authority?

(*Baroness Hooper*) Yes.

Mr Rowe

44. It was suggested to me only today that you take into account, for example, the evidence we have had on one of our other inquiries about maternity care that the total cost to the National Health Service of picking up the pieces from tobacco smoking is running at about the same level as any income that we may derive from tax on tobacco. I just wondered whether you were able to substantiate or deny that?

(*Baroness Hooper*) I probably cannot safely do either, except to say that it is very difficult to estimate all the health consequences of smoking. I know we have estimated a figure. Can you help me Dr Metters?

Chairman

45. I think it is rather less than the revenue that is taken by the Treasury.

(*Dr Metters*) I think the money question is difficult to quantify, but there is no doubt at all that smoking is the single largest preventable cause of ill health and premature death and that among the group that you have mentioned we want, above all, to stop young women and girls taking up smoking because of the harmful effects in pregnancy and in early childhood for the child are demonstrable for all to see. There is absolutely no doubt on that. To turn that into money terms is really rather difficult because it involves estimating what the price of a life lost is. Everybody has different views on that.

Chairman: Can I request, Minister, that if the Department is able to send us details of what the department estimates smoking costs in respect of treatment required and care given within the health service, it would be helpful? I understand that my figure may be wrong and that the income to the Exchequer is about £7.3 billion a year, but that is only one of the many figures that is talked about. But if you can confirm any of these figures, or tighten them up for us and give us specific information, we should be very grateful*.

Mr Sims

46. I am conscious that we must be careful not to spend too much of our time on this issue at the expense of the European dimension. Happily Dr Metters has just answered one of the questions that I would have asked confirming the Department's view of the effect of smoking as such, that it is the largest avoidable cause of death and disease. If that remains the Department's position, is it also the Department's position that they feel that television advertising would encourage people to smoke more and therefore they support its ban, but they do not, apparently, take the same view about poster and newspaper advertising?

(*Baroness Hooper*) I think it is generally agreed that the effect of television advertising—again we are focusing on young people in particular—is far more potent than the effect of posters and newspaper advertising. In fact when I look at one of these rather puzzling advertisements I often ask people whether it would make them start smoking. I find it very hard to believe that some of these advertisements would actually encourage anybody to start smoking. I think the area of sponsorship is somewhat different in this respect. There is a certain logic to the industry's argument that their advertising campaigns on posters and in newspapers are for brand switching rather than encouraging people to start smoking.

47. So, if not persuaded, you think there is some merit in that argument? I am quite prepared to accept that there are different degrees and different effects of advertising, but you seem to be saying almost that newspaper and poster advertising does not necessarily have the effect of encouraging people to smoke more with its various images and so on. That I think is what a lot of people would find rather difficult to accept. That is what seems to be the inconsistency of the Government's position on this and why it is a little difficult to understand why the Government are taking the view they are in contrast to a number of our European colleagues.

(*Baroness Hooper*) Perhaps I can add to that the issue of labelling of tobacco products and tobacco advertisements and the health warnings that have to be contained. It may sound facetious, but I know that there are certain people who think that the Government are wasting a great deal of money in putting up these large advertisements which are essentially health warnings about the dangers of tobacco, because those who have not mastered the mystery of Silk Cut and Gold, whatever it is, advertisements are seeing only the health warning. If you see a series of these posters, unless you know about smoking, the health warning is the only thing that has any impact upon you.

48. Does Dr Metters agree that if tobacco were not known at present but was suddenly introduced, there is no way in which the Government would allow it on the market?

(*Dr Metters*) I was not around in the days of Columbus, but I think probably that if we knew more about the harmful effects we certainly would not have allowed North Sea gas into our homes, a nasty explosive material that should not be allowed anywhere. It is difficult to extrapolate retrospectively.

(*Baroness Hooper*) Perhaps I may take up that point. We were among the first of the European countries to introduce a total ban on oral snuff.

*See p. 19

Chairman

49. You are aware that we have it in the arm of a chair as we enter the House of Commons?

(*Baroness Hooper*) It now has to be labelled to show that it is a potential danger.

50. But it is still there, is it not?

(*Baroness Hooper*) No, oral snuff is chewing tobacco, the Skoal Bandits.

51. I have not taken it, but I gather there is some snuff in that chair.

(*Baroness Hooper*) It is not recommended. In fact it is prohibited.

Mr Sims

52. I should like to move on to the European dimension and the whole question of harmonisation of duties on tobacco and alcohol products. What is likely to be the effect of that on the price which you have mentioned as being a particularly important factor? Perhaps at the same time I could comment on this rather curious EC policy of paying money to some farmers to grow tobacco which again would suggest some inconsistency. Would you like to comment on those two points?

(*Baroness Hooper*) I am delighted that these two issues have been raised. As I said earlier, the answer to this question is to have a package of measures including these two issues. Price we believe is very important. We would clearly not wish to have anything that would decrease the price, either of tobacco or alcohol on health grounds. In anything that we are doing in our negotiations on the harmonisation proposals, which again is not a health department lead, the Treasury is very well aware of the health implications. On the subsidies, again at meetings of the agricultural Council our agriculture Ministers have made the important point—and I have raised it personally at every single health Council that I have attended where we have been discussing the tobacco issue—about the countries such as Greece, who are not only selling cigarettes very cheaply but are growing tobacco, and France. Prior to the tobacco subsidies in the European Community France grew very little tobacco, it now grows a great deal of tobacco. I have impressed this upon Ministers and I believe that although the subsidy is a long way from being eliminated completely it has been cut in the last agricultural round.

Sir David Price: But is it not sheer hypocrisy, particularly with the Greek social services commissioner, when the Greeks are the biggest beneficiary of increased subsidies, it is nearly a billion Ecu in the current year, to grow not less but more tobacco? I understand it is the nastiest tobacco—

Mr Sims: It is almost entirely unsmokable.

Sir David Price:—with the highest tar content and is largely grown to destroy the people in the Third World which, wearing a different hat, the European Community is trying to help improve their life styles. Is it not sheer hypocrisy and is it not time we said so?

Chairman

53. Could you perhaps answer with that the allegation in the statement made by many of those who are opposed to the ban that if we do impose an advertising ban in this country it may reduce the production of the better quality cigarettes in this country and invite into this country the cheaper continental cigarettes which have the sort of effect that Sir David has described in relation to the tobacco that is grown in Greece?

(*Baroness Hooper*) It might, yes.

Alice Mahon: Oh, Chairman!

54. I am just trying to draw out.

(*Baroness Hooper*) Clearly we would take all possible safeguards to avoid that.

Alice Mahon

55. I have been involved with the ASH campaign to lobby the Department to stop this advertising because of the growth in the number of young people and children who are smoking. I disagree with you Minister about some of these posters and adverts. I think they are very sophisticated and clever posters that know exactly what they are doing. Any notion that the tobacco companies are spending all that money, time and effort just to get people to change brands I think is absolutely ludicrous. I think the Department are ducking their responsibility. It is a worrying trend, children increasingly are starting to smoke younger and younger. Many of us are absolutely convinced that this kind of advertising has to be stopped.

Chairman: In short, Minister, do you agree? There is a question mark after what Mrs Mahon has said.

(*Baroness Hooper*) No, Chairman, I cannot agree that advertising is the main influence. I believe it is peer pressure among young people. Any information that I have received from people who are working in the field indicates that peer pressure is the important thing. I believe that the Private Member's Bill that became an Act last year on the protection of children and young people from smoking which emphasises the illegality of sales to under-16s and prevents the sales of single cigarettes will have a profound effect as well as the new strictures in the voluntary agreement about advertising at point of sale, advertising close to schools and things of that kind. A whole package of measures is required to help avoid this problem.

Audrey Wise

56. Minister, you said that you are constantly pressing your European health minister colleagues, particularly the point about the subsidy on tobacco growing, but with what effect?

(*Baroness Hooper*) It is always difficult to give a categorical answer to that. I hope that it will have the effect that they as health ministers return to their own countries and impress upon their agriculture ministers that when they next vote on tobacco subsidies in a European Agricultural Council that they will vote if not for a total elimination of subsidy then a great reduction. That certainly is how we have co-operated with our agriculture Ministers and we know that our agriculture Ministers and our

[**Audrey Wise** *Cont*]
Members of the European Parliament also make this point whenever they can.

Chairman

57. Yes, but we do not grow tobacco in this country, do we?
(*Baroness Hooper*) Not yet.

Mrs Wise

58. I am intrigued by what these meetings must be like. You make your case, which is a good one and one we all agree with, but what happens then? Do they sit and listen to you politely and then move on? Or do they make a counter argument?
(*Baroness Hooper*) No health Minister has yet made a counter argument. Many of the health Ministers support what I say, but say it is very difficult to convince their industrial colleagues.

Mr Sims

59. Do not some of your arguments rather support the case for having a health DG and a health Commissioner? Some of the issues we have been discussing are the responsibility of other people who do not have health as their primary concern.
(*Baroness Hooper*) Yes, but something like tobacco growing would always come up under agriculture. Nevertheless the effect of this new chapter in the treaty will be to improve—
Sir David Price: But if you had a strong input from a strong DG he or she would be level pegging with the Agriculture DG.

Mr Couchman

60. My colleague has reminded me that if I had not started smoking at nine I would probably have grown to seven foot four instead of six foot four! We would not, of course, encourage young children to smoke, but is it not the case that the more you make it a forbidden pleasure the more they seek it out? The more of a mystery you make about smoking the more it becomes attractive to them. Is that not part of the trouble with soft and hard drugs?
(*Baroness Hooper*) It may well be so, but all our health education campaigns directed through the Health Education Authority and other organisations that we fund are directed at taking any excitement or glamour out of smoking in order to dissuade young people from starting.

Chairman

61. Minister, may I put a question of law to you? You may not be able to answer. A specialist firm in European Community law has come forward with the opinion that a ban on tobacco advertising would be incompatible with existing European Community law. Is that correct? Has the Department taken advice on this? If it has not, will it and will you perhaps let us have a paper on it?
(*Baroness Hooper*) I am not sure that the Department has taken advice on this. It is an issue nevertheless that has come before us on the principle that anything which is legally manufactured within the Community or within the country it should be possible to advertise. I know it is a point that has been raised by Germany and this has been one of their difficulties in agreeing to a total ban.

62. So you are saying to the Committee that there is some doubt about whether a ban would be compatible with existing European treaties and law?
(*Mr Heppell*) There has been argument about the legal base for any ban which I believe is a separate point though very close to the question of whether introducing it under one power might be incompatible with another power. If the Clerk could let us see the basis of this legal opinion that would be very helpful and we would certainly gladly respond†.
Chairman: I am sure that can be done. The full text of it could be obtained. Let us now pass on to the purchasing rules and Tom Clarke would like to take over the questioning.

Mr Clarke

63. It was reported in the "Health Service Journal" on 12 December that two NHS units have had to turn to information technology to help them negotiate the EC's purchasing rules designed, in the words of the Treasury, to "strengthen guarantees against discriminatory, nationalistic purchasing practices". Has the Department offered help or advice to health authorities struggling with the rules? Has advice been sought by any health authorities? Finally, has the Department considered issuing a definitive manual laying down how purchasing must be done?
(*Baroness Hooper*) Thank you. we have issued guidance on this subject. The Treasury issued guidance notes on public sector purchasing which explained the general international obligations of public sector bodies in placing supplies contracts. This guidance was circulated to all National Health Service supplies departments in January 1989. The procurement directorate was aware of difficulties that some authorities had in interpreting the rules as you have indicated and therefore organised a series of seminars in the course of 1990 which were attended by supplies staff from all the regions. We also know that there has been a help line available in case further guidance was necessary to deal with particular problems and certain regions—South Western region and the Scottish health services CSA—have also produced guidance notes in a simplified form. These have been issued to all regions.

64. Has NAHAT responded to the guidance?
(*Baroness Hooper*) I am not aware of that. Are we aware of that?
(*Mr Heppell*) Not that I am aware of.
(*Baroness Hooper*) I can find out, if you are interested to know.

65. Yes. This is available, obviously, in printed form. The Committee does not have a copies of the guidance. Is it possible for us to have them?
(*Baroness Hooper*) We would be very happy to let you see copies. It is a complicated area*.
Chairman: We move now to another important area, the mutual recognition of professional

†See p. 20
*See p. 19

[**Mr Clarke** *Cont*]
qualifications which generates quite a lot of heat from time to time.

Audrey Wise

66. Is the Department satisfied that the medical education of student doctors, nurses, dentists and other health professionals receive in other member states is to a level that would be acceptable to the UK examining bodies?

(*Baroness Hooper*) Of course we have freedom of establishment for all the health professionals. Most of them have been in effect for a number of years. There has been agreement about accreditation and standards of education and training so that a doctor, a nurse, a dentist or any other kind of health professional has the opportunity to work in another member state country by producing their certificates which have now been accepted on a European Community basis. Nevertheless I recognise that there are some concerns in this area and I have been having meetings recently with representatives of the Royal Colleges as well as representatives of the British Medical Association. The BMA has for a number of years had a committee which has been monitoring this. The committee is also attended by officials from the Health Department so that we are aware of what is going on. These bodies are all aware of the implications of what is going on on the European Community scene and are keen to ensure that the sort of standards and the differences in approach that we have in this country where we have, as I understand it—perhaps Dr Metters will come in here in a moment—a consultant-led profession whereas in other countries there is a specialty-led profession.

Chairman

67. What is the difference?

(*Baroness Hooper*) To give the example that was quoted to me, any doctor in most of the other European countries would be eligible to test eyes. If a doctor here who is a specialist in cancer of the bowel, say, were asked to test eyes he may not be as up to date with it as another person in the field. That may not be a very good example. Perhaps Dr Metters can give a better example.

(*Dr Metters*) The difference between the continental consideration of a specialist and our own consideration of a consultant is that a doctor after a fairly limited period of training, perhaps as little as three years in many continental countries, can say he is a specialist in endocrinology. Under our terms a specialist in endocrinology would be a consultant who has held an NHS appointment. That would probably require at least six to eight or even more years' training. So there is a difference in the length of time before somebody can call themselves a specialist between continental Europe and this country. Nevertheless we are hoist here with Directive 75/362, which says that member countries shall recognise the diploma certificates and other evidence of formal qualifications awarded to nationals of other member states. That directive has been operative for some time. So if a doctor comes to this country bearing a certificate authenticated from their equivalent of the General Medical Council, we, under that directive, are obliged to accept his registerable qualifications.

68. But there is no guarantee surely, Dr Metters, that he would be taken on and given any appointment, is there?

(*Dr Metters*) I was just coming to that Chairman, that in the NHS all appointments are by open competition so that the candidates, whether they are from EC states or from the UK then have to present their credentials and it will be immediately apparent whether they have done a three year training or an eight year training. The appointments committee naturally takes the best person that is for the job. So that for the National Health Service appointments there is a built-in hurdle additional to the recognition of a diploma by our General Medical Council. Of course, a doctor who wished to practice privately in this country, if he were able to register with the General Medical Council, could then put up his plate and practice. He would, of course, be subject to the usual restrictions on the advertising of his services that are incumbent upon any doctor.

69. But you do not think that a doctor coming from Europe might then take a complaint that he had not been appointed to a position in this country to the European Court on the grounds that we were unfairly discriminating against other countries' medical qualifications?

(*Dr Metters*) I think that if an appointments committee was to behave in a way that could be called in question, he would have every right to take his complaint to the European Court. But one would hope that in reaching their conclusion as to who was best qualified for the job they would not only look at the paper qualifications but also the period of training that was behind them for some specialist coming from an EC country.

Mr Rowe

70. That is all very fine and funny, but if you have a situation, as we had in one of our local hospitals recently, where 62 candidates applied for a post and not a single one was British born and very few of them had even been near a British training establishment, how does the health authority refuse to appoint someone from Europe, even if they regard the three years as inadequate training experience?

(*Dr Metters*) There will be a specialist adviser member of the appointments board appointed by the relevant medical Royal College or faculty who will say that none of these candidates is of consultant status and will advise, and we hope persuade, other members of the appointments board that they should readvertise the post rather than appoint someone who is not appropriately skilled and qualified.

Chairman: A very positive response.

Audrey Wise

71. Is there any particular country whose medical education causes particular concern?

(*Dr Metters*) That is a very difficult question to answer because it depends a little on the speciality in which the doctor is subsequently working. There are in some countries concern about the basic level of their medical qualification and that concern is shared within those countries, but I would—

Audrey Wise: Which are the countries?

[**Audrey Wise** *Cont*]

Chairman: What are the countries? We would like to know.

Audrey Wise: You must know.

Chairman: He does know. I think we are entitled to this information. I am not seeking to put you in a difficult spot, or Mrs Wise is not.

Audrey Wise

72. I do not mind actually.

(*Dr Metters*) I have never myself quizzed any of the doctors coming from the EC as to their basic knowledge, but I have heard concerns expressed about the qualifications, skills and experience of some doctors coming from Italy, for example.

Chairman: We are grateful for that answer.

73. Is there any way in which the take up of this freedom to come here is being monitored? Does the Department know how many people are coming? Is there any monitoring of any kind done?

(*Dr Metters*) We have some figures dating from last year which showed that the number of doctors coming to practise in the NHS from the Community were just over 1,200 in post in the NHS, most of whom were in junior hospital training posts. That excludes doctors from the Republic of Ireland.

74. Looking at this from a rather different point of view, that of doctors whose qualifications are accepted here, although they were not obtained here—such as doctors from the Indian subcontinent, for example, of whom there are a considerable number here. They will find, will they not, that although they are accepted to practise here they do not have the free right to move to the European Community?

(*Dr Metters*) If they have right of residence in this country and have a registerable qualification with the General Medical Council they would be able to apply to work as a doctor in another EC country.

75. Even if their qualification was obtained overseas?

(*Dr Metters*) Their qualification would have had to have been accepted by our General Medical Council for them to practise in this country in the first place. There is at the moment a lot of discussion in the Committee of Senior Officials on Public Health, where I am one of the two UK representatives, about the recognition of third country diplomas because some countries, notably Spain and Portugal are very keen that their should be recognition of diplomas and degrees obtained by their nationals in country in South America, for example. We naturally have concern that if the Spanish or Portuguese equivalent of the General Medical Council are to register doctors who have qualified elsewhere in the world that that shall be a certification that our General Medical Council would accept without hesitation. But that is still in discussion and there is not yet a proposal.

76. We were told when we went to Brussels that nationals from one member state have no automatic right to work in another member state if their qualifications were obtained outside the Community.

(*Dr Metters*) That is third country diplomas of which I was just speaking.

77. So there are quite a lot of doctors here who are recognised to practise here, but who obtained their qualification elsewhere. They would not have the right to move, would they?

(*Dr Metters*) If they have a registered qualification accepted by the General Medical Council here and have right of abode in this country.

Chairman: I think somebody disagrees with you who is a member of the General Medical Council.

Mr Sims

78. Without referring to the written word, I think Mrs Wise is correct that somebody registered with the General Medical Council who has trained in this country and qualified in this country would have free movement within the continent, but many doctors, particularly those from the Indian subcontinent—who qualified there, whose recognition was accepted by the General Medical Council and who are able to practise in this country and do so—are not able freely to practise in the EC. That is my understanding of the position. They have certainly made representations to me to that effect.

(*Dr Metters*) I think we are saying the same thing, because they would not have right of abode.

Audrey Wise: There are lots of them with right of abode.

Chairman: In order to move this on, as we have two very important areas still to cover, can I suggest, Minister, that you arrange for a paper on this, perhaps one side of A4, to be submitted to this Committee on this issue as soon as you possibly can. There seems to be some doubt and confusion.

Mr Sims: It is an issue on which overseas doctors feel very strongly, so it would be good to have it cleared up.

Audrey Wise: There are many possibilities of accusations of racism being built in to the EC. It is important, so I would be very grateful. It would be helpful to have not only a paper, but when you have clarified it what the Government's attitude to it is.

Chairman: No doubt that could be the final sentence on the one side of A4*.

Audrey Wise

79. Looking at a different aspect, another problem relates to social workers. Our social work qualification is a two year one, not a three year qualification. Is there any likelihood of United Kingdom social workers having their qualifications recognised by the rest of the Community?

(*Baroness Hooper*) There is a general directive under consideration which would cover qualifications requiring fewer than three years of study. That is still under discussion and so obviously it would, if agreed eventually, affect social workers.

80. What is the position with social workers qualifying overseas where they do take three years? Can they come here, or is the whole thing gummed up?

(*Baroness Hooper*) At present there is a general directive which affords mutual recognition for qualifications with a longer than three year period of study, so in that case I see no reason why a social

*See p. 19

[**Audrey Wise** *Cont*]
worker with longer than a three-year qualification would not be able to apply for a post in this country.

81. So there could be incoming movement, but not, at present, outgoing?
(*Baroness Hooper*) Not under our present arrangements. As a postscript to that, may I just say that on the doctors' directive that we have been discussing—although that was brought in in 1975—the fact that there are only 1,200 doctors from other European countries who have taken up the challenge to come here is an indication of the fact that there is not a great deal of movement likely in these fields. Language of course is a problem.

Chairman

82. But bearing in mind the single market of 1 January 1993, there may, following that date, be rather more movement than there has been in the past?
(*Baroness Hooper*) It makes no difference in this respect. But there may be a raised awareness, yes.

83. That is right. Can we now move on to medicines and the single European market and make particular reference to the supplementary protection certificate for medicinal products, particularly pharmaceutical products? An agreement has recently been reached, subject to final ratification and dotting of the "i's" and crossing of the "t's". Is your Department satisfied with the compromise proposal that is on the table currently? Perhaps you can indicate at the same time what would have been your Department's ideal in respect of this matter. How easy was it to reconcile the widely differing advice that the Government no doubt received from the pharmaceutical industry and others regarding this very critical proposal? From the chair I must declare a constituency interest, not a financial vested interest, in that ICI Pharmaceuticals is the largest single employer in my constituency and they make a major contribution not only to the success of ICI as a company but also to my constituency. They have been deeply concerned about what is proposed.
(*Baroness Hooper*) Again perhaps I should start by saying that this is a matter that is dealt with by the internal market council and therefore the DTI has represented us in the negotiations. It was at the last meeting of the internal market Council that a compromise proposal was put forward by the Dutch presidency which gives a maximum of five years' patent term extension to give a maximum of 15 years assured protection. We regard this as a reasonably good outcome because it is certainly within the negotiating range which was acceptable to us. We believe it goes towards negotiating a level playing field for the pharmaceutical industry vis-a-vis Japan and the United States.

84. Can I press you or one of your colleagues on the transitional arrangements relating to existing drugs, where there is considerable confusion and muddle and whereby there is unlikely to be a level playing field? They may give an additional period of patent life in one or more country of the EC, but this may not be true across all countries within the European Community. Are the Government prepared to seek further modifications to eradicate this muddle and confusion which could produce a very serious situation for pharmaceutical companies that manufacture, research and develop in this country?
(*Baroness Hooper*) We are considering the implications at the moment of what is a revised draft from the Commission on these transitional arrangements. We have not yet formally seen the proposed text. I understand that the intention is to refer the draft to something called the Attaches Group Meeting before the end of January. We shall therefore be looking at this draft text shortly.

85. There are two things about this. First of all, I must express surprise that you have not seen the text because pharmaceutical companies are already in touch with Members of Parliament, who therefore are aware of what has happened, and the Department itself is not aware of the text.
(*Baroness Hooper*) That often happens, but we have not seen it.

86. You actually have not seen it?
(*Baroness Hooper*) No.

87. But you are saying to the Committee that some concern is felt within the Department about the transitional arrangements and that you may seek to get a fairer or more level playing field for this area before the final "t's" are crossed and the final "i's" are dotted and the agreement is final?
(*Baroness Hooper*) Obviously we shall seek to get the best possible transitional arrangements for the UK.

88. Mr Heppell you just looked at the Minister. Are you prepared to add anything further to that?
(*Mr Heppell*) No, that is fine.

89. Mr Allen?
(*Mr Allen*) No, indeed, I have nothing to add to it.

90. Dr Metters? I am trawling!
(*Dr Metters*) No.

Sir David Price

91. I think you all agree that pharmaceuticals are central to the whole of public health policy, particularly if one thinks in terms of health care. We have plenty of evidence that many pharmaceuticals keep people out of hospital and enable them to have care in the community. I am thinking of schizophrenics and depressives, to take two examples. Can I take you through the various stages in the development of a new pharmaceutical and ask you at each stage what you are doing to try to get a level playing field? All the information I have is that it is not only not level, it is particularly peaky and troughy. The first is the research rules, for example, I understand that if you can satisfy the French Government that the new product you are developing has been done in a French laboratory you get into the fast track and receive lots of grants and so on. If, on the other hand, you develop that product somewhere else in the Community, you do not. Secondly is the whole question of the validation of a new product. We all have some form of legislation on this. My information is that it is incredibly uneven, but it is also very important because it ties in with patent life. Thirdly, the product launch—again my information is that the French, if it has come out of a

[**Sir David Price** *Cont*]
French laboratory, put it straight on to the autoroute, as it were, but if it has come from a British or a German laboratory it goes on to the side track. There is then the whole question of initial pricing and again some countries give the new product much more beneficial price from the point of view of the manufacturer than others do. There is then the follow up: how do you deal with inflation? Then there is the public purchasing policy because although nobody has quite the same form of health service, each one is a bit different, they all have some form of public purchasing policy for pharmaceuticals for their population. They are all different and then there is the question of patent life. All these are relevant. Without going through each of them in detail I am trying to give you, as I see it, the whole scene. It is not to me sufficient to say "That is in a different DG. That is a matter for the DTI". In reality what matters is the availability of the appropriate drugs at reasonable prices. There is also the allied question of the definition of a pharmaceutical product. As I understand it, we and the French have rather similar definitions and therefore a lot of things we can buy over a supermarket shelf. You are not allowed to do it in Germany or Holland, particularly in Germany, and most pharmaceuticals have to be sold through a registered pharmacist. These are not just matters for trade, they are matters for health.

(*Baroness Hooper*) This is precisely the reason we wanted a definition within the treaty to give validation to the activities of health ministers in this area. It was very unsatisfactory. Although we on a home basis deal with some of these issues, at the European level we do not. The reason I mentioned it was being dealt with by another Council and another Department is because sometimes the timetable of what stage the proposals have reached is not as precise as when one is dealing with it oneself. As far as the various issues that you have raised are concerned, I think you were suggesting that France gives subsidies to research and product development that are not given in other countries. This is probably questionable. Some people would say that we give a certain amount of Government support to research, but nevertheless if a case is made in a particular instance then a complaint can be made to the Commission in order to expose the fact that there is not a level playing field in this area. That issue is already covered. As far as validation of medical products is concerned, there are moves currently under way for harmonisation of this. We believe that the way our Medicines Control Agency operates is both efficient and effective and we would wish to see it as something of a model for the whole of Europe. We are pressing in that direction.

92. I got the impression when we were in Brussels last year that there was a desire, at least among some officials, to have a European validation and therefore if we had common rules, a new drug would be validated in one country under the European rules and that validation would be accepted by all the other countries. Are we moving towards that?

(*Baroness Hooper*) It would be rather similar to the trade mark and patent arrangements. We are moving towards that, yes.

Chairman

93. Have you anything further to say to the original question?

(*Baroness Hooper*) I wanted to come back to the questions on pricing systems. Again in any stance that we are taking, our policies are aimed to ensure that any pricing system should not be excessively rigid, does not impede the free circulation of goods and does not impinge directly on the organisation of member states health care systems, because even with the new chapter on public health as a result of the Maastricht treaty there is no competence as far as the organisation of health service delivery is concerned.

94. Dr Metters, would you like to add anything to the very wide question that Sir David put to the Minister from your own particular standpoint?

(*Dr Metters*) My concern is that any pharmaceutical that is brought to the market in this country should be safe, of good quality and efficacy. The purpose should be to ensure that whether we have a unified system covering the 12, or 12 different equivalents of our Medicines Control Agency, all of which approve or provide product licences, that the provenance of those licences should be the same. While the Commission's proposals for a European Medicines Evaluation Agency have at present skirted round some of the details, it is absolutely essential that this is correct before we move towards a harmonised system because, at the end of the day, it will be the patients and the ordinary people who will suffer if we have different levels of quality and safety applying to pharmaceuticals that come on to a common market.

95. Unless everybody can be totally confident in the ability of that particular body.

(*Dr Metters*) Of course.

Sir David Price

96. Does not this issue come absolutely straight within article 1 of the new Title XV of public health under the new treaty? Let me remind you of what it says: "The Community shall contribute towards ensuring a high level of human health protection by encouraging co-operation between the Member States". Is this not precisely what we want? In other words, common validation and this goes back to validating a new drug product in relation to side effects, how much clinical trial has to be done and so on.

(*Dr Metters*) That is a different argument, if I may say so, because there is a balance between the extent to which a drug is tested before it is given its licence and the efficacy of the system for looking for adverse effects afterwards. That is not an argument on which there is a black and white answer. If you have a very good system for detecting side effects after the drug is on the market, then perhaps you do not have to go to quite the same lengths as you would if you do not have a very good system for detecting adverse reactions. In no member state in the Community, or indeed anywhere in the world, do we yet have a system for detecting as high a proportion of adverse reactions as we would wish. Unfortunately there is a natural reluctance of doctors to report adverse reactions, which is a constant problem to the Medicines Control Agency. If we are to do this on a

[**Sir David Price** *Cont*]
European level we have to get it right otherwise we have to be sure that any drug coming forward to be licensed by any of the agencies within the Community and put on the market has to be of the highest standard because it will be all the more difficult to detect problems thereafter.

Chairman

97. May I put one or two very specific questions to you? This one to you, Dr Metters: how soon will the situation be remedied whereby one member state permits a particular medicine to be freely available without prescription, but another Member State does not even allow it into the country? I quote here an example: it is not permitted to take certain medicines containing codeine into Greece, and anyone caught carrying a bottle of a particular brand of cough medicine, which is very widely available within this country, without an individual letter from his doctor faces a theoretical 10 years imprisonment in Greece if he is found out. When will the playing field be made level?

(*Dr Metters*) I do not know, Chairman. I hope that he might get out before the Community has sorted this one out, but it depends on the rate at which the Community proceeds. It may be very difficult because there are some entrenched positions in countries that take particular exception to some pharmaceuticals which we can buy as over-the-counter products.

98. That is what I am saying. Over the counter one can buy this bottle of cough medicine.

(*Dr Metters*) I am afraid I would not like to predict.

99. Mr Heppell, can you help us.

(*Mr Heppell*) No, sir.

100. Minister, perhaps you cannot either?

(*Baroness Hooper*) I cannot, but I would like to add that we would not ourselves like to lose the right to withdraw a certain product from circulation if we so chose.

101. Can we then quickly move on to the directive on organisation of working time? Again this is quite controversial and could have a major effect. Paragraph 4.5 of your Department's memorandum states: "Negotiations on the Directive on organisation of working time are under way and an 'orientation debate' took place in the Council in December 1991. The proposals could"—as you know, Minister—"affect the employment of staff in the NHS and local authority care establishments". I put the question therefore to you. If the Directive were to pass into legislation, would our Government in the United Kingdom seek a derogation?

(*Baroness Hooper*) We certainly have been very much opposed to these proposals. They have, as you have indicated, been in the course of negotiation for some time, since March 1991. The draft Directive was discussed at the last social affairs Council in December, but no vote was taken. We have argued against it for a variety of reasons, but from the health point of view it would very much affect the arrangements for employment and training that we have.

102. Are you saying therefore by implication that the United Kingdom would seek derogation?

(*Baroness Hooper*) I think it would be open to us either to seek derogation or, under the new arrangements depending again on timing and the implementation of Maastricht, to claim subsidiarity.

103. Do any of your colleagues wish to add anything to that? So that is the Government's policy and attitude. Can I put a last question to you. What is the United Kingdom hoping to achieve in the Community in respect of health during the period of our presidency which begins in the second half of this year?

(*Baroness Hooper*) To some extent we have already covered this ground, or at least touched on it. We would certainly seek to ensure that the direction of the European Community in the health field is contained within the overall proviso that what we do in the European Community should be something which is better done at a European Community level. We would seek, whether it is as initiatives, to hold events which could lead to further initiatives to ensure that the kinds of things that I have touched on—the common database systems and arrangements, the improved collaboration on communicable disease information, work in the research field, as well as the programmes on cancer, AIDS, drug prevention and elderly people—are moving forward in the right direction.

104. Do you think the Government will continue to support the initiative of the Dutch when they held the presidency until the end of the year, their attempt to give the health impact of environmental issues a higher profile within the Council?

(*Baroness Hooper*) That is something which is already on the agenda that we shall seek to move forward on. Also under the Dutch presidency we started discussion on critical choices in health care which again is something which ties in very well with our own White Paper targeting approach. This is something that we shall seek to continue.

105. On a point of interest, Minister, can you explain why the United Kingdom took up the cudgels on behalf of food importers from Peru, who are affected by action in respect of the cholera outbreak? I refer to paragraph 4.4 of your memorandum.

(*Mr Heppell*) Because on this occasion the European Commission did not, in the view of the United Kingdom, have the powers to take that action. It was challenged by the United Kingdom and the proposal taken to the European Court. The Commission then changed tack and used powers which it was entitled to. Therefore we finished up where we wanted to finish up. Had we not challenged the European Commission it would have been an extension of powers.

106. I am very grateful for that response. Obviously on that issue anyway the British Government were standing up for our interests and in the best interests of the Community. Minister, I thank you, Mr Heppell, Dr Metters and Mr Allen—although he has been very silent. I am sad, I tried to draw you in, Mr Allen.

(*Mr Allen*) I am thinking, Chairman, thinking!

[**Chairman** *Cont*]

107. Perhaps you would have been there, if there had been a snick, as a long stop. I thank you very much, Minister, for coming and answering so frankly and so fully the very many questions which we put to you. It has been very helpful as part of our inquiry. Thank you.

(*Baroness Hooper*) Thank you, Chairman, it has been a very useful discussion and we shall follow up on any of the issues that we have undertaken to do so. That is perhaps where Mr Allen will come in.

Chairman: I am most grateful, thank you for the explanation.

APPENDIX

Supplementary Memoranda submitted by the Department of Health

I enclose supplementary information on points raised by the Committee at their hearing on 15 January.

The Committee requested, at Question 45, details of what the Department estimates smoking costs in respect of treatment required and care given within the health service. We have concluded that the estimates contained in the Health Education Authority's recent report, "The Smoking Epidemic" are the best currently available. The costs to the NHS are estimated to be £437 million annually. This figure is for hospital costs only and does not include the costs of the care given by GPs or at health clinics or other care in the community. The Committee also asked about income to the Exchequer from the taxation of tobacco. Excise duty on tobacco raised £5.6bn in 1990-91. VAT is thought to have earned another £0.5 billion to this, making a total of about £6.1 billion.

The Committee also asked for the Department's views on the legal opinion given last July to the Confederation of European Community Cigarette Manufacturers Ltd. The advice of the Department's lawyers is being sought and we will provide the Committee with a response as soon as possible. *(See p. 20)*.

The Committee asked, at Question 65, for copies of guidance on EC purchasing rules. These are enclosed *(not reported)*. The Department's Health Circulars, HC(80) 12 and HC(78)6, were substantially amended by publication of Treasury guidance, which was sent to all Regional Supplies Directors under cover of a letter, EL(89)MB/67, on 17 March 1989. The Department also issued supplementary guidance (undated) in that year, which is enclosed *(not reported)*. We are not aware of any response by the National Association of Health Authorities to this guidance. We understand that the Treasury are in the process of revising their guidance to simplify it.

Finally at Question 78, the Committee asked for a short memorandum on the recognition of the qualifications of nationals of EC member states with non-EC qualifications. This is covered in the note below.

Mutual Recognition of Professional Qualifications

1. Under existing EC medical directives, which have been in force since 1976, nationals of EC member states, with recognised medical qualifications obtained in EC countries, have the right of access to employment in any EC member state. Some nationals of EC member states, including naturalised doctors from third countries, hold qualifications obtained in non-EC countries which do not carry the same *automatic right of recognition* in other member states, notwithstanding that these qualifications may meet the EC standards required by the directives.

2. Each member state can decide to recognise a particular overseas medical qualification for registration to practice within its own territory. However, such recognition is not binding on other member states.

3. There appears to be considerable momentum from a variety of sources for the mutural recognition of medical qualifications obtained in non-EC countries partly because it is perceived that the lack of mutual recognition is seen as discriminatory and that the position of these doctors is anomalous compared to some other professions. (Mutual recognition of non-EC qualifications held by certain other groups of workers who are nationals of member states is allowed for by the First General Systems Directive 89/48/EEC).

4. This is also reflected in the concern of the European Court of Justice (ECJ) and the Commission that EC nationals right of access to employment should not be restricted and the increasing vulnerability to challenge in the ECJ of any decisions refusing recognition of overseas qualifications held by nationals of EC member states. It seems quite possible therefore that mutual recognition of non-EC qualifications in the health sector held by nationals of EC member states will become the subject of an EC Directive.

5. At present the GMC does not accept some third country qualifications which are accepted in other member states. Several member states have also expressed concern about overseas qualifications accepted by other member states.

6. Automatic acceptance of non-EC medical qualifications should not be perceived as a lowering of medical standards. The Department does not oppose in principle the mutual recognition of third country medical qualifications. However, we would wish to insist on safeguards to maintain standards of medical care

in this country and to reassure the medical profession that any system introduced for mutual recognition would be acceptable.

7. The European Commission is presently considering the possibility of mutual recognition between member states of non-EC medical qualifications. They have asked the Committee of Senior Officials in Public Health (CSOPH), on which the Department is represented, to consider whether the medical directives should be amended so as to provide for the recognition of third Country qualifications held by community nationals where:

— these qualifications are of a level at least equivalent to that required to satisfy the qualitative and quantative criteria stipulated by the medical directives; and

— the holder of the qualification has at least 3 years professional experience in the member state which recognised the qualification.

8. CSOPH has recently gathered information from member states about their assessment of third country qualifications and this subject is down for discussion at their next meeting in June. The Department is currently assessing this information as to whether we are satisfied with the arrangements in other member states and will feed our comments into the next meeting.

The Legal Opinion given to the Confederation of European Community Cigarette Manufacturers Ltd

Department of Health lawyers have received a copy of the legal Opinion referred to by the Select Committee. They consider that the measure is compatible with Article 100a and that a ban on tobacco advertising is not inconsistent with European Community law. It is to be recalled that Member States have varying provisions relating to tobacco advertising and that tobacco advertising on television was prohibited by Directive 89/552/EEC.

There are essentially three main arguments to support the view that the proposal is compatible with the use of Article 100a. First, the proposal can be regarded as equalising the conditions of competition within the Community. It is not correct to say that if a ban in a minority of Member States distorts trade then a ban in all Member States further distorts trade. The effect of the proposal is to harmonise the laws in Member States taking as its base the laws that exist in the minority of Member States. It also follows from Article 100a3 that a high level of health protection must inform any standards which are set. In certain cases this standard ought to be able to extend to a ban where this is the only way in which a proper level of protection can be ensured. Since the aim of the proposal is to equalise the conditions of competition in Member States it is not relevant that some advertising does not transcend national borders.

Secondly, having regard to advertising services, the proposal establishes a Community-wide system for the advertising of tobacco products. In the absence of harmonised Community rules on the advertising of tobacco products it would remain possible for Member States to introduce divergent rules. This would mean that in order to market tobacco products throughout the Community those providing advertising services or manufacturers would need to have different types of graphics or slogans, for example for each particular tobacco advertisement depending on which the Member State the advertisement was to appear. Therefore common rules on tobacco advertising would facilitate this type of medium. It is accepted that a ban on tobacco advertising can amount to harmonisation. Although the proposal bans tobacco advertising except in tobacco sales outlets and even then Member States are able to prohibit advertising in such places the proposal sets out the conditions for tobacco advertising. With respect to the argument that nothing of any meaningful substance is left to the national jurisdiction, it is not unusual for Directives adopted under Article 100a to leave no discretion to Member States

Thirdly, the proposal will facilitate trade in goods which carry advertising: for example magazines. Non-harmonised rules on advertising affect the physical movement of goods across borders by requiring the product to be altered to take account of diverging national legislations.

The legal opinion is mistaken in stating that the Community has no powers to legislate in respect of the substance of the criminal law. The Community frequently adopts directly applicable rules, contravention of which is enforced by the criminal law of the Member States. In the United Kingdom such enforcement is effected under statutory instruments made pursuant to section 2(2) of the European Communities Act 1972, or other relevant power, creating appropriate offences and prescribing penalties.

Department of Health lawyers accept that Community law takes account of the European Convention on Human Rights, including article 10. However it is well established that the fundamental freedoms under that Convention are not absolute and, subject to appropriate safeguards, cannot prevent Community action which is in other respects lawful.

February 1992

APPENDICES TO THE MINUTES OF EVIDENCE

Memorandum submitted by the Department of Health, March 1991 (E3)

CURRENT EC INITIATIVES/ACTIVITIES AFFECTING THE DEPARTMENT OF HEALTH

I. Health in the EC Treaties

1. The EC Treaties contain a number of references to matters which affect health, notably Articles:

48-51 providing for the free movement of people (which is the basis for measures concerning the mutual recognition of qualifications),

100A providing for the free exchange of goods (single market) (which is the basis for measures to harmonise the marketing of health care products including pharmaceuticals and health warnings on products such as tobacco),

118a (regarding the health and safety of workers),

130(r) (protecting human health as regards the environment).

2. The Community has also launched a number of initiatives relating to health issues based on mixed competence, that is partly within the terms of the Treaty (Article 235) and partly by agreements between Health Ministers as representatives of the member states meeting within the Council. The Ministers of Health have met regularly on this mixed competence basis during each presidency in recent years. They have approved a number of programmes, which are currently under way or at an advanced stage, designed to foster the exchange of information, health promotion, co-operation in research and promotion of pilot projects in certain countries.

II. Department of Health Lead Activities

3. Community programmes under paragraphs 1 and 2 above include:

3.1 *AIDS*

A number of resolutions have been passed in the recent past concerning information and education campaigns. Recent proposals have been put forward for a European programme of acton against AIDS for 1991 to 1993.

3.2 *Drug abuse*

There is a continuing programme of research and exchange of information.

3.3 *Cancer*

A second "Europe against Cancer" Action Programme for 1991 to 1994 was approved at the May 1990 Health Council.

3.4 *Tobacco*

Under the Europe against Cancer programme directives on cigarette labelling and tar yield have been adopted and a proposal to extend the scope of the labelling directive to cover tobacco products other than cigarettes is under discussion. This proposal also includes a ban on the marketing of oral snuff. A directive on the partial harmonisaton of tobacco advertising was withdrawn following the Health Council meeting of 3 December. The Commission are now expected to bring forward a further proposal for a total ban.

3.5 *Acute human poisoning*

A proposal for co-operation and exchange of information among European poison centres was adopted at the December 1990 Health Council.

3.6 *Nutrition*

A Resolution for action on nutrition and health was approved at the December 1990 Health Council. The Commission are currently consulting member states on the programme of action to be adopted. 1994 will be declared European Year of Nutrition.

3.7 *Medicines*

3.7.1 A number of proposals have been put forward in this area as part of the programme of legislation in preparation for the Single European Market. They are mainly connected with the harmonisation of national laws on the trade in pharmaceutical products.

3.7.2 Proposals are currently under consideration on advertising of medicinal products, a European Medicines Evaluation Agency for the licensing of medicinal products, alternative medicines and the so called "Three Pack" proposals which include measures on wholesale dealing, the legal status of medicines and information for patients (labelling of pharmaceutical products).

3.8 *Medical Devices*

A directive regulating the marketing of implantable devices (eg heart pacemakers) has recently been agreed by the internal Market Council. A proposed directive to regulate other devices is currently under discussion.

3.9 *Health Staff*

A number of directives ensure mutual recognition of professional qualifications throughout the EC (doctors, nurses, dentists etc). Other staff and qualifications are to be covered in general directives affording mutual recognition to qualifications and training requiring less than three years study.

3.10 *Elderly*

An EC action programme was agreed by the Social Affairs Council in November 1990 which includes the exchange of information, co-operation in research and promotion of pilot projects. 1993 will be European Year of the Elderly and of Solidarity between Generations.

3.11 *Disabled*

The second EC action programme (HELIOS) runs until December 1991. This includes pilot projects and the EC HANDYNET and HANDYAIDS initiatives. Proposals from the Commission for a third programme are expected shortly.

3.12 *Research*

The Department of Health, together with the MRC, provides the UK input to the Medical and Health research element within the EC Research Framework Programme. The main areas of research concern Cancer, AIDS, age related health problems, Environmental and Lifestyle problems, Medical technology and Health Services research. The Department also contributes to radiation protection and human genome analysis elements and AIM (computers in medicine) within the Framework programme.

3.13 *Infant milk and follow up formulae*

MAFF leads on this proposal but Department of Health officials are involved in the negotiation of this draft directive which aims to regulate the composition and marketing of infant and follow up formulae. It is anticipated that the proposal will be agreed upon early in March 1991.

III. Other Health Related Activities

4. The Department also has an interest in a number of other EC activities on which other Departments lead. DH keeps in close contact with other Government departments on these issues.

4.1 *Liability of Suppliers of Services*

A draft directive has been proposed by the Commission affecting negligence claims against providers of services including health and personal social services. The proposal reverses the burden of proof for allegations of negligence. Emergency services are excluded from the scope of the proposed directive but it is not yet clear whether this includes ambulance services. In its present form the proposal would include health and personal social services but the Commission have indicated that a separate directive on these subjects may be put forward at a later date. Negotiations by officials in the Council working group have recently started with DTI taking the lead for the UK.

4.2 *Convergence of Social Protection Policies*

The Commission have proposed a Council recommendation including references to health care provision for those in receipt of social benefits. Social Security lead on this issue which is currently under negotiation in the Social Afairs Council.

4.3 *Environment and Health*

Department of the Environment normally lead on the many existing and proposed directives in this area. DH offers scientific input on human health aspects and on interaction with WHO activities in this area.

4.4 *Food Safety*

MAFF take the lead on existing and new directives but DH has a substantial interest and provides a major policy and scientific input. A large number of directives are under consideration and a proposal on Food Hygiene in expected shortly. A proposal for a zoonoses regulation is currently being considered by the Commission.

4.5 *Organisation of working time and other Social Action programme proposals*

The Department of Employment leads on this proposal for a directive governing the time worked by shift workers. The proposal could affect the employment of staff in NHS and local authority care establishments. Negotiations on the Directive are under way.

4.6 *Public procurement, Health and safety at work and Alcohol*

The Department liaises closely with other Government Departments which lead on these issues on matters affecting health and the NHS.

IV. Community Competence

The Government is of the view that no amendment to the Treaty of Rome is necessary for the Community to undertake any of the activities of the kind described above. The Inter Governmental Conference on Political Union is, however, considering matters of community competence and this includes competence in the health field.

Memorandum submitted by the Association of Pharmaceutical Importers (E4)

We fully understand your decision to examine the implications for health policy of current developments within the European Community and ourselves believe it to be a topic vital for the future.

In this connection you may be interested to note that our Association has been in dialogue with the Commission over the past 12 months; namely DGIII responsible for the pharmaceuticals sector but also DGIV about competition issues within the European industry.

That dialogue was initiated by a paper we prepared on fair competition in the pharmaceuticals sector. Our paper covers a number of points including the failings with the product licensing system and certain uncompetitive practices of pharmaceutical companies. I believe it may well be relevant to your considerations.

At the Commissions's request we prepared two separate follow-up papers, one for each Directorate General. As a result, DGIII has opened an Article 30 case against the Medicines Control Agency while DGIV has begun a pan-European research project which is being coordinated by a UK-based research company, Remit Consultants. The study's objective is to examine why the parallel trade in pharmaceuticals is not increasing as fast as the price differentials in certain country markets suggest it should.

With regard to current European initiatives, you will undoubtedly be aware of the three draft directives currently under consideration on the wholesale distribution and medicinal products for human use, the legal status for the supply of medicinal products for human use and the labelling of medicinal products for human use and on package leaflets. These have of course already been considered by the House of Lords Select Committee on the European Communities but, to the extent that they are relevant to your investigation, could I draw your attention to the long memorandum of evidence which we submitted and which was published in HL Paper 77.

Arising out of that Ken Collins MEP is currently considering an amendment we have proposed. We have also been in touch with BEUC on the subject.

In short we have considerable experience which we believe would be relevant to your investigation and would be very happy to make whatever contribution we can to the deliberations of the Committee.

March 1991

FAIR COMPETITION IN A SINGLE MARKET: CERTAIN ISSUES IN THE PHARMACEUTICAL SECTOR

1. Introduction

1.1 This document has been prepared by the Association of Pharmaceutical importers, a British trade body, to outline five key competition and regulatory issues in the pharmaceuticals sector.

1.2 Two of the issues are essentially British in perspective:

— the time taken by the British Medicines Control Agency to process applications

— the fees charged by that body for doing so

but both relate firmly to Community requirements.

1.3 The other three are very clearly pan-Community:

— product availability in different Community countries

— the use of "unnecesary" product differences as a barrier to free trade

— the need for a pan-European pharmaceutical product licensing authority.

2. The Time Taken to Process Licence Applications

2.1 The British system for processing and granting product licences for parallel imports [PL(PI)s] is unreasonably slow and inefficient and takes far far longer than the 45 days which the Commission believes it should take.

2.2 This impedes proper competition and gives effective early warning to pharmaceutical companies that they are likely to face competition on particular products. The resulting scope for delay and obfuscation in response, and manipulation of supply and demand long before the licences have been granted, is clear.

2.3 Our understanding is that licence applications should in the opinion of the Commission be processed within 45 days—

"... information [given by the importer] must allow the competent authorities in the Member State into which the product is imported to check, within a reasonable period, that the proprietary medicinal product that is the subject of parallel importation is effectively covered by the marketing authorization already granted to the manufacturer or his duly appointed representative. In the Commission's view, **this period should not exceed 45 days from the time the parallel importer gives ... information to the competent authorities**." [Extract from "Parallel Imports of Proprietary Medicinal Products for which marketing authorizations have already been granted (Communication from the Commission to the Council), COM (81) 803 final", dated 17th December 1981]

2.4 The British Government recently acknowledged in a Parliamentary answer that the average time taken to grant a licence is 19 months. Many have been outstanding for much longer than this—four years or more in the experience of our members.

2.5 One can anticipate the likely British government reply if challenged. It would probably include reference to a lack of response from other countries and the pharmaceutical manufacturers—most specifically in relation to site inspection. But is that requirement reasonable or acceptable—by what authority does the British government insist on its right to inspect sites in other Community countries?

2.6 Fundamentally the British licensing system gives no incentive to the Medicines Control Authority to process applications quickly or efficiently. There is no accountability—applicants do not even have the right to information on why applications take so long. If the system which the British government seeks to operate in practice precludes many licences being granted within a "reasonable" time, does that constitute compliance with Commission requirements?

3. The Level of Fees Charged by the British Medicines Control Authority.

3.1 Against that background the British Medicines Control Agency has recently increased fees to 70 per cent with the minimum of warning, giving a total increase 140 per cent within the last year. Further increases are anticipated. These are supposed to put the Authority on a sound financial base and to allow the Authority to operate as "six businesses". As they are necessarily a monopoly supplier of an essential commodity, the application of the concept of their operating as a business is interesting —no normal commercial criteria can apply.

3.2 Furthermore the fee structure—standard charges per application—tends to favour large multi-national companies rather than small and medium sized operations.

4. Product Availability in Different Community Countries

4.1 National trade mark law and licensing systems interact in a manner which restricts the operation of a Single Market and facilitates attempts by pharmaceutical companies to block deliberately its operation.

4.2 This can happen because the licences granted to importers in the United Kingdom only allow the import of named products to a precise formulation from a specific, identified and approved source—all of which are validated by the ECMA (European Community Marketing Authorisation) Number.

There are a number of aspects:

4.3 Differences of brand names can effectively constitute non tariff barriers. These differences occur for a number of reasons:

- linguistic differences: the French feminise a name by adding an "e";
- the trade name in one country may simply be incapable of being registered in another;
- companies make minor changes to the composition of products for no therapeutic reason but solely to prevent imports;
- companies use different brand names within different Community countries.

But the effects are uniform. Companies can protect their UK market. In the UK, notwithstanding that a PL(PI) specifies that named products are therapeutically equivalent, if a pharmacist meets a scrip on that basis he is deemed to have substituted one product for another—a professional offence for which he can be severely disciplined.

4.4 Manufacturers deliberately block the operation of the marketplace. Techniques include:

- restriction of supply—restricting the supply of product in countries known to be the source of imports by only supplying a percentage of the amount ordered; thus only 1000 units are supplied in response to an order for 5000;
- multiplication of batch numbers—as UK importers have to maintain a record and sample of each individual batch, manufacturers deliberately mix the different batches when supplying individual orders;
- restriction of raw material supply—this automatically limits the quantity of finished product available in particular markets;
- switching production sites—effective because licences are specific to individual production locations.

4.5 The transition arrangements for Spanish and Portuguese accession have a particular effect. Article 47 covering patent protection blocks imports from these countries to the UK and other Member states. It has been made clear by certain companies that legal action will be taken against importers. It is unclear whether those who framed the accession treaty intended to have this effect and it is certainly not in line with fair competition in a single market.

5. The use of "Unnecessary" Product Differences as a Barrier To Free Trade

5.1 Manufacturers frequently change the nature of the product in a particular country to prevent its export to other Community countries. These changes can be:

— to the non-therapeutic elements in the product—eg the nature of the external coating on a tablet;

— to the form of the product—eg switching from tablets to capsules;

— to the presentation and packaging—eg from bottles to strip packs.

5.2 In all cases, because UK licences are so specific, these changes necessitate the importer obtaining a new licence, with all the difficulties and delays this involves, as outlined above.

6. Creation of A Pan-Community Licensing Authority

6.1 The only real effective long-term solution to these problems is the creation of a pan-Community licensing system under a single authority which will issue, monitor and control product licences throughout the Community.

6.2 The new authority should be instructed to operate in a manner which ensures the operation of a single free market in pharmaceuticals within the Community to the benefit of its citizens. It should have the specific task of preventing abuses of the operation of such a market.

6.3 Such a system is the only way to achieve the objectives of the Single Market programme in this sector.

March 1990

Memorandum submitted by the European Generics Association* (E7)

SUPPLEMENTARY PROTECTION CERTIFICATES—THE RIGHT PRESCRIPTION?

The European Generics Forum objects to the European Commission's Proposal for Supplementary Protection Certificates for pharmaceutical products in its current form because:

— it grants the multinationals an extra ten year monopoly on top of the twenty years they already have

— it is not an issue for which an EC Regulation is the appropriate instrument

— it has the wrong legal basis

— it is unnecessary—existing EC law already grants drug companies ten years of exclusive rights to sell their products

— it gives US, Japanese and Far Eastern generics rivals a head start over European generic and bulk drug manufacturers

— it is retrospective, granting patent extensions to products already on the market—thus throwing into complete confusion product planning which generic companies made based upon the current patent situation.

The right way forward

The European Generics Forum calls upon the EC Commission to withdraw its proposed Regulation for an SPC. If an SPC is to be offered in Europe, the appropriate means is by an amendment to the European Patent Convention. In addition, any SPC should take into account the legitimate considerations of *all sectors* of both the European pharmaceutical industry and European consumers.

Consequently, the EGF calls on the EC Member States to ensure that:

— the supplementary protection period be shortened from the ten years currently proposed to a maximum of five years. The patent extension period should not place generic producers at a competitive disadvantage against non EC producers on European and world markets

— the Commission look more closely at the operation of the 10 year marketing rule and assess how far it already fulfils the functions envisaged by the SPC proposal

— any provision of an SPC is balanced by binding measures which will increase competition in the pharmaceutical market through facilitating the introduction of generic products onto the market by allowing preparatory work during the patent protection period as well as an accelerated market authorisation procedure for generic products

— an SPC only be offered to products first patented after the Regulation comes into force.

*Submitted under the former name of the European Generics Forum

THE EUROPEAN GENERICS FORUM AND THE EUROPEAN GENERICS INDUSTRY:

Impact of the proposed regulation on supplementary protection certificates [Com (90) 101 final, Official Journal Number C114,8.5.90.]

Introduction

Generics companies produce alternatives to branded pharmaceutical products once their patents have expired. Bulk manufacturers produce the raw material used to produce the generic product.

Many generic companies are, in effect, the "generic arm" of multinational pharmaceutical companies. Such companies may not therefore share the concerns of the European Generics Forum at the impact of the supplementary protection certificate proposal (SPC).

The European Generics Forum (EGF) is made up of independent generic product and bulk manufacturers from Member States. Independent generics companies and bulk manufacturers operate in almost all Member States and generics is a significant section of the European pharmaceutical market. The total market is forecast to grow by almost 10 per cent, or 47 billion ECUs between 1989 and 1993.

Their products are in wide use in national health services and the retail market and are generally held to offer a high quality, low price spur to competition in the medical marketplace.

The EGF believes that the proposed Regulation will severely damage their ability to compete both in Europe and on the world market, in comparison with their American counterparts and the rest of the world market. Figure 2 in this briefing document demonstrates what the EGF anticipates will happen to the generics industry in Europe, in comparison with the American experience, if the Regulation is enacted in its current form. The EGF has a number of specific concerns and objections to the proposal which are set out in this document.

Fundamentally EGF seeks equitable protection of all areas of the industry. Forum members consider that their interests, along with the interests of European consumers, have not been taken into account properly by those drafting and taking decisions upon the proposed regulation: indeed they feel that in many cases decisions were taken in virtual ignorance of the overwhelming concerns of the independent generic industry.

Costs and the consumer

The Commission's explanatory memorandum states that there is a possibility of a price reduction for certain medicines as a result of the longer effective patent life. There is no incentive for a manufacturer to reduce medicine prices significantly before expiration of patent protection.

The EGF regrets that the draft Regulation was drawn up after little consultation of independent generic manufacturers. BEUC, the European consumer's organisation takes the view that the proposal does not reflect consumer concerns. BEUC calls for compensatory measures for generic products, fears that the SPC will lead to high prices for longer periods, and observes that the proposal "does not contain any measures which would reinforce the competitive mechanism of the pharmaceutical market."

High quality, lower cost medicines—the interest of the European consumer—will not best be served by unreasonably extending the period of time during which pharmaceutical companies can operate a monopoly on their products. There is little scope for lower prices for consumers since the draft legislation does not provide counterbalancing mechanisms to promote competition immediately a patent period has expired.

Legal basis for the proposed Regulation

The current proposal is based upon Article 100(a) of the EEC Treaty, which sets out the means by which the objective of establishing the European internal market by 31 December 1992 (laid down in Article 8a) are brought about.

The EGF believes that this basis is wrong. The proposal directly affects property rights and ownership. Moreover, the proposal can only be enforced by means of the legal mechanisms while define ownership. For example, should a breach of the regulation take place, the holder of a patent would seek redress by suing for patent infringement.

The EGF takes the view, in consequence of the controversy surrounding the proper legal basis for the Regulation, that patent extension for pharmaceutical products are the legitimate concern of the European Patent Office.

Separate from this legal issue of principle is the detail of the draft regulation. The EGF believes that, regardless of the outcome of the property ruling, proposals identical or equivalent to the draft SPC are likely to be advanced. **It therefore wishes to comment on the draft regulation where its members' interests would be affected.** Figure 1 demonstrates the projected mechanics of patent extension set out in the Commission's document.

Period of exclusivity

The Commission's explanatory memorandum to the proposal states that the exclusive exploitation period of a patented pharmaceutical product is reduced to an estimated eight years as a result of authorisation procedures and preventative controls. But this is not the real picture. Truly innovative drugs in practice get a much longer period of protection, because their multinational inventors have a commercial incentive to seek authorisation more quickly. They ensure that they do not drag their feet during the authorisation application procedure.

In fact, the introduction of Council Directive 87/21/EEC of 22 December 1986, to have been implemented by most Member States by July 1987 and by Greece, Spain and Portugal by 1 January 1992, precludes the authorisation of a non-proprietary medicine within 10 years of the authorisation of the original proprietary. This "ten year rule" can be avoided only through the development of full pharmacological and toxicological test results and clinical trials which are beyond the scope or desire of most non-proprietary pharmaceutical companies.

And the Directive has proved effective; most EC health authorities will not consider applications to register a pharmaceutical product if this ten year rule applies. The authorisation procedure for a generic product after application then takes generally between 18 months and two years. **The EGF wishes to highlight the existence of these new measures already designed to guarantee high technology products a minimum period of exclusivity.**

The international comparison—Decline of innovation in Europe

The Commission's explanatory memorandum states that the number of new molecules of European origin which have reached the R & D stage has fallen over the last ten years in comparison with activity in this area in the US and Japan. The European market share has fallen from 65 per cent to 40 per cent of new molecules. (NCE)

An examination of the total number of patents filed in the European Community,shows that this trend is not restricted to the area of pharmaceutical development alone, but is reflected in all areas of development where patents are issued. The European market share in patent applications has fallen from 59 per cent (1975) to 43 per cent (1984). This is, however, symptomatic of a more widely spread problem of reduced technological innovation which could require a broader solution.

The setting of the duration of the certificate to coincide with the level of protection available to other sectors of technology should not shroud the global conditions prevailing in the pharmaceuticals sector itself. A competitive advantage in the non-proprietary medicines market may be lost if a higher degree of protection for innovative pharmaceutical products is offered than that available in the US or Japan. The scale of such potential loss, especially for export, should be considered in the context of the total US generic market ($3.752 billion in 1989).

Differing time periods

The United States and Japan addressed the issue of shortened effective patent life as early as 1984. Neither country has gone as far as adding a potential ten years to patent life. Revisions of the Patents Law in Japan (January 1988) and the Waxman Hatch Act in the US (September 1984) have introduced extensions up to a maximum of five years in cases where the effective patent life of a pharmaceutical product was severely eroded by protective authorisation measures.

A quid pro quo for generics

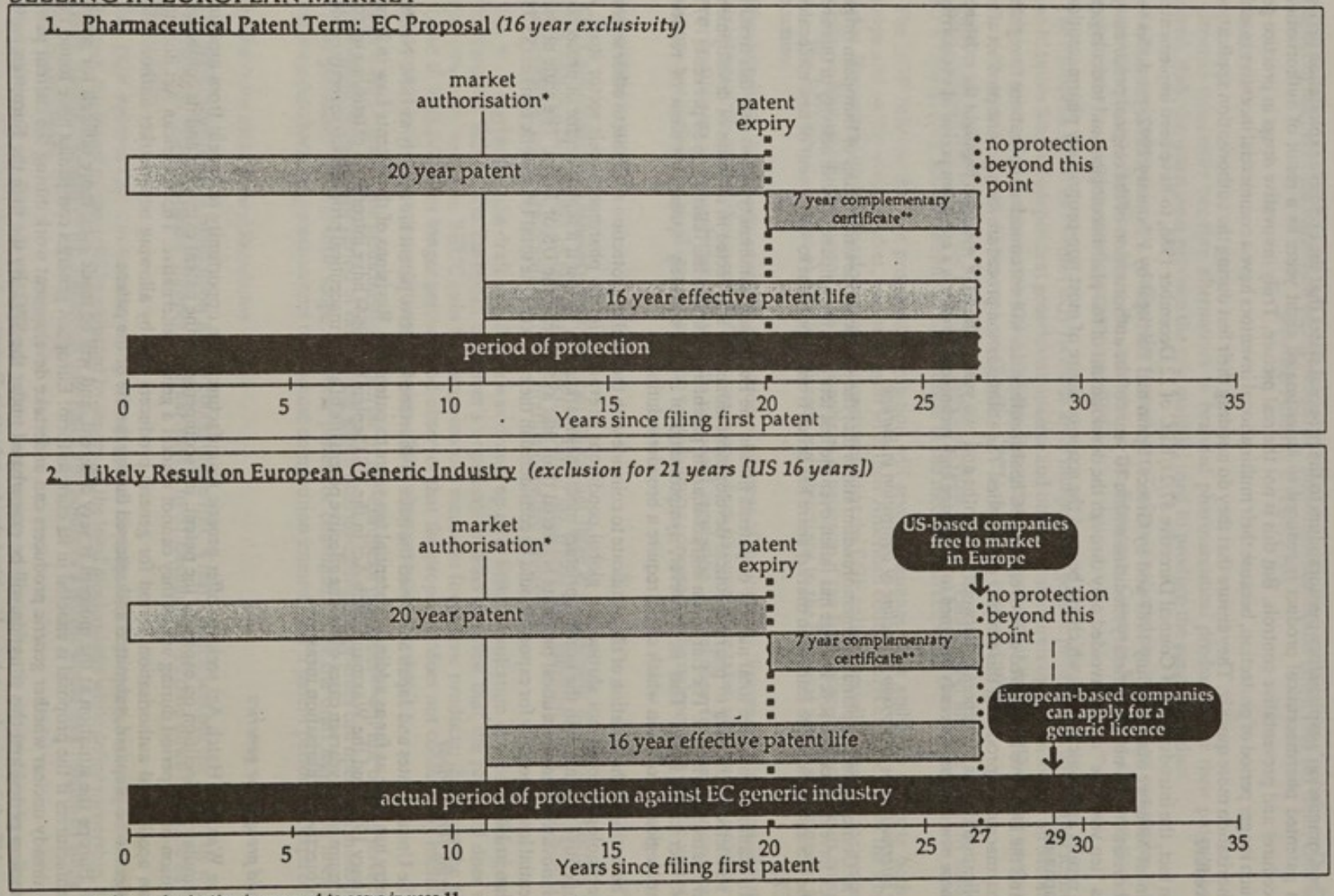
The Waxman Hatch Act seeks to offer generic manufacturers the opportunity to benefit from measures to stimulate competition on expiry of the patent, in recompense for the patent extension and its consequent extension of the period during which they cannot market a generic alternative. The American Act does this by an accelerated authorisation period for generic producers and by allowing new market authorisation dossiers to be prepared, submitted and assessed during the life of the patent.

In Europe the situation at the moment is very different, and will be made even more difficult for generic manufacturers if the proposal is enacted in its current form. European generics companies have found that it is already unclear whether generic producers can undertake development work during the current patent protection period and this situation will be exacerbated under the SPC. By the time the European patent expires US generic rivals can have launched their products in Europe.

In endeavouring to redress the balance between the European Community, the US and Japan, the draft regulation tips the scales too far the other way. **The SPC should contain a clear commitment to introducing an accelerated authorisation procedure for generics.**

The EGF believes that the extension of the effective patent life of a product should be balanced with an opportunity for those companies involved in the production of off-patent drugs to have their product on the market **immediately** such a patent extension lapses.

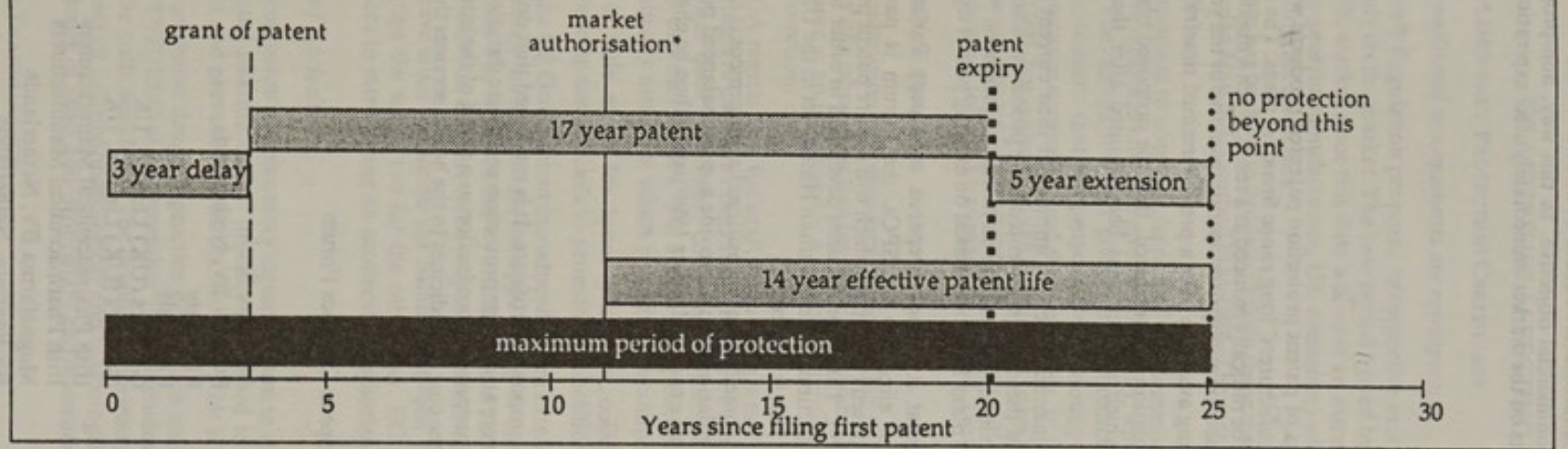
SELLING IN EUROPEAN MARKET



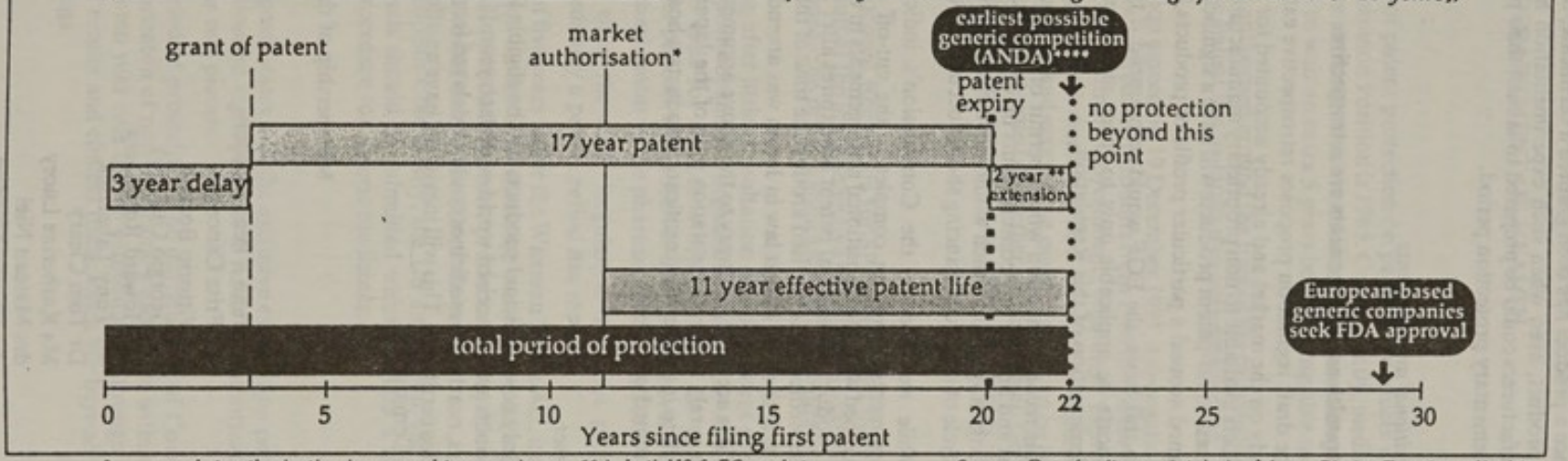
* *market authorisation is assumed to occur in year 11*
** *maximum duration of certificate for market authorisation at year 11*

SELLING IN US MARKET

3. US Pharmaceutical Patent Term (under Waxman-Hatch Act)



4. Typical US Pharmaceutical Patent Term Extension *(exclusion for 11 years [EC--bulk drug & dosage form--at least 16 years])*



* *market authorisation is assumed to occur in year 11 in both US & EC markets*
** *currently the US gives an average of 2 year's extension*
*** *ANDA - Abbreviated New Drug Application*

Source: Data for figures 1-4 derived from, *Piecing Together a Healthy Future*, June 1990 (produced by Touche Ross on behalf of the Association of the British Pharmaceutical Industry)

Once a product has been granted a certificate, other manufacturers should be allowed to experiment with that product, even when such experimentation has a commercial objective. In this way, non-proprietary manufacturers could be prepared to launch their products on the market immediately after expiration of the supplementary protection period.

Transitional arrangements

The transitional arrangements are retrospective.

The draft regulation proposes retrospective extensions of patent protection patented products which are already on the market and already accounted for in manufacturers' long range financial plans. The range of products available to non proprietary manufacturers will be radically reduced as a result. Such a major change in access to off-patent products will have a significant impact on enterprises operating on five or ten year plans designed around a particular profile of products becoming available over a pre-determined timeframe.

On this basis, the EGF would recommend if the regulation is introduced, that the proposed restoration certificate be applicable only to those medicines for which a patent has been granted after the date of implementation of this Regulation.

This recommendation would permit off-patent drug manufacturers to implement their current five year plans and honour any commitments made on the basis of these plans. Patented drug producers also operate on long-range plans which would not currently feature extended patent life on marketed products. No gap in the cycle of research financing should occur since current plans have been based on existing patent legislation.

While we welcome the Commission's indication that it is not prepared to accept Parliamentary amendments removing completely the cut-off date for eligibility for SPCs, the Forum is particularly concerned with the transitional arrangements in the proposed regulation which will restore patent protection to a product whose legal patent life expires after July 1992. This date has been developed in order to include those medicines authorised around the time of the introduction of the Waxman Hatch Act in the US in 1984. The fact that the Patent law in Japan was amended in 1988, is ignored.

If it is accepted, contrary to the above argument, that some form of transitional arrangement is necessary, then surely the implementation date of the Japanese legislation would provide a more balanced point from which to introduce the certificate. Products whose patents expire only after 1996 would then be eligible for a shortened certificate.

Impact

Only new medicinal products will be eligible for the proposed certificate. It is estimated that only 50 new products are authorised world-wide each year. If there were an average protection certificate duration of eight years, nearly 400 medicines could be delayed from non-proprietary production as a result of the introduction of this certificate. This will inevitably have an affect on the cost of medicines to the health services throughout the Community.

Membership of the European Generics Forum

Mr Juan a Pena Esteller	Afaquim, Spain
Mr Fritz Cancrinus	BOGIN BV, Netherlands
Dr Vittorio Bozzoli	FIS, Italy
Dr Georgio Guidolin	FIS, Italy
Dr Howard Rosenberg	Generics (UK) Limited, UK
Mr Tony Tabatznik	Generics (UK) Limited, UK
Dr Tom Cleary	Irish Pharmaceutical Manufacturers
Ms Katherine Lucey	Irish Pharmaceutical Manufacturers
drs Matean Niel	Magnafarma BV, Netherlands
drs Charles Gusdorf	BV Pharbita, Netherlands
Mr Rene Kappers	Pharmachemie BV, Netherlands
Legal adviser	
Mr Stephen Kon	S J Berwin and Co, UK
Secretariat	
Ms Anne Norris	Westminster Communications, UK
Mr Jonathan Roberts	Westminster Communications, UK

Supplementary Memorandum submitted by the European Generics Association (E37)

EC ACTIVITIES AFFECTING THE DEPARTMENT OF HEALTH

A. Supplementary Protection Certificate

1 *The transitional arrangements are retrospective*

The draft Regulation proposes retrospective extensions of patent protection on patented products which are already on the market. The base period agreed by the Common Position is 1985. Consequently, medicines on the UK market since this date will have an extra 5 years market exclusivity. Aside from the damage this will do to generic manufacturers, UK consumers will have to wait an extra 5 years before being able to buy more affordable medicines.

The date has been set in order to include those medicines authorised around the time of the introducton of the Waxman Hatch Act in the US in 1984. The fact that the Patent law in Japan was only amended in 1988, is ignored.

It is important to note that, as part of the Common Position agreed on 19 December 1991, a derogation on retroactive measures has been given to Germany, which allows retroactivity to start from 1988 on the German market. The derogation was given on the insistence of the German Government, who have expressed particular concern that the proposal will seriously damage generic medicines and cause great expense to health insurance companies and their members. In fact Germany had wanted the measures only to be back-dated to 1990, but settled for 1988 in order not to endanger being out-voted altogether in the Council. Generic medicines are frequently prescribed by German doctors. Despite the importance of generic medicines in the UK, no demand for 1988 was made by the UK Government.

2 *Cost and the Consumer*

The Commission's explanatory memorandum on the Proposed Regulation for SPC, states that there is a possibility of a price reduction for certain medicines as a result of the longer effective patent life. However, in reality, there is no incentive for a manufacturer to reduce medicine prices significantly before expiration of patent protection.

The EGA regrets that the draft Regulation was drawn up after little consultation of independent generic manufacturers or consumer organisations. BEUC, the European consumer's organisation, takes the view that the proposal does not reflect consumer concerns. BEUC calls for compensatory measures for generic products, fears that the SPC will lead to high prices for longer periods, and observes that the proposal " does not contain any measures which reinforce the competitive mechanism of the pharmaceutical market."

There is little scope for lower prices for consumers since the draft Regulation does not provide conterbalancing mechanisms to promote competition immediately a patent period has expired.

When the US Government introduced patent extensions of five years under the Waxman Hatch Act, it also offered generic manufacturers the opportunity to benefit from measures to stimulate competition on expiry of the patent. The Act does this by an accelerated authorization period for generic producers and by allowing new authorization dossiers to be prepared, submitted and assessed during the life of the patent.

In endeavouring to redress the balance between the European Community, the US and Japan, the EC proposal tips the scales too far the other way. EC proposals should be submitted which contain a clear commitment to introducing an accelerated authorization procedure for generic medicines.

3 *Period of Exclusivity*

The Commission's explanatory memorandum to the proposal states that the exclusive expoitation period of a patented pharmaceutical product is reduced to an estimated eight years as a result of authorization procedures and preventive controls. However, this is not the real picture.

Truly innovative drugs in practice get a much longer period of protection. The introduction of Council Directive 87/21/EEC of 22 December 1986 precludes authorizaton of non-proprietary medicines within 10 years of the authorization of the original proprietary. This ten year rule can be avoided only through the development of full pharmacological and toxicological test results and clinical trials which are beyond the scope or desire of most non-proprietary pharmaceutical drugs.

B. Price Transparency

The EGA has already submitted a written memorandum to the European Commission concerning the pricing of medicines for human use.

In the memorandum, the EGA proposes that the Commission considers in its proposals to the Council, a framework for establishing a policy of generic substitution for proprietary medical products after the expiry of the patent life of such products.

The EGA believes that Generic substitution is the key to major savings in the European pharmaceutical market which totals $35 billion and is growing. It is estimated that by the end of the century less than 10 per

cent of drugs patented will continue to have patent protection. All these will thus be open to generic competition if substitution is allowed.

The 1990s will be a period of rapidly escalating health costs aggravated by the growth in the proportion of elderly people in the industrialised countries. Governments and health insurers are desperately looking at ways to cut costs. During the lifespan of the patent, when the branded company has a monopoly, it nurtures relationships which tie doctors to the brand. Yet, ultimately, the biggest consumer of the drug industry is the State. (Attached is an extract from the EGA's memorandum to the European Commission which relates to the UK market).

February 1992

ANNEX: GENERIC SUBSTITUTION AND THE UK MARKET

UNITED KINGDOM

The largest unbranded generic market is the UK*which totals £150 million or 7 per cent of the total drug bill.

The UK also permits a form of substitution as a result of the hospitals and the "white list", which was introduced in 1985, positively encourages the use of generics by prohibiting certain categories of branded products and only reimbursing the generic version of those branded products. This list comprises a small number of products which the government insists must be prescribed generically by doctors, if the government is to pay for them. In other words, the "white list" is a form of forced substitution.

A further area of generic growth is the "open market" where doctors are encouraged, but are in no way required, to write the generic name. The result is that a few drugs have achieved a significant generic market share.

The table below shows the difference between what the UK government will reimburse to the pharmacist depending on whether he supplies the brand or the generic equivalent of the same drug. All of the generic products listed in the table represent more than 50 per cent of the branded market.

UK REIMBURSEMENT PRICES—BRANDED AND GENERICS

Selection of Major products

BRAND	GENERIC	BRAND PRICE	GENERIC PRICE	SAVING FROM GENERIC %
Penbritin	ampicillin	GBP 71.20	GBP 33.38	53
Lasix	frusemide	43.80	4.00	91
Normison	temazepam	49.34	24.12	51
Valium	diazepam	23.30	1.20	95
Imuran	azathioprine	65.61	28.50	57
Aldomet	methyldopa	59.40	34.15	43
Zyloric	allopurinol	20.30	2.52	88
Inderal	propranolol	2.70	.40 pence	85
Indocid	indomethacin	4.97	.80 pence	82

Clearly if substitution existed in the UK and free competition were allowed, the price difference between what the government would pay for a generic and a brand, and the consequent savings, will tend towards those shown in the table. Moreover, if substitution were allowed, the generic market would be far larger than only 7 per cent of the drug bill.

David Mellor, the former Minister in the Department of Health stated that £75 million per annum was saved by the "white list". He also stated that "tens of millions of pounds is mis-spent because of a refusal of some GP's to prescribe generically ... although generic prescribing has doubled in recent years there were still doctors who prescribed the branded product unnecessarily." (SCRIP 4/8/89) What David Mellor did not mention is that doctors have little incentive to prescribe generically, they often do not even know the generic name so that only if the pharmacist were allowed to substitute would the generic normally be dispensed. After ten or fifteen years of writing a brand name and being subjected to a barrage of marketing pressure to write a brand, it is unlikely that a doctor will suddenly switch to writing a generic name; few doctors know when

*In the European Community.

the patent has expired and many are not in the habit of remembering the generic or chemical name of the brand.

Memorandum submitted by Mr Wilfred Aspinall, Member of the European Communities Economic and Social Committee (E17)

PUBLIC HEALTH IN THE EUROPEAN COMMUNITY

I attach my views in respect of the new Title included in the so called "Non Paper" which is currently being considered by the Intergovernmental Conference.

I am more concerned by what is not included and which might be assumed to be included at a later stage.

At present "Public Health" is covered by a number of Directorates, although DG V has perhaps the best claim to coordinate health issues. There is however some inconsistency in the Commissions general objectives towards health which means that some issues are being undertaken without a proper strategic policy.

TITLE XIV—PUBLIC HEALTH

GENERAL COMMENTS:

The wording in the new Title is very bland and at face value presents no specific problems.

The incidence of movement of workers and the free movement of goods in an internal market will give rise for greater care in public health across the European Community.

Europe will need to adopt preventive measures and control will be necessary once customs barriers are open and European citizens have the means to travel, at will, throughout the EC.

The Title does not appear to interfere with the internal running of health care and merely refers to preventative actions, coordination and liaison between Member States to maintain and promote human health protection.

Specific Comments of the Articles

1. The European Community will need to create a budget line for health protection if it is to achieve the stated objective.

Equally by introducing these Articles Member States must fully acknowledge that "Public Health" is the responsibility of Member States and that action taken at European Community level can only be minimal.

There could be some Member States who will feel that once this Title has been included it falls upon the Community to undertake all health protection especially in areas of *disease* which transcend all Member States.

Where health promotion in some Member States is not so advanced this may become an area of concern. Funds set aside for Public Health protection must be adequate, however, they must be well managed.

The Title should not be used as an excuse to expand Community nor Commission competence nor to seek enhanced funding. The main thrust of public health protection should remain under the control and strategic planning of Member States.

2. Liaison and encouragement by the Commission of the activities of Member States would be a useful tool and may encourage more preventative health promotions.

3. Cooperation with third countries is essential to establish greater awareness towards public health.

4. It is essential that EC objectives are scrutinised by the European Parliament and the Economic and Social Committee.

National Parliaments should also be given the opportunity of receiving information and being able to scrutinise and comment where the objectives of the proposal will affect public health in Member States.

The Proposals which emerge from the Commission may not be Directives and therefore require no legislative action. A decision of the Council to allocate funds or a Communication urging Member States to undertake certain public health activity may have considerable impact on public health. These must be carefully examined.

5. This section refers to the provisions of Title X and as such it has a serious impact on Community R & D in medical research.

Title X expands the role of the Commission, Article 130n only requires the European Parliament and the Economic and Social Committee to provide an opinion on provisions referred to in Articles 130j to m.

This means that although scrutiny will be exercised over the presentation of the multi-annual framework programme the specific and detailed individual programmes will be under the control of the Commission.

Currently each specific programme is examined and scrutinised by both the EP and ESC. This must continue to be so.

There is a charge against the Community that insufficient funds are allocated to medical health research and it is true that better results may be gained if greater use of coordinated medical health research funding was examined in a Community spirit.

The need for demorcratic control must however be exercised especially when we are dealing with public health issues that affect ethical and moral standards.

Title X therefore needs amending.

CONCLUSION

In conclusion I would suggest that:

A. There is a need for greater public health prevention to be undertaken at a European level.

B. The role of the Commission should be restricted to:

— coordinating public health protection

— liaison between Member States on their programmes

— urging specific programmes that transcend Member State borders.

C. That funds allocated to medical health research should be reviewed to take into account this new title.

D. That funds should only be allocated for R & D including medical health research providing there is total democratic scrutiny by the European Parliament and the European Economic and Social Committee.

E. That Community programmes should be reported to the European Parliament, Economic and Social Committee and the Council (and thus Member States National Parliaments).

F. That a Directorate General of the Commission should be given the task of coordinating public health protection and coordination to cover *all* aspects of this Title.

July 1991

Supplementary Memorandum submitted by Mr Wilfred Aspinall (E20)

You asked for a reaction from the UK Members of the European Economic and Social Committee in respect of the new title XIV which is currently being considered as a part of the debate on political union.

The Section within the ESC responsible for this subject is the Environment, Public Health and Consumer Affairs Section. Those Members who have been able to agree a statement would have preferred to have been approached direct rather than through a third party. This would have saved considerable time.

There are 24 UK Members of the ESC all with equal status.

The creation of an internal market with the freedom of movement of goods and services, mobility of workers, especially in the professions, will require Member states to liaise with one another on preventative public health measures.

Currently a number of Commission Directorates have an indirect responsibility for "health" although the topic does not have direct community competence. This indirect responsibility does confuse issues and will need to be reviewed with a view to creating one specific Directorate for health issues.

It is not clear which DG would be able to claim total responsibility although DG V currently has responsibility for hygeine which is a part of some Member States public health inspectorates.

It should be noted that the new Title refers to "public health".

The competence of the Commission should not be expanded at a loss to the right of individual Member States to initiate their own policies and therefore the support for such a Title must be qualified.

No Community proposal should interfere with the management of health care in the Member States and should concentrate merely on preventative actions, coordination and liaison between Member States to maintain and promote human health protection.

Public health action at a Community level can therefore only be minimal, encourage control and strategic planning over health issues that transcend Member States borders.

By including such a Title in a new Treaty it should be understood that there is no hidden meaning and responsibility, it should be made clear in the Title exactly what the competence of the Commission is and what it can do.

Our contacts in the Commission lead us to believe that there is no clear understanding of a definition for "Public Health". Before this Title is agreed we should ensure that everybody has the same meaning.

Equally the Title should be explicit in its understanding for Member States to have the final responsibility for public health funding in their own countries.

Liaison and management of public health issues should be handled by the Commission to bring about a definition of standards within the Community as a whole.

All programmes and inititiatives should be scrutinised by the European Parliament and the European Economic and Social Committee and Reports of the Commissions activities should be sent to these bodies in addition to the Council.

In the original Title there was a reference to Title X (Research and Technological Development) this does not appear in the current text. The text of Title X does however create some concern since this excludes scrutiny by the European Parliament and the European Economic and Social Committee on certain specific R & D programmes. This is a drastic change from the current structure under which specific R & D programmes are considered.

Since public health issues could be included in any specific programmes under R & TD programmes we need to ensure that ethical and moral issues are kept under control.

This Title needs amendment.

CONCLUSION

1. Greater public health preventative action should be undertaken at a Community level.

2. The role of the Commission should be restricted to:
   - — coordinating public health protection
   - — liaison between Member States.
   - — encouragement of new techniques
   - — coordination of research and public health education.

3. That all Community action programmes should be controlled with ethical and moral issues being fully scrutinised.

4. That the EP and ESC should be required to give an Opinion on all Community actions in the field of public health.

5. That a specific Directorate General of the Commission should be allocated the task of coordination public health issues.

6. We would suggest that the Committee considered the text of the "Non Paper" as a whole to ensure that no other reference is made to public health.

The undermentioned are all Members of the Environment, Public Health and Consumer Affairs Section and would be delighted to provide any further information and opinions to the Committee.

The text of the new Treaty will change during the IGC debate and therefore it may be necessary to make update comments between now and December.

Wilfred Aspinall
Jocelyn Barrow
Neville Beale
Felix Kafka

July 1991

Supplementary Memorandum submitted by Mr Wilfred Aspinall (E39)

THE EUROPEAN COMMUNITY AND HEALTH POLICY

INTRODUCTION:

CHAPTER XV "PUBLIC HEALTH"

The objective set out in this Article relates to coordination and liaison; therefore, the main thrust of health requirements for the citizen of the European Union remain with Member States.

Point 4 of the Article does, however, give some flexibility adopting the procedure in Article 189b of consulting the Economic and Social Committee and the Committee of the Regions. This allows for measures to be introduced but excludes any harmonisation of the Rules and Regulations of a Member State.

The new Chapter is therefore very limited in its application and it will only be what the Commission takes as initiatives and the Council of Ministers agrees with.

Research and Development

Since my last communication with the Committee, Article 130I of the Treaty has been changed so that the Council acting by qualified majority shall adopt specific programmes under the Multi-Annual Framework Programme once it has consulted the European Parliament and the Economic and Social Committee.

In the original draft from both the Luxembourg and the Dutch Presidency the European Parliament and the Economic and Social Committee were not involved in this procedure.

This will have a material affect on any specific programme which is proposed effecting medical health research.

General Comments

It is important that within the Treaty on European Union there should be a public health chapter. Movement of goods and people could endanger citizens like possible diseases which must be contained and preventive measures taken.

Since my appointment to the Economic and Social Committee in 1986, I have endeavoured to press for greater attention to be taken on health issues at a Community level on the basis of subsidiarity.

At our Plenary Session on 29/30 January in the presence of the President in office of the Council of Ministers I pressed for two points to be considered.

1. That the commission should be urged to establish an individual Directorate General or at least a Health Policy Unit (perhaps on a similar basis as the Consumer Policy Unit) which would then provide an autonomous free thinking examination of health issues and at the same time be in a position to examine all Community proposals that may have a element of health provisions included in their text. This would involve liaison with various DGs.

Coordination obviously needs to be mounted between the individual Directorate Generals who have responsibility for harmonizing procedures in research and development.

2. The Community should establish an overall European Ethical Standards Committee which could come under the umbrella of a Health Policy Unit and thereby coordinate any ad hoc ethical committees that may be established.

As the Rapporteur for the ESC Opinion on Europe against Cancer and a member of the scrutiny group that analysed the Europe against AIDS proposal, I do believe that Community funding of these projects needs to be better managed.

It appears to me that communication with citizens and the use of funds provided for NGOs must be more professionally administered. Under the Europe against Cancer Programme it was brought to my attention that some of the organisations that were involved in the individual Member States to disseminate Community information did not have the adequate means to do so. The result was leaflets and other publicity material gathered dust.

I have included this statement simply because Community funds should be professionally managed and Public Health is a very serious issue.

HEALTH IN THE EC TREATIES

Evidence by Baroness Hooper

The following are some observations on the evidence provided by Baroness Hooper together with a statement made by the Department of Health.

Question 6 (Sir David Price)

I would refer you to my comments above. Public Health will have a very limited Community competence and I do not think it justifies a separate DG. However, a Public Health Unit would be appropriate.

I would just mention that the committee responsible in the European Parliament and the Economic and Social Committee come under the title of "Environment, Public Health and Consumer Affairs".

Both the European Parliament and the ESC have separate committees covering Social Affairs.

There is some inconsistency in the process of scrutiny if the Commissioner responsible for public health remains that for social affairs and the subject is covered by DG V. A separate policy unit would of course resolve this issue.

It might be worth the Committee noting at this stage that when a Commission proposal is drafted it is then circulated amongst all the Directorate Generals so that the various interests can be taken into account. A vital link in this liaison are the Cabinets of each individual Commissioner and often negotiations take place to ensure that no conflict of interest exists.

Question 19 (Mr Couchman)

I mentioned earlier in my comments that the programmes "Europe against AIDS" and "Europe against Cancer" had in my view only been reasonably successful. The Direction under which these two programmes had been developed with the limited resources at their disposal could not fulfil the objective of appealing to all the citizens within the European Community.

The programmes could only therefore be directed towards encouraging Member States to implement these programmes and in any case it is only they who have the means of communication with their citizens.

With regard to medical research I would argue that the funds available are inadequate at a Community level to digest the full implications to protect the interests of the citizen. Duplication of research projects needs to be fully examined as does ethical standards.

Since medical research comes under DG XIII I would argue that this presents a further and valued establishment of a Public Health Policy unit.

Question 20

I do not see any problems with research and development coming under the responsibility of a separate commissioner to that of public health provided there is adequate liaison.

Question 23 (Alice Mahon)

The funding of the European Year of the Elderly will undoubtedly be cosmetic simply by the amount of funds that will be made available and will be inadequate to provide for this important public relations exercise across 12 Member States.

Clearly we must have cost efficiency but at the same time if the funds are limited then so should the objectives.

Question 29 (Mr Rowe)

The use of the NGOs is of course important but the competent authorities in the Member States should advise the Commission whether they believe that NGOs do have the professionalism to undertake the work that is required.

Unless this recommendation is made and accountability afforded in respect of Community funds then it is clear to me that the influence that should be exerted will be negligible.

Question 32 (Mr Hinchliffe)

As the Chairman of the scrutiny group looking into the Community proposal relating to the advertising of tobacco products (I had previously been the Rapporteur for tar yield in cigarettes and Chairman of the labelling directive), it appears to me that there is a total inconsistency between the Commission's proposal and then subsidising tobacco in certain Member States.

I am totally convinced the current proposal on the advertising of tobacco products must be supported in its entirety.

The arguments presented by the tobacco industry that they are only persuading people to change brands have been totally disproved and the imaginative advertisements that currently are on display aim to attract the non smoker. The number of people who are ceasing to smoke voluntarily or involuntarily due to health reasons or death must be made up otherwise the tobacco industry will begin to make losses.

The argument that is presented that the advertising sector will suffer revenue must be upheld but at the same time given adequate notice of the withdrawal of these advertising revenues, agencies will be able to diversify elsewhere.

The same argument can also be put forward in respect of the sponsorship of sports and other activities by the tobacco industry.

We should not wish to see hardship for any sector and adequate time should be provided for diversification to take place but at the end of the day politicians must make a decision.

A total ban on advertising in all European Countries would protect the interest of the health of our citizens and not just those who smoke but also those who have to suffer "passive smoking" and therefore the potential reduction of tobacco consumption and the potential savings of health care will be important.

I do not believe that voluntary agreements between governments and the industry will be adhered to.

Question 55 (Alice Mahon)

It is quite clear to me that advertising of tobacco products is not the only reason why young people start smoking but it is certainly one. Peer pressure does have some effect.

Tobacco products should be sold at specific outlets and certainly an Act of Parliament to make it illegal for sales to be made to under 16s will have some effect.

The point is of course we must also be looking at those who are over the age of 16.

Question 57 (Chairman)

I cannot say that I am an expert in the growth of tobacco but I doubt whether there will be any question of any economic benefit from the production of tobacco in the UK. As I understand the tobacco plant requires a certain type of soil.

Question 61

There is a constant argument in the Tobacco industry that cigarettes are not illegal and a product that is not illegal can be advertised.

Surely the point here is that the European Community can introduce a new law in the same way that the House of Commons can introduce new legislation which repeals previous laws.

The present advertising of tobacco products does not make smoking illegal but it does prevent the advertising of tobacco products except in specified sales outlets and thus endeavours to protect people from the influence of smoking.

The current imaginative advertising methods which often have nothing to do with the product itself, but advertise on the basis of using attractive looking people, athletes, sports activity even misleading innuendo is there to attract the attention of the citizen to that advert.

It might be said that the Government health warning is the only reference to the question of smoking and that is now used to the advantage of the tobacco industry.

Question 66 (Audrey Wise)

A scrutiny study group which I am a member is currently looking at a Directive which consolidates previous Directives on the implementation of mutual recognition of doctors qualifications.

In our opinion it is likely that we shall mention two points which we consider to be important. The first will be regarding language where we feel that adaption tests should be taken, the second is in respect of knowledge of the social security system that exist in the Member State where the doctor is to work.

It is stated in the evidence that the number of doctors who are moving around Member States are few but this may increase as we get a new generation of qualified doctors especially bearing in mind the NHS has many qualities for teaching doctors that other Member States cannot boast.

With regard to the general directive on mutual recognition of diplomas covering the three year qualification course which was to be implemented on 1 January 1991 I would suggest that the Committee takes some information regarding the actual implementation of this Directive since it is only in the latter months of 1991 that some Member States actually nominated their competent authorities to carry out this exercise.

In respect of the supplementary Directive which covers the two year courses or two years experience in the profession concerned this has not yet been adopted.

As a past member of Health Authorities in the UK I would confirm the statement by Dr Metters regarding the appointment not only of consultants but also levels of registrars and senior registrars.

Finding myself as the sole lay person acting as Chairman of the Appointments Panel I would rely very much on the outside assessor to indicate whether or whether not the individual was capable of undertaking the function.

Question 75

There is some concern that some Member States will recognise qualifications from some of their past colonial interests and thereby provide entry for certain professions into the community. Under the provisions of mutual recognition of diplomas this could happen.

Question 91 (Sir David Price)

I support the Community proposal for an extension in the patent of medicinal products which will bring us into line with the protection which is accorded to the inventor in the USA and Japan.

The cost of research and development in medicinal products is enormous and from the time that this patent is made until potential payback is accorded is minimal unless this new provision is adopted.

In respect of the problems of over the counter sales of medicinal products this I would like to see changed and a common practice apply across the Community. We need to adopt the UK practice. The current monopoly of the pharmacist is extensive in some Member States and it will take some time for this to be broken. It is my view that the Community should endeavour to do this.

February 1992

Memorandum submitted by the British Medical Association (E32)

EVIDENCE GIVEN BY BARONESS HOOPER TO THE HEALTH COMMITTEE, 15 JANUARY 1992

1. The BMA and Europe

Via its long-established European Communities Committee, which includes members and observers from other organisations, the Association monitors any developments within the Communities which are likely to affect health in general, or the practice of medicine in particular. Since 1989 the secretariat has produced a monthly bulletin, "EURO brief", which is circulated to BMA staff, elected members, subscribers and also to the Clerk of the Health Committee. This will be expanded during 1992. As the only medical body in the UK which represents the whole profession, the Association is represented on a number of non-statutory organisations seeking to support the interests of the medical profession and the highest standards of health care within the Community. Delegations attend meetings of the European Union of General Practitioners, the European Union of Medical Specialists, the Permanent Working Group of European Junior Hospital Doctors and the Standing Committee of Doctors of the EC. The Standing Committee is the umbrella organisation which acts as the "voice" of doctors in the EC. The other organisations work through it in order to ensure co-ordinated action.

2. General Comments

We welcome the inclusion of public health in the Maastricht Agreement, which at last provides a firm legal basis for European Community health initiatives, in particular the funding of bench work research. We fully support the view that the Community should act only in areas where collaboration among member states will be of greater benefit than action by single states and that duplication of the work of other bodies, such as the World Health Organisation, should be avoided. We note with satisfaction that the funding and administration of health care systems continues to be a matter for individual member states, but also that the Department of Health is to be strengthened, with greater emphasis on European Community work.

3. Need for a Health Directorate/Directorate-General within the Commission

As the Health Committee is already aware, many branches of the Commission are involved in work related to health. Much concern has been expressed in the past over the apparent lack of communication and co-ordination amongst them. The establishment of a separate Directorate-General does not seem to be a realistic goal at present, but the BMA Council has recently resolved that there should be one focus within the Commission which would be responsible for co-ordinating health-related activities for which executive responsibility is taken by various Directorates-General.

We note that Mr Heppell, Deputy Secretary, NHS Policy Board, referred in his evidence to the Committee to strengthening of the Commission's staff to cope with the additional workload anticipated. We have long been concerned about the lack of support and resources available for much health-related work. One obvious example is that of the Commission's own Advisory Committee on Medical Training, which has been severely hampered in its work in recent years because of underfunding and understaffing. We believe that the Department of Health shares our concern and we hope that the situation will now improve.

4. EC Action Programmes

We do not wish to comment in detail on the action programmes and forthcoming initiatives referred to in the Health Department's evidence to the Committee. We hope that these programmes will receive widespread and constructive UK support. One point to be made, however, is that greater efforts are needed to inform practising doctors in the UK of, and involve them in, initiatives such as the Europe against Cancer programme. The BMA has recently produced a video "Helping Harry", aimed at helping general practitioners to counsel patients with cancer, which was co-sponsored by the above programme, and we are aware of other valuable activities sponsored by the Commission. However, in 1989, which was designated "European Cancer Information Year", we received a number of complaints that publicity material intended for general practitioners was not distributed by the Health Education Authority. Anecdotal evidence indicated that thousands of leaflets and posters were printed and not distributed.

5. Tobacco Advertising

The Association's support for the proposed EC directive on tobacco advertising is well known. We were encouraged to hear from Baroness Hooper that the Department of Health is still considering its position on this issue in the light of all the circumstances. Evidence from Canada and New Zealand supports the view that a ban on tobacco advertising would lead to a reduction in tobacco consumption and in the prevalence of smoking.

Our priority, and that of the Department, is to discourage children from taking up smoking. Advertising reaches everyone, not just adults. Baroness Hooper wonders whether some of the more cryptic cigarette advertisements are appealing to children. Recent research by the Advertising Research Unit at the University of Strathclyde demonstrates that children are **particularly** responsive to these advertisements.

As regards the legal basis of the proposed directive, members of the Committee will have received a copy of a legal opinion on this matter prepared for the BMA.

Baroness Hooper stated that there are five countries in the European Community opposing the ban. More recently, Denmark has altered its position and is now supporting the ban. Greece's position fluctuates. We hope that the UK will consider the evidence and support a ban as a means of achieving the smoking targets set out in the "Health of the Nation" Green Paper.

We should welcome any figures from the Department of Health on the cost of smoking to the National Health Service.

6. Medical Training: Mutual Recognition of Qualifications

6.1 *Background*

The two "Doctors' Directives", which provide for the mutual recognition of medical qualifications, were adopted in 1975. Doctors who are citizens of EC member states, and who have completed their **basic** medical training in EC member states, are eligible for registration in other member states. There is also provision for the mutual recognition of specialist training, and a 1986 directive covers specific training for general practice. The 1975 directives have been updated at intervals to include new specialities and new member states, but have not been changed in substance. The Commission is now working on a draft "consolidating" directive, incorporating all legislation relating to the medical profession into one document.

The 1975 legislation lays down minimum requirements for both basic and specialist training, but we believe, as do others, that these need to be extended.

6.2 *Basic Training*

As regards basic training, a particular problem in some countries seems to be the lack of practical experience gained by undergraduates. Evidence is largely anecdotal, but the problem seems marked particularly in Germany, where the undergraduate course is largely theoretical. Both our Medical Students Group Committee and our Medical Academic Staff Committee have noted the increasing number of German medical students seeking to undertake elective periods in this country, some staying for several months and moving from medical school to medical school. The volume of letters of enquiry we receive from these students bears this out and leaves little doubt that they are attracted by the high standard of training in the UK. There is now some concern that this large intake will overburden the system, placing UK students at a disadvantage.

The problems of young Spanish doctors have also been drawn to the attention of the Association recently. As Spain does not require the equivalent of the pre-registration "house officer" year, many Spanish doctors come to the UK, fully qualified and entitled in law to full registration with the General Medical Council. They then apply for "senior house officer" posts, for which they are often very ill-prepared as far as practical skills are concerned. A growing number are now seeking junior house officer posts, although they are fully registered, in order to make good the shortfall in their practical experience.

6.3 *Specialist Training*

Baroness Hooper and Dr Metters in their evidence referred to the different status of the "specialist" in many EC member states. This is a complicated area; in many states patients have direct access to specialists in "liberal" practice and such specialists cannot easily be compared with consultants in the NHS. EC legislation lays down minimum training periods for particular specialities, most of which are considerably shorter than those which apply in the UK. Training is divided into general professional training and higher training only in the UK and the Irish Republic and many believe that there are discrepancies in standards throughout the EC.

It is correct that appointments to consultant posts in the NHS are made on merit. However, it would not be acceptable to reject an EC specialist on the grounds of inadequate training; if another member state recognises someone as fully qualified, the UK must do likewise. There was a case recently in which a French specialist was turned down, on the advice of the relevant Royal College, for a post for which she was the sole candidate and for which she had been encouraged to apply. We understand that the case is now with the European Court and are concerned that those who serve on appointments committees are not always fully conversant with EC law.

EC specialists may of course establish themselves in private practice in the UK, but risk having difficulty in being reimbursed by provident associations such as BUPA and PPP, whose criteria seem effectively to exclude them and which therefore require some legal examination. Legal difficulties may also arise now that the Medical Register is to acknowledge the completion of higher training with a "T", which will be awarded on the advice of the relevant Royal Colleges. Although the GMC maintains a seperate register of EC specialists, those who are not deemed to qualify for a "T" may believe that they have been discriminated against and

choose to take legal action. The Association has already discussed this matter with officials of the Medical Manpower and Education Division of the Department of Health.

The Commission's Advisory Committee on Medical Training (see section 3) is currently re-examining basic training and has just established a working group to re-examine specialist training and the need for current legislation to be extended. In view of all the problems mentioned, it is vital that full support is given to the work of the ACMT, which includes, from each member state, representatives of the practising profession, university medical faculties and registering authorities. The European Union of Medical Specialists, of which the BMA is a member, is also very concerned with specialist training. It is in the process of establishing "European Boards" to examine training requirements for the various specialities and hopes to work closely with the ACMT. This initiative seems to be broadly supported by medical bodies in the UK, such as the Royal Colleges, although there are a number of details which have yet to be clarified.

6.4 *Medical Migration*

To comment briefly on migration statistics, it is obvious from available statistics that the UK imports far more doctors than it exports within the EC. Some probable reasons for this are as follows:

- The reputation of postgraduate training in this country;
- The high level of medical unemployment in countries such as Italy, Germany and Spain;
- The language barriers which tend to affect British doctors to a greater extent than their European counterparts.

7. "Third Country" Qualifications

The Association is well aware of the position of doctors, such as those from the Indian sub-continent, who are British citizens and have practised medicine in this country for many years, but who obtained their primary medical diplomas outside the EC. We have been discussing the problems with the Overseas Doctors' Association.

Doctors in this position are not covered by the 1975 "Doctors' Directives", ie they have no automatic right to registration in other EC member states. Their cases will be considered on an individual basis; there is nothing to prevent any member state from accepting them. We understand from colleagues who were involved in discussions some years ago that there was at the outset an understanding that their applications would be treated sympathetically, and we have not yet been asked to consider any cases of discrimination. The Overseas Doctors' Association has some evidence of unsuccessful applications, which is largely anecdotal, and we hope that they will be able to help us with further details.

This is obviously an issue of principle, raised at a time when many ethnic minority groups are concerned at the development of what they perceive as a "Fortress Europe". We understand that the European Commission is now looking at possible solutions. A 1989 directive (89/48/EEC), which established a general system for the mutual recognition of professional qualifications gained after three years' study, but which does not apply to professions with their own legislation, may provide a model. It provides for professionals who are citizens of a member state, and who have been registered and in practice there for a minimum of three years, to be eligible for registration in other member states.

Any agreement would of course have to be reciprocal. We have already mentioned that many EC countries have large numbers of unemployed doctors, and further extension of rights of establishment could potentially have a considerable impact on medical manpower planning in this country. Problems with standards of training must also be resolved if rights are to be extended.

8. Medicinal Products

As a general comment, the Association fully supports the efforts of the Health Department to ensure that products placed on the market in this country are safe and of high quality and efficacy and that equally high standards apply in other countries where UK citizens may choose to live and work. We are co-hosting a seminar with the Association of the British Pharmaceutical Industry in March, at which we hope to examine in detail the possibilities for a European Medicines Evaluation Agency.

The Association, in common with counterparts throughout the EC, was recently very concerned about the proposal for a directive on the advertising of medicinal products, which it was feared would prohibit or restrict pharmaceutical sponsorship of postgraduate medical education. Happily, the problem now seems to have been satisfactorily resolved as a result of amendments to the directive.

9. Organisation of Working Time

The proposed directive on the organisation of working time is clearly relevant to the Association's continuing efforts, with the Department of Health, to establish effective working patterns and reduced hours of work for junior doctors. However, this does not preclude an awareness of the major practical difficulties which this legislation would create, for NHS hospitals in particular, if adopted. A maximum working week of 48 hours and a maximum working day of 12 hours, both of which have been under discussion, would make it extremely difficult to provide continuous care. We also question the apparent assumption that night work

is injurious to health. We understand that the Department of Employment has attempted a preliminary analysis of the cost to hospitals of implementation and found these to be very high.

February 1992

Memorandum submitted by the Association of the British Pharmaceutical Industry (E33)

The Association of the British Pharmaceutical Industry represents 110 pharmaceutical companies with establishments in the United Kingdom. Its membership accounts for over 95 per cent of home sales to the National Health Service (£2.9 billion) and over 90 per cent of export sales (£2.2 billion in 1990) of prescription only medicines. Its membership also accounts for over 85 per cent of sales of generic prescription medicines and vaccines to the National Health Service.

In this interim memorandum the ABPI will deal in specific terms with just one matter that was included in Health Minister Baroness Hooper's evidence to the Committee on 15 January. That is her remarks relating to the EC Council of Ministers' agreed policy decision taken on 19 December 1991 with regard to patent term restoration for medicinal products.

The Committee will be aware of the conclusions that were reached with regard to the European Commission's proposed regulation. The one aspect that remains to be resolved is the position that will be taken by the individual member states over the transitional arrangements.

As was pointed out to the Committee, the agreement reached by the Council of Ministers on 19 December, allows individual member states to select a date between 1 January 1982 and 1 January 1988 that will determine which existing products will qualify for the new Supplementary Protection Certificate (SPC).

Our information indicates that Italy, France, Denmark, Holland, Belgium and Luxembourg will all select *1 January 1982* as the date from which products introduced since that date and still in patent by 1 January 1993 will qualify for the restored five years of patent life conferred by the proposed SPC.

This Association welcomes the commitment given to the Committee by Baroness Hooper that the British Government *"will seek to get the best possible transitional arrangements for the UK"* (para 87 in the Minutes of Evidence 15 January 1992).

This can only mean that the UK Government has decided to join the majority of other member states within the EC who intend to nominate *1 January 1982* as the "start-up" date for the restored patent protection.

The Association believes this outcome will encourage the research-based pharmaceutical companies in the UK to invest even greater human and financial resources in the search for and development of treatments and cures for the many diseases that remain to be conquered or more adequately treated. Furthermore it will be of benefit to the European Community Economy as a whole in that it will assist European-based pharmaceutical companies to remain internationally competitive with their counterparts in Japan and the United States—which was, of course, the original purpose of the European Commission's initiative on this issue.

It will go some way towards overcoming the pharmaceutical industry's disappointment that the UK Government sought to reduce the original SPC provision from 10 years to five years. It was the UK Government's stance on this issue that was, in part, responsible for the Council of Ministers agreeing to only a five-year SPC provision.

It is this Association's view that the interests of patients suffering from degenerative conditions like Alzheimer's disease, Parkinson's disease, motor neurone disease, and multiple sclerosis would have been better served by the original 10-year provision. The revised arrangement will discriminate against products that for good reasons take longer to test and evaluate—the very ones that should be given every possible encouragement.

For example if the average development time for products in these therapeutic areas was to cover 15 years, the ensuing effective patent life—under the revised draft regulation—would be only 10 years compared with 15 for most other products.

The original 10-year SPC provision would have been far more equitable in that it would have conferred a "norm" of 15 years' effective patent life on most products irrespective of the time it took to test and evaluate them.

It was this point that was made cogently by the recent Report from the House of Lords Select Committee on the European Communities that urged the UK Government to give its full support to the EC's original proposal.[1]

The Report said: "Cures for these diseases, which cause much human suffering, will only be found by large-scale investment and complex research. The available term of patent protection should be such as to guarantee a fair return on this investment.

The potential benefits to society of finding cures for these diseases are such that in our opinion they outweigh the danger—so far as it exists at all—of some increased cost to consumers for the drugs which are produced."

We hope, therefore, the Select Committee will keep this matter under continual review and will, at the same time, urge the European Commission to review the effect of reducing the SPC provision from ten to five years

at the earliest date—and certainly not later than five years after the implementation of the new regulation once it comes into effect.

This interim memorandum of evidence has been submitted at the earliest possible date because of the urgency required to acknowledge and endorse the wisdom of the UK Government's commitment on the transitional arrangements.

In a subsequent memorandum of evidence the Association will address other issues raised in Baroness Hooper's evidence to the Committee with particular reference to the future arrangements for the licensing of new medicines in the Community.*

[1] 1st Report Session 1991–92. House of Lords Select Committee on the European Communities. "Patent Protection for Medicinal Products". HMSO.

February 1992

Memorandum submitted by Action on Smoking and Health (E36)

SUMMARY

ASH recognises the importance of the European Community in matters concerning health and the potential significance therefore of the extension of Community competence to matters of public health policy, albeit this will under the Maastricht agreement extend only to making recommendations, not to approving Directives. We believe that if this extension is to be productive a Commissioner and Director-General for public health policy will need to be appointed.

Our evidence takes note of the several Community measures bearing on tobacco. In particular, we draw attention to the desirability of the tax regime requiring our partners to set higher rates of specific (flat-rate) duty, so as to raise the prices of some very cheap brands and reduce the risk of large volumes of cheap personal imports under the Single Market.

ASH draws attention also to the inadequacy of the present labelling directive (on health warnings etc), which appears to set maximum as well as minimum standards of health protection and is having unfortunate consequences even in countries who are candidates to join the Community.

ASH notes the lack of adequate EC action on smoking in workplaces and in indoor public places, and comments briefly on the tobacco regime under the CAP, where subsidies need to be abolished totally, albeit by stages over a short period.

Turning to tobacco advertising, we outline the case for a ban, based on the unique dangers of smoking, the link between advertising and children's smoking, and the fact that bans elsewhere have reduced levels of smoking.

In the remainder of our evidence we comment in detail on points arising from Baroness Hooper's evidence, including:

— lessons to be drawn from experience abroad (New Zealand, Canada, Italy, Portugal)
— the inadequacy of "voluntary agreements" on advertising
— Denmark's decision to support a ban
— the fact that sports sponsorship is advertising, and that its loss would not be serious for sport, amounting as it does to only 3 per cent of total commercial sponsorship
— the vulnerability of children to cigarette advertising
— the nonsense of the tobacco industry's claim that the sole function of advertising is to promote brand-switching.
— controls on sales to under-16s
— the legal basis of the draft Directive.

We attach to our evidence a copy of the ASH brief on the debate about tobacco advertising, which enlarges on and sets in context the points arising from Baroness Hooper's evidence.

THE EUROPEAN COMMUNITY AND HEALTH POLICY

1. ASH is grateful for the invitation to submit evidence to the Committee. What we have to say falls into two parts:

I: comments on the impact of the European Community on health policy generally and tobacco control in particular;

II: comments related directly to the evidence given by Baroness Hooper on behalf of the Department of Health as regards the proposal for a ban on tobacco advertising.

*As a supplementary memorandum, the ABPI referred the Committee to a memorandum submitted to a House of Lords Committee. See Third Report from the House of Lords Select Committee on the European Communities, Session 1991–92. HL (1991–92)12, pp 67–75.

I: The EC and Health Policy

2. ASH has no policy on questions relating to the UK's membership of the European Community and the extent of its competence, but we recognise its growing importance as the providing the context for the government of the UK. It is therefore inevitable that health policy is affected by European Community considerations, and we have accordingly noted with interest that at the Maastricht summit it was agreed to extend the direct competence of the Community into matters of public health policy, albeit on a non-mandatory basis.

3. Hitherto, health has been brought in on the basis of other remits of the Community, principally trade and competition. This has made for difficulties in attaining health objectives. Nevertheless, ASH has welcomed those EC Directives on tobacco policy that have had clearly beneficial effects for health and the use that has been made of the provision under Article 100(A)(3) of the Treaty that measures of harmonisation in preparation for the single market should be based on a "high level of health protection". It will be much preferable to see initiatives taken explicity for reasons for public health.

4. We note that the new competence will extend only as far as making recommendations and not to the introduction of Directives, but that both qualified majority voting in the Council of Ministers and the new procedures for co-decision making, which give slightly increased powers to the European Parliament, will apply in the field of public health. The Parliament has been consistently more in touch with public opinion and ahead of the Council of Ministers in matters concerning tobacco; and the application of majority voting will help to overcome the obvious reluctance of some governments to take action on smoking.

5. There are strong arguments, given the extended competence, for the appointment of a Commissioner or a Director-General for Health, but indications from the Commission are that no such appointments are planned. Without them, health will continue to be an orphan area of policy pursued by the existing officials only in the absence of competing priorities closer to their central remits. The Select Committee may wish to consider recommending that the UK Government takes a more constructive stand on this organisational issue.

6. The EC's primary intervention in matters concerning tobacco is in the tobacco regime of the Common Agricultural Policy. In addition, however, it has adopted a number of Directives aimed at controlling the use of tobacco. These include:—

(a) Council Directive 79/32/EEC on taxation, which has been extended indefinately, although on the face of the Directive it is time-expired;

(b) Council Directive 89/552/EEC on television broadcasting, which included a ban on TV advertising of any tobacco products and came into effect last October;

(c) Council Directive 89/622/EEC on labelling, which was amended and extended by the Council of Health at their meeting in November 1991;

(d) Council Directive 90/239/EEC on maximum tar yields;

(e) Council Directive 89/654/EEC on workplace safety and health requirements ("protection of non-smokers from discomfort caused by tobacco smoke" in restrooms).

In addition, there was a Mixed Resolution (89/C 189/01) on smoking in public places, adopted on 18 July 1989, and a Decision of the Council (90/238/Euratom, ECSC,EEC) to support a five-year action plan under the Europe against Cancer programme.

7. Each of the Directives represented some advance when it was adopted, but none is satisfactory as it stands. this is not the place to go into detail, but some comments may be useful on tax, on labelling and on smoke-free air.

8. **Tax:** It is by now well recognised that price is the most important short-term determinant of tobacco consumption. The graph of consumption is a mirror image of the graph of real price: raising the tax on tobacco produces an immediate fall in demand, the price elasticity being of the order of -0.5. The UK Government has recognised this relationship for many years, and the use of tax to pursue the public health policy of reducing smoking has become established. With the coming of the single market, the lower prices of cigarettes in most Community countries (only Denmark has higher prices than the UK) will become a matter of concern.

9. The structure of tax in the UK is:

(a) a specific excise duty—currently £40.15 per 1000 cigarettes

(b) an *ad valorem* excise duty—currently 21 per cent of the total price (including all taxes)

(c) VAT—currently 17½ per cent.

10. Community law (see para. 5(a) above) requires that specific duty must be no less than 5 per cent and no more than 55 per cent of the total tax burden on cigarettes "in the most popular price caregory". A recent agreement by ECOFIN (see Hansard, written answers col. 423, 25 June 1991) sets the minimum value of the

specific and *ad valorem* duties together at 57 per cent of the retail price including tax of the "most popular price category" of cigarettes.

11. In the UK, the specific duty is close to the upper limit. In many other Community countries the specific element is much lower. As a result, tax there is much more strongly proportionate to the manufacturer's price. Consequently low-price cigarettes carry a much lower tax burden and are very cheap by UK standards, the price differential between the top and the bottom ends of the market being exaggerated by the price structure.

12. This may be illustrated as follows: supposing that a manufacturer offers two brands, one at 50p per pack (just below the current UK price of leading brands), assumed to be the "most popular price category", and one at 15p. With VAT at 17.5 per cent, the extreme tax regimes permissible under EC law are as follows:

pence	M'fers price	Specific duty	Ad valorem	VAT	Retail price
Specific duty at 55 per cent:					
	50	70	31	27	178
	15	70	22	19	126
Specific duty at 5 per cent:					
	50	6	96	27	179
	15	6	36	10	67

13. With the minimum specific duty, the "spread" of prices is much greater, with the lower price little more than one-third of the higher, while with the maximum specific duty the lower price is over two-thirds of the higher. In real life, prices in the UK and Denmark are in fact higher than the high range prices quoted here, while prices of the cheapest cigarettes in some EC countries are in fact much lower than the low prices quoted.

14. Clearly, given the price sensitivity of the market, the tendency under a tax regime where the specific duty is low will be for taxation to drive smokers towards the cheap end of the market, which allows them to continue smoking as much as before at the same price, while at the extremes providing them with tobacco with higher tar and nicotine contents.

15. It is the low levels of specific duty in most EC countries that are of concern to those who wish to combat the damage smoking does to health. With the single market and the possibility of personal imports of almost unlimited size as long as they are for personal and family use, the risk is that large quantities of cheap cigarettes will be imported so that the health effect of tax increases in the UK is progressively blunted.

16. The UK Government, we are pleased to note, is firmly seized of this risk and is of the same view as ourselves: that our partners need to be urged to raise the specific element of the taxation, i.e., the flat-rate element that is not variable with the manufacturer's price, and to incorporate the changes in amendments of the relevant Directives.

17. **Labelling:** "Labelling" in this context refers to the printing of health warnings and nicotine and tar contents on packets. Until 1992, the health warnings on packets in the UK appeared under the terms of so-called "voluntary agreements" between the Department of Health and the industry (as is still the case with warnings on advertisements).

18. The UK Government are to be congratulated on their implementation of the Directive on three counts: their choice of the strongest warnings; their dropping of the attribution to the Chief Medical Officers, and their increase of the area on each relevant face of the packet used by the warnings from the 4 per cent minimum to 6 per cent.

19. Regrettably the tobacco industry is determined to resist and frustrate measures to improve public health by cutting down smoking. They are reliably reported to be planning to print their own attribution (to the EC Directive itself) in an attempt to detract from the force of the warnings. They have, moreover, already launched a legal challenge to the Government's decision to go beyond the minimum area. This will be decided in due course by the European Court of Justice (ECJ).

20. The Directive under which these warnings are required is currently being amended so as to extend to tobacco products other than cigarettes a requirement for similar warnings and (more importantly) to outlaw the sale of oral moist snuff (such as Skoal Bandits) in all countries of the EC. This prohibition is a very welcome measure and one for which the UK Government may again take a large measure of credit: the need for it is yet another illustration of the tobacco industry's complete want of regard for health of their customers—who in the case of Skoal Bandits would have been predominantly young.

21. ASH nevertheless has serious criticisms of the Directive as it stands:

(a) It is not clearly drafted, as witness the ambiguity which has permitted the industry to launch the legal case referred to above;

(b) It appears to set maximum as well as minimum standards of health protection, outlawing attempts to impose other rules about packaging—although a favourable decision by the ECJ in the case reffered to above may open the possibility of a less restrictive interpretation.

22. For the present, the wording of the Directive has most unfortunate consequences:

(a) It has permitted the tobacco industry to mount their legal challenge to the UK (and Italian) Governments' implementation of the health warnings.

(b) It has made it impossible for member states to take further measures on their own account, such as designating the position of the warnings on the packets or requiring them to be printed on a plain panel contrasting with the main packet. (Panels of smokers convened on behalf of the Health Education Authority indicated that they wanted warnings to be starkly worded, large, and prominently positioned.)

(c) It is deterring outside the EC who are candidates for membership, from implementing labelling regulations superior to the EC's. For example, the Swedish government decided in December precisely on this basis to nullify a decision on health warnings made by the Swedish National Board for Health and Welfare the previous January. It had been hoped that the entry of Sweden, with the new warnings, to the Community might become the occasion for a strengthening of the labelling regulations.

23. **Workplaces, public places:** ASH regrets that more has not been done either domestically by the UK Government or at a European level on protection of the public or of people at work from passive smoking. The Directive on workplaces protects non-smokers only in restrooms. It therefore falls behind current good practice in the UK and yet will not come into effect before 1994 in existing workplaces. There is a need for legal protection from passive smoking for employees in the workplace, who usually have no freedom of movement while at work to get away from smoke.

24. The resolution on public places resulted from a failure to agree a directive to guarantee smoke-free air in indoor places frequented by the public. In the UK it has produced only the Code of Practice published by the Department of the Environment last December. This is excellent as a code of practice—but effective action will be achieved only when the law is used to require action by proprietors and managers of such places—banks, shops, cinemas, etc. This is the lesson from other countries, e.g. many states in the USA, Belgium and Ireland.

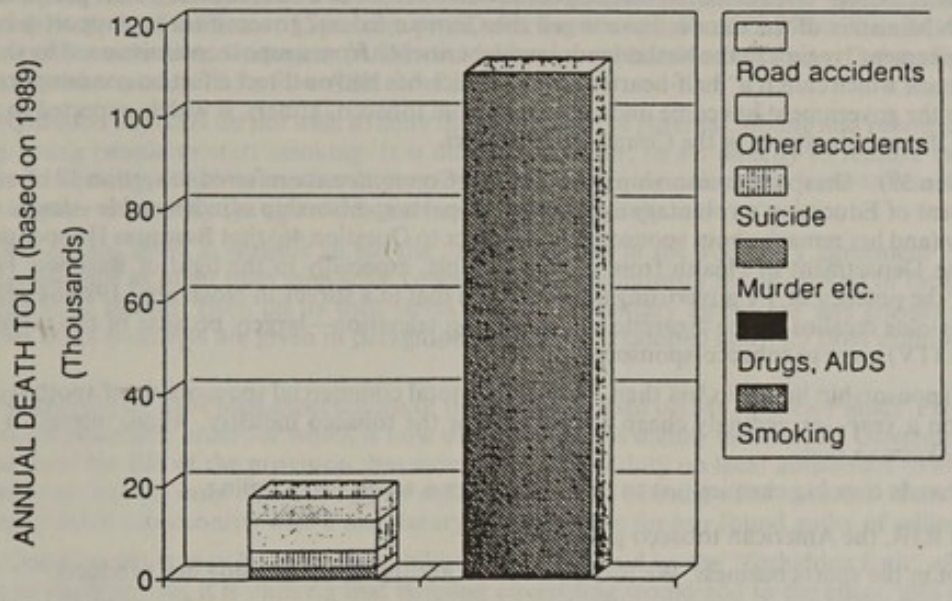
25. **The CAP tobacco regime:** Little needs to be said about the scandal of £900 million a year (and rising) being spent on promoting the growth of largely unsaleable high-tar tobacco by Community farmers: the present situation has few if any defenders in the UK. It has rightly been said that under the CAP it is not tobacco but tobacco subsidies that are farmed—and in this branch of farming it is the Italians that are the past masters. Varieties of tobacco for which there is no market whatever are produced in huge quantities entirely as a result of the EC's support of prices through subsidies to the processors. These middle-men take EC cash both to enable them to buy at artificial prices from the growers and to enable them to subsidise the sale of unwanted tobacco at market prices that are often close to nil. If spending were diverted to direct support of the farmers concerned plus research to find alternative, socially useful crops, a great deal would be achieved for the health not only of many EC citizens but also of countless others in the third world and central Europe where EC tobacco is dumped at give-away prices.

26. The UK Government has long and honourable record of opposition to subsidies for tobacco, but it may be that they do not appreciate the full complexities of the regime (on which see *British Journal of Addiction*, (1991) 86, 1191–1202) and the Hydra-headed nature of the beast. All attempts hitherto to set quotas and reduce subsidies have failed unequivocally. Nothing less than an unqualified decision to cut the subsidy to zero over a strictly determined period will be satisfactory.

II: Tobacco Advertising

27. The matter currently highest on the EC agenda in relation to tobacco is the proposal from the Commission to ban all forms of advertising. This has majority support in the Council of Ministers but is just short of the number of votes needed to approve it. The UK is in the pivotal position in the vote.

28. Support for the proposed ban extends to the whole health community—all NHS regions, all the medical Royal Colleges, every medical body and charity in the least concerned—and to nearly three-quarters of the general public. There is no difference between supporters of the three main parties in the strength of their support for a ban. Smoking causes enormously more avoidable deaths than any other cause, as the following graph vividly illustrates:



29. The case for an advertising ban is based on

(a) the unique dangers of smoking (one in four smokers is killed by a smoking-related disease; tobacco has no safe level of use: it kills when used as the manufacturers intend; yet damage to health is slow and cumulative and is therefore often discounted);

(b) the fact that cigarette advertising is demonstrably implicated in children's smoking (for example, child smokers buy the most heavily advertised brands, unlike adults, and by the age of 15, prevalence of smoking is already 25 per cent, compared with adult levels of 30 per cent); and

(c) the fact that bans implemented elsewhere have resulted in significantly reduced levels of smoking and of recruitment to smoking among young people.

We attach a copy of ASH's full arguments in favour of the ban but comment below on some of the points raised in Baroness Hooper's evidence. We include references to the numbers of the relevant questions.

30. (Question 32) ASH considers that the onus of proof should be on the tobacco industry to prove the harmlessness of their advertising, contrary both to intuition and to a large volume of evidence. However, ASH is naturally glad that the Chief Economic Adviser to the Department of Health has now advised Ministers that evidence from Norway and New Zealand shows that bans on advertising have a significant effect in reducing smoking. We welcome the Department of Health's decision that the Chief Economic Adviser's report, when complete, should be published.

31. Baroness Hooper claims that in New Zealand as well as Canada the introduction of advertising bans was accompanied by price rises. While this is technically true, the price increases in New Zealand were trivial and can in no way explain the large drops in tobacco sales that followed the ban. We draw attention to the note in paragraph 8.2.1 of our Brief (attached), which points out that the real price of tobacco rose by only 2.2 per cent in the relevant period.

32. Advocates of a ban do not claim (as implied by Baroness Hooper) that it would have a greater effect than price increases. Nor is it justified to attribute differences in levels of smoking in the UK and other countries without bans and in the two EC countries with bans (Italy and Portugal) to that difference alone. In particular, it should be noted that in Portugal the most popular brands of cigarette still costs as little as 60p for 20, while the Italian "ban", introduced in 1962, has been almost unenforced. On Italy, see paragraph 8.8 of our Brief, which points out

(a) that fines for breaches were negligible until 1983;

(b) that since 1983 indirect advertising has continued at a high level; and

(c) that the price of cigarettes has halved in real terms since the ban was introduced.

It has been reported in the last few days that the Italian Government plans to introduce a law to ban indirect advertising (in, for example, television advertising for Marlboro cigarettes which purports—though only the attentive viewer will notice—to be for helmets for racing drivers): the Italian authorities are therefore clearly aware of the shortcomings of their law.

33. Baroness Hooper refers to the UK's "very strict voluntary agreements" on tobacco advertising. The claim that such agreements are strict is unsupportable and there is no evidence that they have detracted from the overall effectiveness of cigarette advertising. The Committee are referred to section 15 of our Brief.

34. (Questions 33, 34) Denmark has recently come out in favour of a ban, contrary to its previous policy. All the Health Ministers of the Lander have urged the German federal government to support a ban. The "voluntary agreement" regime in the Netherlands is under criticism from a report commissioned by the Dutch Government itself which calls it a "half-hearted policy" which has had no direct effect on consumption levels. Greece, where the government has come under pressure from tobacco farmers, is widely expected to support the ban when it comes to a vote in the Council of Ministers.

35. (Question 39) On sport sponsorship generally, the Committee are referred to section 12 of our Brief. The Department of Education's voluntary agreement on sports sponsorship is indefensible—and it appears from her reply (and her remark about sponsorship in answer to Question 46) that Baroness Hooper may wish to distance the Department of Health from it. It is notable, especially in the light of Baroness Hooper's assessment of the potency of TV advertising (Question 46) that in a survey in November 1989 64 per cent of five-to-16-year-olds recalled seeing cigarette advertising on television—largely because of the exposure the BBC (but not ITV) gives to tobacco-sponsored sport.

36. Sports sponsorship brings in less than 3 per cent of total commercial sponsorship of sport, worth less than £5 million a year—exceedingly cheap advertising for the tobacco industry, whose interest is clear: a Rothmans spokesman said:

> No-one hands over big cheques just to give themselves a warm fuzzy feeling

and one from RJR, the American tobacco giant, said:

> We're not in the sports business. We use sports as an avenue for advertising our products.

37. It is clear that there would be little difficulty in finding alternative sponsors for the high profile events the tobacco industry currently support—and the new Foundation for the Arts and Sport, with its £60 million budget, would be well able to take over the whole portfolio if need be. (See section 12.4 of the Brief.)

38. (Questions 40, 41) New Zealand achieved a drop in consumption of approaching 10 per cent within six months of introducing its advertising ban. A drop of 20 per cent over 10 years—about 1.9 per cent a year—is not a proud achievement when so many lives are at stake if additional measures would have achieved more. In Canada a combination of tax increases, health warnings and a ban on advertising produced cuts in consumption of 3.6 per cent per annum on average from 1983 to 1988, followed by cuts of 7.6 per cent in 1989 and 6.7 per cent in 1990. Thus the Canadians achieved in one year (1989) three-quarters of what the UK achieved in ten.

39. (Questions 46, 47) Unfortunately Baroness Hooper's sanguine outlook on poster and newspaper advertising is not justified by the research on its effect on children. (Shop-front advertising and advertising in magazines, often on the back cover for maximum visibility, are other ways that tobacco is promoted to children.) Studies in the UK and elsewhere have shown that children who smoke consistently buy the brands that are most heavily advertised, whereas adults tend to buy unadvertised or less advertised brands. This is dramatically demonstrated by the figures quoted in paragraph 7.1.6 of the ASH Brief. (Section 7 of the Brief quotes more evidence of the effect of advertising on children and its targeting on them.)

40. Moreover, if non-smoking children at the age of 10-12 have favourable attitudes towards cigarette advertisements they are twice as likely to become smokers within a year as non-smoking 10-12 year-olds whose attitudes are unfavourable.

41. Again, it is clear that children from a very young age recognise cryptic cigarette advertisements for what they are and are attracted by them. Their very nature as coded, cryptic messages encourages children to notice and understand them, so that they can "join an adult club". ASH does not find it "hard to believe that some of these advertisements would actually encourage anybody to start smoking": advertising combines with and reinforces other influences (parental and sibling example etc) to produce a cumulative change of attitude. In particular it provides an image of glamour, sophistication, masculinity or femininity, social ability etc (according to the brand). The tobacco industry, which relies so much on marketing expertise, knows very well what it is doing and does not waste money on expensive and unproductive campaigns.

42. The argument that advertising's only function is to promote brand-switching has been described by David Abbott, of the leading British agency Abbott Mead Vickers, as *so preposterous it is insulting* and by a "guru" of the US advertising scene, Emerson Foote, as *complete and utter nonsense*. Section 13 of the ASH Brief shows that the expenditure could not be justified on these grounds alone. (The tobacco industry and its allies like to claim that they are dealing with a "mature market"—an extraordinary claim in a situation where 70 per cent of the public are not customers and where about 190,000 new smokers have to be recruited every year—160,000 of them, as it happens, children below the age of 16.)

43. However, the motivation of the tobacco companies is irrelevant: it is the effect of their advertising that matters, and that is demonstrably to maintain the social acceptability of smoking, to encourage children to start smoking and (very important) to reinforce the habit once started.

44. (Question 52) We have commented above on both taxation and the CAP, and we are supportive of the Government's policy on both, wishing only (while recognising the political realities) that they would pursue matters more vigorously.

45. (Question 53) The risk of imports has been played up by the tobacco industry in a way that is surprising when imports account for less than 10 per cent of the UK market. The real threat is to profits if, to retain

market share, the industry has to reduce its margins. Given that profits are typically very large (e.g., Rothmans made £343 million or 15 per cent profit after tax on net sales of £2,293 million in 1990-91) there is ample scope for reduction of margins. (ASH would of course wish to see any effect on price offset by increases in tax.) (See also section 11.7 of the ASH Brief.)

46. (Question 55) ASH do not wish to deny the importance of parental, sibling and peer-group example in leading young people to start smoking. It is difficult, however, to act directly to remove these influences, whereas advertising, which is another important element in the equation that leads to one in four children being a regular smoker by the age of 15, can be eliminated entirely.

47. We do not think it realistic to see the "new strictures in the voluntary agreement" referred to by Baroness Hooper as other than minuscule concessions by the industry in the interest of face-saving for the Department of Health. Even on its own terms, the new voluntary agreement was gravely disappointing. Examples of its weakness are given in paragraphs 15.3 (third example) and 15.5 (first example) of the ASH Brief.

48. Neither do we have high expectations of the new Act, based on Mr Andrew Faulds' Private Member's Bill (a commencement order for which is now overdue). This is mainly because the Government forced the removal from the Bill of the provision that would have laid a duty on local authorities to enforce the Act. ASH believes that the only effective way of enforcing the law banning sales to under-16s is to reintroduce licensing of retail tobacconists with a mandatory loss of licence for any found guilty of selling to children.

49. (Question 60) It may be that a few children are influenced by the "forbidden fruit" effect to take an interest in smoking, but it is unlikely that banning advertising would add to the effect, and it is difficult to imagine that it would make the situation worse than at present, when there is a rising trend of smoking among those aged under 24, including under-16s. It is not illegal for under-16s to smoke—or indeed to buy—tobacco, and ASH is unaware of and would oppose any proposal that it should be made illegal.

50. (Questions 61, 62) The Commission's lawyers are satisfied that the draft Directive is properly introduced under Article 100(A) of the Treaty, and the Legal Committee of the European Parliament, to which the question was referred after intense lobbying by the industry, has just rejected the argument that the Directive is not acceptable under that Article. A paper prepared by Counsel for the British Medical Association, of which ASH has had sight, comes to the same conclusion. It is noteworthy also that the UK Government has not challenged the legal basis of the Directive.

February 1992

Memorandum submitted by the Coronary Prevention Group (E38)

We very much welcome the Maastricht agreement on Public Health, expecially insofar as it says that "Health Protection demands shall form a constituent part of the Community's other policies". We also are aware of the amendment on Consumer Protection as it too has health implications.

As an organisation concerned with the prevention of the UK's biggest killler, coronary heart disease, CPG believes that the European Community (EC) has an important role to play in public health policy. It is our opinion that the UK Government should seize the opportunity presented by its Presidency of the Council later this year to take the initiative and establish health promotion as an integral and central part of the EC's activities. Our proposals are based on two premises.

1/ The Community's Aspirations to Closer Economic Union must be Matched by a Development of its Social Role.

As the Community has evolved from an organisation designed to promote free trade to more of a social and political union it has started to recognise the social responsibilities which must accompany its growing powers in economic matters. Concerns with health, the social fabric and the environment are central to a balanced community. Disease prevention largely depends on social factors. Many are linked to matters such as regulations on nutrition labelling which have been seen by the Community as economic matters related to promoting trade. Therefore a Community which concerns itself with economic matters but is blind to the effect they have on health, will not serve the interests of disease prevention.

2/ Present Community Policies fail to take Health Promotion into Account and in many Cases are bad for Health.

Major areas of EC policy are at best blind to health. For example the Common Agriculture Policy fails to mention health. As a result billions of pounds are spent in subsidising food and agricultural products which are either intrinsically bad for health (such as tobacco) or unhealthy if consumed in excess (such as dairy products). The money could be better spent in reducing the cost of healthy foods. If the subsidies simply resulted in building up stores it could be defensible as a way of supporting the income of farmers—presuming they could not make a more constructive living. However the surpluses have a nasty way of finding their way back into the food chain—through differential subsidies of highfat milk for schools and subsidised sales of butterfat to food producers to high tar tobacco dumped on the Third World. The CAP needs be reformed to take account of the health needs of the consumer rather than simply the profits of some farmers.

Important policies on food labelling have been designed more on the basis of promoting free trade rather than promoting health. To give an example the Commission is currently considering a Directive on the definition of health claims such as "low fat". They have been proposing to define such terms on the basis that they are true relative to similar product. Thus it would be true to claim a product was low fat it it was x per cent lower in fat than a similar product even if the product itself was intrinsically high in fat, eg a spreading fat. From a health point of view this would be very misleading but the Commission's priority is to guarantee fair competition. Organisations such as CPG and the IHN argue for absolute definitions linked to medical recommendations.

Our main recommendation is that the UK should mark its Presidency by taking an initiative to establish health promotion as an integral and central part of the Communities activities. We would make the following specific recommendations:

1/ **Establish a Commissioner and a Directorate for Public Health.**
The difficulties of reorganisation cannot be dismissed lightly. Yet CPG believes there has never been a better time to grasp this nettle as we approach the appointment of new Commissioners and the probability of new Member States joining the Community. The UK has a particular opportunity as it holds the Presidency of the Community in the second half of this year. Without such a reorganisation EC policies will continue to have contradictory or negative effects on public health.

2/ **Launch a review of the health impact of current EC policies to ascertain their effect on health and thereby identify candidates for amendment.**

3/ **Facilities collaboration between non governmental organisations and the European Commission in the development of a health promotion strategy for Europe.**

The Coronary Prevention Group believes the EC's activities should be concerned with doing what is best done at a Community level and the guiding principle should be to add value rather than replace activities done at a national, regional or local level. The Community has much to gain by collaboration with health education authorities and with non governmental organisations (NGOs) which have expertise in developing and implementing public health policies on a wide range of issues. There are many organisations and groupings who could contribute to policy making. The WHO, for example, is developing a European Health Forum of national agencies concerned with health promotion. NGOs are establishing a European Public Health Alliance which will incorporate organisations expert in issues as diverse as AIDS, patients' rights, cancer and Alzheimer's disease. The International Heart Network (IHN) is a member of this Alliance and the Coronary Prevention Group was IHN's co-founder. This Network brings together heart foundations all across Europe in pursuit of their common interest in preventing cardiovascular disease.

The EC cannot and should not hope to duplicate the experience of such organisations but should draw on their collective knowledge and, through them, encourage the spread of best practice. The Commission should therefore establish and fund mechanisms to facilitate collaboration, both amongst NGOs and other health promotion agencies and between them and the Commission.

4/ **Encourage international collaboration by health educators to spread best practice.**

5/ **Encourage common data collection practices which will help underpin Community wide health promotion and disease prevention policies;**

6/ **Promote more common and joint research;**

7/ **Ensure that Community institutions and regulations give more support to the activities of non governmental agencies in Member States involved in health promotion.**

To this end it would be particularly useful if the Commission established a forum to discuss these matters with international organisations such as the IHN or the European Public Health Alliance to establish what measures would be useful.

8/ **The UK should follow the example of the Dutch Presidency and convene a meeting of Health Ministers and health experts to discuss fundamental health policy issues for Europe.**

In many of the above areas the UK should anticipate the widening of the Community by spreading these ideas and collaboration measures to non EC States.

CPG is also the Secretariat to the International Heart Network (IHN) which it co-founded in 1987. The IHN brings together heart foundations all across Europe in pursuit of their common interest in preventing heart disease through public measures. The IHN has a fully staffed office in Brussels and we believe more voluntary bodies should become involved in European policy making in this way.

While we would be glad to enlarge on our evidence we summarise our views here in the interests of brevity and in recognition of the Committee's heavy work load.

February 1992

Memorandum submitted by the National Pharmaceutical Association (E40)

ORAL EVIDENCE FROM THE DEPARTMENT OF HEALTH

The National Pharmaceutical Association represents the vast majority of community (retail) pharmacists in the United Kingdom. It has in voluntary membership some 7,000 pharmacy proprietors collectively owning 10,000 pharmacies. The NPA is actively involved in pharmaceutical European matters, mainly through its representation on the UK Delegation to the **Groupement Pharmaceutique de la Communauté Européenne (GPCE)** which voices European community pharmacists' views in Brussels. We welcome the opportunity to comment on the oral evidence on "The European Community and Health Policy" recently taken by the Health Committee from Baroness Hooper and officials from the Departments of Health.

Questions 32-51: Tobacco Advertising and Sponsorship

We are disappointed that the UK is one of the five member states who oppose a total ban on tobacco advertising. Strict voluntary agreements on methods of advertising, price restraint and public health education are not enough to decrease tobacco consumption and, in particular, discourage young people from taking up the habit. Considering the high costs of advertising, we do not accept the tobacco industry's claim that poster and newspaper advertisements only seek to encourage brand switching. Even if they don't attract new young smokers, surely they must increase the number of cigarettes smoked.

We share the Government's concern about tobacco sponsorship in sport. It is totally illogical to link a healthy pastime with a habit which is the single largest preventable cause of ill health and premature death in the United Kingdom. We feel that sport sponsorship is even more likely to encourage young people to smoke than poster and newspaper advertising.

Question 81: Freedom of Establishment for Health Professionals

The Directives covering free movement and right of establishment for pharmacists were implemented in 1988. Since then the number of pharmacists moving to and from member states has been even lower than for doctors. Since April 1988, the Royal Pharmaceutical Society of Great Britain—(the body responsible for registration of pharmacists in the UK) has registered 119 pharmacists from EC member states and, on behalf of UK pharmacists wishing to register in other EC member states, has forwarded 154 certificates of identity. Half the reciprocal registrants are transferring to or from the Irish Republic.

Question 91: Classification of Pharmaceutical Products

Sir David Price talked about the differences in the way non-prescription medicines are sold in the European Community. In most EC countries non-prescription medicines are restricted to sale through pharmacies. However, in the UK, Ireland and Holland, (and not in France as Sir David understands) some can also be sold through other outlets. In the UK, these outlets include supermarkets, drugstores, grocery stores and even garage forecourts. We agree with Sir David's comment that the availability of non-prescription medicines is "not just matters for trade, but matters for health". Whilst non-prescription medicines are safe if used correctly, problems can occur if different products are taken together. For example remedies containing paracetamol are available outside pharmacies. Combining two or three remedies containing this painkiller can lead to a fatal overdose. It is not enough to label a medicine with ingredients and dosage instructions and expect people to cure themselves. We believe that, in line with the majority of other member states, all medicines should be for sale in the UK in pharmacies only, where qualified pharmacists will be on hand for consultation and advice. We regret that the draft EC Directive which deals with classification of medicines—Proposal for a Council Directive concerning the legal status for the supply of medicinal products for human use (COM(89) 607 final—SYN 2301)—leaves it to individual member states to decide whether or not the sale non-prescription medicines should be restricted to pharmacies.

Question 94: Licensing of Pharmaceutical Products

We share Dr Metters' view that, whatever licensing system is introduced at European level, it should ensure that every pharmaceutical brought to the market is safe, efficacious and of good quality. In addition, we think that a similar licensing system should be introduced for so called "dietary or food supplements". Currently, provided they carry no medical claims, these products are not subjected to any clinical trials or tests as conventional medicines even though they can be harmful. During the past three years, two food supplements—germanium and tryptophan—have been withdrawn from sale by the Department of Health on safety grounds.

QUESTION 96: REPORTING ADVERSE DRUG REACTIONS

It is well known that the doctors' voluntary scheme of reporting adverse drug reactions (ADRs) to the MCA is not as effective as it should be. No fewer than 80 per cent of General Medical Practitioners have never submitted a single "yellow card"! We share Dr Metters' view that any system introduced at European level must work better, ensuring that ADRs are properly monitored. We would like to see pharmacists, as well as doctors, becoming involved in reporting ADRs. Not only does their extensive knowledge of medicine equip them to identify possible reactions but they are also easily accessible to the public and often the first port of call if a patient has a problem with their treatment.

February 1992

Memorandum submitted by the Royal Pharmaceutical Society of Great Britain (E42)

REGISTERING AUTHORITIES

The Royal Pharmaceutical Society of Great Britain is the registering body for pharmacists in this country. Our remit covers England, Scotland and Wales. The Pharmaceutical Society of Northern Ireland is the registering body for that country, so that the RPSGB and the PSNI, between them, deal with the registration of pharmacists for the United Kingdom. In that regard, we can be compared with the Royal College of Veterinary Surgeons or the General Medical Council or the General Dental Council, all of which administer sectoral EC Directives relating to free movement of professionals. This Society deals with the registration of all pharmacists, including those operating in the hospital and industrial sectors.

FREE MOVEMENT REQUIREMENTS

As the registering body for pharmacists for Great Britain, the Society was naturally particularly interested in the evidence given to the Committee relating to free movement of professionals. As I have indicated earlier, pharmacy is one of those professions with a sectoral Directive. The movement of pharmacists within the EC is governed by legislation in member states based on the provisions of Directives 85/432/EEC and 85/433/EEC. A basic requirement of article 2 of Directive 85/433 is that "each member state shall recognise the diplomas, certificates and other formal qualifications listed in article 4 *awarded to nationals of member states by other member states* ...". The first requirement for free movement is therefore that one must be a national of a member state. Article 2 of Directive 85/432 makes it clear that the course of study leading to the award of one of the certificates which provides the right to free movement must be in a university of the member state or a higher institution recognised as having equivalent status to a university. For pharmacy we have 16 schools of pharmacy in the United Kingdom, 10 of which are in the university sector and the remainder currently in the polytechnic and central institution (Scotland) sectors. The next requirement of Directive 85/432 is that a course of training should comply with certain requirements listed in that article and in paragraph 5 of article 2 of the same Directive. For the United Kingdom the certificate providing the right to free movement is the certificate of registration as a pharmaceutical chemist which equates with the right to register as a pharmacist in this country. In some other EC member states, the corresponding certificate is one confirming the granting of a university degree or diploma.

ACQUIRED RIGHTS

For those who hold the certificate of registration as a pharmaceutical chemist but obtained that certificate some years ago as a result of taking a course of education and training which did not comply with the provisions of Directive 85/432, there is an "acquired rights" provision in Directive 85/433. This provides that those who hold such a certificate are entitled to free movement if the competent authority issues a certificate stating that the holder of that qualification has been effectively and lawfully engaged in the practice of pharmacy in a member state for at least three consecutive years within the preceding five years, provided that the activity in which he or she has been engaged is regulated in that member state. Thus I, as Secretary and Registrar of the RPSGB, am able to issue appropriate certificates for those who are registered as pharmaceutical chemists in Great Britain and who have been engaged in community or hospital pharmacy consecutively for three out of the preceding five years or have been engaged as a "qualified person" in the pharmaceutical industry, which is a regulated occupation. Difficulties are encountered with pharmacists who have been engaged say in the academic sector or in the pharmaceutical industry in quality assurance or production, which are not regarded as "regulated activities".

COURSE OF TRAINING

May I now turn to a matter which is assuming greater importance for future generations of pharmacists in the United Kingdom.

The requirement in article 2 of Directive 85/432 is that the required certificate "shall testify to the completion of a course of training covering a period of least five years" comprising at least four years of full time theoretical and practical training in a university (or its equivalent) and at least six months of in-service training in a pharmacy open to the public or in a hospital under the supervision of the pharmaceutical department of that hospital. It was necessary to grant the United Kingdom a derogation from the requirement

when the Directive was agreed. The situation is that the course of education and training in Scotland meets the requirements of the Directive. In England, Wales and Northern Ireland, however, the academic course leading to the award of a degree in pharmacy is a three year course and there is a 12 month period of preregistration training, a total of four years. The derogation provided that, if at the time of adoption of the Directive, two courses of training co-existed in a member state, one of which lasted for five years and the other for four years, the latter would be acceptable provided that the certificate testifying to the completion of the two courses were recognised as equivalent in the member state concerned. This derogation was obtained by outlining the progress of education in the United Kingdom from the age of five onwards. The UK negotiators were able to demonstrate that those entering the schools of pharmacy in England, Wales and Northern Ireland with three A Levels (usually in science subjects and certainly including chemistry) were broadly equivalent to those who had completed the first year of basic sciences in the Scottish universities and the central institution at Aberdeen. The United Kingdom will be under some pressure in seeking to maintain this stand in future. The Government has been pressing for a widening of access to undergraduate course in England and Wales and this is something which RPSGB would certainly support because it would enable pharmacy students to be drawn from a much wider base. On the other hand, it means that students are coming to schools of pharmacy with qualifications other than the traditional three A Levels in science subjects. This means that there must be teaching of these subjects to bring the entrant to a level at which that person can expect to understand the pharmaceutical sciences. At the same time, the RPSGB, which accredits the programmes leading to the award of the degree in pharmacy at the UK schools, is pressing for the introduction of aspects of the social and behavioural sciences to the pharmacy courses because we believe that an understanding of, for example, why people react as they do when they are well is vital for the education of the person who will be providing pharmaceutical services directly to the public. At the same time, the basic pharmaceutical science base of the pharmacy degree programme must be maintained and this means that the schools of pharmacy in Great Britain are finding it extremely difficult within a three year course to meet the triple requirements—broaden the base of entry, maintain the pharmaceutical science foundation and introduce relevant aspects of the social and behavioural sciences. There seems to the RPSGB to be no alternative but to consider a lengthening of the undergraduate course in Great Britain from three to four years. The possibility of that being necessary in some courses leading to professional qualifications was recognised by the Committee of Vice Chancellors and Principals when the memorandum relating to broadening access was circulated.

The EC Committee on Pharmaceutical Education and Training, which is established under the aegis of the EC Commission to oversee the implication of Directives 85/432 and 433, will shortly begin an examination of the undergraduate courses in each of the EC member states and the points I have made will clearly all come to light at that time. We are bound to come under pressure from colleagues in other EC countries, some of which, like Germany, have already extended the length of their course leading to qualification in pharmacy to meet the requirements of the Directives.

Third Country Qualifications

Some of the discussions at the meeting of the Health Committee on January 15 related to persons who have third country qualifications and who say, have the right to practise in Great Britain. As I have indicated, the requirement, certainly so far as the pharmacist Directives are concerned, is first that the person must be a national and secondly must have undertaken the course of study in a member state. This seems to be in line with the answer that was given on behalf of the EC Commission by Mr. Bangemann, published in the Official Journal of the EC of March 25, 1991, which confirmed that the General Medical Council was not required to recognise a diploma held by a Dutch doctor who had completed most of his training in a non-member country, Egypt. (See Annex).

Reverting to pharmacy, there are four routes to registration as a pharmacist in Great Britain. The first applies to those who study pharmacy in this country and undertake preregistration training here. The second route is open to nationals of other EC member states. The third route relates to pharmacists from countries such as Australia and New Zealand with which historically this country has had reciprocal agreements for the recognition of qualifications which have led to registration as pharmacist in the countries concerned. The fourth route is open to those who are registered as pharmacists in all other countries and they apply to the RPSGB under a procedure within which their qualifications are individually assessed. Within that fourth category we find that most of the pharmacists concerned have to undertake a course of study specially designed for overseas pharmacists which may be in one or more of the pharmaceutical sciences, depending upon the course content leading to the individual's qualification. Normally, the person concerned then has to undertake a period of practice experience in this country prior to registration. We would certainly feel that a person who had obtained registration as a pharmaceutical chemist in Great Britain under that procedure would be equipped to practise pharmacy in other EC member states but, of course, the person would not be eligible if he or she was not a national of an EC member state. On the other hand, we could accept that other EC countries may not be prepared to recognise pharmacists registered in Great Britain as a result of reciprocity agreements based on historical ties with countries such as Australia and New Zealand. The "established rights" provisions of Directive 85/433 seems to offer an appropriate opportunity for those pharmacists if they have practised in Great Britain for three consecutive years within the last five, but again the question of nationality is raised. I understand that the question of "free movement in the services sector" is under consideration within the GATT negotiations as part of the Uruguay round. We also have to have

regard to the Treaty that is said to have been signed between the European Community and the EFTA countries, although to date we have not been able to receive from our Department of Health the relevant details of that agreement in so far as they affect the EC Directives relating to the free movement of pharmacists.

ADDITIONAL CONDITIONS

Finally, may I turn to the question on which the RPSGB feels strongly. If a pharmacist registered in Great Britain wishes to practise in another member state of the EC, I, as Registrar of the RPSGB, will issue a "Certificate of Identity". This will confirm that the person holds the certificate of registration as a pharmaceutical chemist as specified in article 4 of EC Directive 85/433. The Certificate will go on to say that the person has received that Certificate after undertaking a course of education and training which complies with article 2 of Directive 85/432 or, alternatively, has been awarded as a result of a course of education and training that did not comply with article 2 or 85/432 but the person has been engaged in one of the activities specified in article 1 of Directive 85/432 for three consecutive within the last five. I will also confirm that the person is in good standing with the Royal Pharmaceutical Society of Great Britain. It is the RPSGB's view that this document accompanied by a health certificate and, if required, a further character reference should be sufficient to smooth the passage for registration in another EC member state. Too often we find, however, that although the persons qualifications may be accepted by the Government in another member state additional conditions are then specified by the professional body for pharmacists. These conditions can take many months to comply with and usually involve quite considerable expenditure associated with certification of documentation by notaries. This kind of problem has been faced by British pharmacists seeking the right to practise in Italy, France, Spain and Portugal. I should emphasise that the number of pharmacists from Great Britain seeking to move to other EC countries is not high—a total of 154 Certificates of Identity have been issued by me since the EC Directives came into effect since April 1988 and 84 of these have been Certificates of Identity for Ireland. Nevertheless, for an individual the experience can be frustrating, time consuming and quite unnecessarily bureaucratic. I should add that under the pharmacist Directives it is not possible for a member of state to impose a language test for the right to practise. On the other hand, it is of course perfectly legitimate for an employer to seek proficiency in the language of the member state concerned sufficient to enable that pharmacist to discharge the duties associated with the particular job. The proficiency may vary quite widely from the person who has to communicate with members of the public and members of other professions on the one hand to another pharmacist who may be working say in a quality assurance laboratory in the pharmaceutical industry with professional colleagues with whom a good deal of communication may be in the form of written reports.

I do hope that this information is of interest to the members of the Health Committee. I shall of course be happy to provide to them any additional information they may require about the Directives governing the free movement of pharmacists within the European Community.

February 1992

ANNEX

Official Journal of the European Communities 25 March 1991

WRITTEN QUESTION No. 936/90 by Mrs Jessica Larive (LDR) to the Commission of the European Communities

(17 April 1990) (91/C79/16)

Subject: Recognition of final doctors' diplomas and admission to the profession

1. What interpretation should be placed on Article 1(2) and Article 2 of Council Directive 75/363/EEC[1] concerning the co-ordination of provisions laid down by law, regulation or administrative action in respect of doctors which state that:

> "A complete period of medical training of this kind shall comprise at least a six-year course of 5,500 hours of theoretical and practical instruction given in a university or under the supervision of a university."
>
> "It shall entail the successful completion of six years study within the framework of the training course referred to in Article 1."

Does this mean that:

(a) The complete period of medical training must be carried out in one Community Member State or

(b) Some of the training may be undertaken elsewhere, with that period being recognized by the university within the European Community and the candidate finally obtaining a complete final diploma from that European university?

In other words, is it a question of six years study in the territory of Community or of a diploma awarded at the end of a recognized course of studies?

2. Does the Commission consider that the British General Medical Council may refuse to register a Dutch doctor on the grounds that he obtained his medical degree at the University of Utrecht after less than six years study there (the individual concerned was exempted from a number of examinations since he had completed more than six years full-time medical study at an Egyptian university)?

Answer given by Mr Bangemann on behalf of the Commission

(11 July 1990)

The Dutch doctor completed most of his training in a non-member country, Egypt. He underwent medical training in that country lasting more than six years, for which he was granted exemptions by the University of Utrecht, subsequently gaining the medical degree conferred by that university on completing supplementary training lasting 18 months.

The Commission considers that this situation is not covered by the provisions of Article 1(1), (2) and (3) of Directive 75/363/EEC, which are to be read in conjunction with *inter alia* recommendation 75/366/EEC concerning nationals of the Grand Duchy of Luxembourg who hold a diploma in medicine conferred in a third country[2]. Furthermore, this situation resembles that referred to in article 1(5) of the Directive, which states that "Nothing in this Directive shall prejudice any facility which may be granted in accordance with their own rules by Member States in respect of their own territory to authorise holders of diplomas, certificates or other evidence of formal qualifications which have not been obtained in a Member State to take up and pursue the activities of a doctor." Accordingly, as Community law stands at present, the General Medical Council may refuse to recognize the diploma.

In this connection, the Commission would refer the Honourable Member to its answer to Written Question No. 1197/89 by Mr Alvarez de Paz[3].

Memorandum submitted by Rhône-Poulenc Rorer (E43)

EC LEGISLATION RELATING TO THE PHARMACEUTICAL INDUSTRY—A BRIEFING NOTE

The nature of the regulatory framework which is evolving at European Community level under the Single Market programme will be an extremely important determinant of the success or otherwise of the research based pharmaceutical industy in Europe. While, on the one hand there is signficant potential for cost saving from the harmonisation of technical standards and regulatory approval systems, there are equally major threats for the industry, particularly from the export of products from those markets where unrealistically low prices are enforced by the authorities, to Member States where economic conditions for the industry are

[1] OJ No L 167, 30.6.1975, p 14.
[2] OJ No. L 167, 30.6.1975.
[3] See page 3 of this Official Journal.

more favourable. This paper attempts to provide a summary of the current status of pharmaceutical legislation at EC level, while presenting Rhône-Poulenc Rorer's (RPR) view on the most important issues.

EC policy on the pharmaceutical industry has evolved from the technical and thence to the economic and political planes and in broad terms Rhône-Poulenc Rorer is in agreement with this step by step approach from the European Commission. To date most of the compromises reached are reasonably satisfactory but two of the most important issues, namely future regulatory systems and pricing/reimbursement, have yet to be determined. Currently there are nine important proposed Directives or Regulations relating to pharmaceuticals at various stages in the legislation making process in Brussels and Strasbourg.

1. Regulation to Establish Supplementary Protection Certificates for Medicinal Products to Restore Patent Term

Currently pharmaceutical products have a 20 year duration of patent protection in most EC Member States but regulatory and testing demands have increased over the years to a point where on average about 12 years from this period of protection are lost in the development phase before products can be brought to the market. The residual average eight years of effective patent life remaining is frequently insufficient for industry to recover its research and development costs and make reasonable commercial returns. RPR therefore welcomes the political agreement reached at the Internal Market Council in December which, through establishing a Supplementary Protection Certificate linked to the first marketing authorisation will provide industry with a period of protection of up to 15 years. While the Common Position from the Council of Ministers still has to be formalised, it is now anticipated that this Regulation will complete its second reading and start to take effect in early 1993. This Regulation, which is an excellent example of co-operation between industry, the EC and the Member States will be extremely important in encouraging research investment by the pharmaceutical industry in Europe. RPR has an element of disappointment in that the transitional date provided in the regulation has been brought forward from that originally proposed by the Commission (it seems all Member States will adopt 1 January 1985 except Germany which has chosen 1 January 1988). Nonetheless RPR welcomes the progress made in this field and looks forward to adoption of the Regulation.

2. Future Systems for Marketing Authorisations

RPR has used existing Community level procedures to obtain marketing authorisations for its products. However, the existing multi-state procedure (often referred to as the CPMP procedure) has been beset by disagreements between the authorites of the Member States and RPR is keen to see the current procedures develop into a system for drug approval which is effective, authoritative and speedy.

The Commission's proposal released in late 1990 is a highly technical package, comprising one Regulation and three Directives. The Regulation would establish a European Medicines Agency and a new centralised Community procedure, compulsory for biotechnology products and available on an optional basis for other innovatory medicinal products, leading to a Community Authorisation valid in all 12 Member States. The Directives would establish a decentralised procedure, based on the principle of mutual recognition to allow the extension of a marketing authorisation from a first Member State to the others. This system differs from the current multi-state procedure by establishing binding decisions in the event of disagreement between Member States. The Commissioner's proposal was given a first reading in the European Parliament in June 1990 but has subsequently come to a standstill in the Council's first reading because of a dispute over the legal base chosen for the Regulation. For the present, discussion on the technical content of the package has stopped and it is not clear how the current impasse is to be broken.

RPR supports the concept of twin procedures (decentralised and centralised) in the Commission's proposal. It does however wish to see equality between these two different routes with a free choice of routes for applicants and mechanisms to achieve clear binding decisions. While RPR recognises that some Euro-level body will be necessary to administer the centralised procedure and to adjudicate in disputes arising under the decentralised procedure it has some misgivings regarding the Agency proposed since it perceives there is a danger that this could become a large bureaucratic and non-responsive organisation. RPR also has concern in that the Commission's proposal envisages quite a rapid shift from the national to the new European procedures. It is vitally important for all concerned that a step by step approach is taken, such that the new systems can be put in place and proven to be effective before the existing systems are cut off.

3. Economics of the Industry

The Price Transparency Directive, which came into effect in 1990, was the first incursion by the EC into the question of pricing and reimbursement. Essentially is sought to enhance the transparency of Member State decisions regarding product pricing and reimbursement and to provide time limits within which such decisions should be taken. In practice the transparency directive has had limited impact and the EC pharmaceutical market remains far away from the Single Market ideals because each Member State has its own unique system for controlling pharmaceutical pricing and admission to reimbursement. The key challenge to be faced by both government and industry is how to deal with these disparities in the lead up to the single market. A new approach must be found which meets the objective of cost containment on the part of governments and the achievement of a normal and efficient market necessary to provide a strong foundation for the European pharmaceutical industry. A point of particular concern is that of individual

product price controls which force artificially low pharmaceutical prices in some Member States. As technical standards and procedures are harmonised and with new regulatory procedures in prospect there is a danger of greatly increased movement of pharmaceutical products from low priced Member States to high priced Member States. This phenomenon, commonly known as parallel importation, already occurs and in effect amounts to the export of the price control systems of the low price Member States. Were this current trade significantly expand it could seriously jeopardise the industry's profitability and thus its ability for future research investment.

RPR believes that ways have to be found to produce a freer pricing environment and as first steps would suggest:

1. Political consideration needs to be given as to how the pharmaceutical industry in Europe will evolve in the next 10 years, the environment in which it operates and how its competitiveness worldwide can be involved.
2. the legislative follow-up to the transparency directive should include a "standstill" clause to oblige Member States to consult the Commission before altering their domestic pricing and reinbursment systems in order to prevent still further divergence of practice.
3. A fundamental principle should be established and recognised throughout the Community; pricing is an industry matter and reinbursement is a government matter. Economic and social/welfare policy are different and must be managed differently:

Finally gradual moves towards free pricing must be made. The absence of free pricing leads to price discrepancies and therefore to unfair competition:

4. ADVERTISING

The Advertising Directive has recently completed its second reading in the European Parliament. In its early stages the proposal had included restrictive conditions which would have precluded industry sponsorship of scientific congresses and severely restricted or debarred sampling. An acceptable compromise on the former has now been reached while the question of sampling restrictions has been left to the discretion of the Member States. RPR believes that samples have a role to play both in enabling GP's try out new products and as starter packs in emergency situations or where the patient cannot quickly reach the pharmacy. RPR therefore trusts that the Member States will not impose unnecessarily restrictive sampling rules.

5. RATIONAL USE

There are three further pharmaceutical directives, commonly referred to as the "rational use" package.

The Wholsale Distribution Directive seeks to Harmonise the conditions under which wholesalers operate.

The Labelling and Package Inserts Directive lays down standardised labelling requirements and require the inclusion of a patient information leaflet with all pharmaceutical packs.

The Product Classification Directive harmonises the criteria to be used by the Member State Authorities in deciding whether a product should be prescription only or available over the counter.

These directives have recently completed the second reading in the European Parliament and in broad terms acceptable compromises have been achieved.

In summary, RPR believes that the broad direction of the Commission's legislative programme to date is correct. However, it is imperative that the key outstanding issues of future regulatory systems and pricing/reimbursement are addressed through a step by step approach and in a manner to ensure the future viability of research in Europe. As regulators strive to reconcile the economic well-being of the industry with containment of healthcare costs consideration must be given to the position of the industry in Europe given increasing competition from America and Japan. In this regard, RPR believes it would inappropriate for future legislative responsibility to be referred to DG V or another non-industry oriented Directorate.

RPR hopes that this briefing paper will be of assistance and will be pleased to provide further information if required.

February 1992

Memorandum submitted by the Tobacco Advisory Council (E44)

Whilst we are in broad agreement with the views on advertising expressed to the Committee by Baroness Hooper, we would very much like to respond to comments made by Alice Mahon MP, on the subjects of children and smoking—and why tobacco companies advertise.

1. CHILDREN AND SMOKING

Contrary to Mrs Mahon's assertion, there has been little change in the prevalence of smoking by young people since the mid 1980s. Any such change has been described by OPCS as "not statistically significant".

In fact, the data produced by the OPCS shows a decline in the numbers of 11-15 year olds smoking since 1982.

The UK Tobacco Industry has always fully supported the law and has spent £3.5 million on a publicity campaign to ensure that shopkeepers are fully aware of their responsibilities concerning the illegal sale of cigarettes to under sixteens.

2. WHY TOBACCO COMPANIES ADVERTISE

Mrs Mahon questions the commercial logic of tobacco companies investing "money, time and effort" in encouraging existing adult smokers to switch brands. She asserts that these resources are directed at encouraging children to take up smoking.

The facts, however, are as follows:

Industry policy, as well as the stringent conditions of the Voluntary Agreement between the Government and the UK tobacco industry, rightly prevent children from being targeted by tobacco advertising. It is interesting to note Baroness Hooper's comment in Question 39 in relation to this agreement, which she describes as "... extremely good and effective". In Question 46 she makes the further observation: "There is a certain logic to the industry's argument that their advertising campaigns on posters and in newspapers are for brand switching rather than encouraging people to start smoking".

This logic is easily explained

On average, around 7 per cent of all existing smokers regularly switch brands each year. A further 26 per cent of all existing cigarette smokers regularly smoke more than one brand. Approximately one third of all existing cigarette smokers are therefore either seeking to change their brand or are regularly purchasing more than one brand.

In 1991 almost 15 million adults smoked manufactured cigarettes which means that there is a target audience for brand advertising of almost 5 million smokers representing a potential market with a retail value of around £3 billion per year. It is against this significant potential that my Industry's net annual media advertising expenditure on cigarettes of around £45 million is directed. This equates with the much quoted gross figure of around £60 million.

The potential for, and rewards from, market share growth achieved through successful advertising in a declining market are therefore very clear and this is the perspective against which the UK Tobacco Industry's advertising expenditure should be viewed.

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