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FOREWORD BY THE MINISTER FOR HEALTH

This volume includes the annual reports for 1990 of the Medicines Commission, the Commission on Safety of Medicines, the British Pharmacopoeia Commission, the Committee on the Review of Medicines, the Committee on Dental and Surgical Materials and the Veterinary Products Committee. Also included is a record of Members' interests in the pharmaceutical industry. The code of practice sets out the standards which Members must follow when they make their declarations. This is important in order to avoid conflicts of interest which might be held to impair the impartiality of their advice.

One of the main ways of improving and maintaining public and animal health is the availability of medicines to treat and prevent disease. The medicines used must be safe, effective and of reliable quality and Members of these Committees play a major part in ensuring that they are so. On behalf of all Ministers charged with the responsibility for the administration of the Medicines Act I am pleased to record our thanks for their help and advice and our appreciation of the considerable commitment in time and effort which is involved.

Virginia Bottomley

THE MEDICINES COMMISSION
ANNUAL REPORT FOR 1990

1. The Medicines Commission was established in 1969 with functions assigned to it under the Medicines Act 1968. The Commission's terms of reference are set out in Appendix I.

2. On the 1 January 1990 Professor Dame Rosalinde Hurley was reappointed as Chairman. Dr Carter, Professor D'Arcy, Professor Dayan, Professor Jones and Mr Tuck were reappointed as members and six new members were appointed to fill vacancies occurring on expiry of other members' terms of office. A full list of members showing their terms of appointment is at Appendix II.

3. There were six meetings of the Commission in 1990.

EUROPEAN COMMUNITIES

4. The Commission were kept informed by Department of Health (DH) officials of the European Communities (EC) Commission's proposals for European legislation within the pharmaceutical sector.

The rational use of medicines and advertising

5. The Commission noted that proposals concerning wholesale distribution, the classification of human medicines, and labelling and leaflet information (the"Rational Use of Medicines") had been submitted to the Council of Ministers in January 1990. Discussion in the Economics Questions Working Party took place during the course of the year but had not been completed. Whilst the proposals were broadly acceptable there were points of detail to be negotiated.

6. The Commission also noted that the EC Commission had submitted a proposal on pharmaceutical advertising but that negotiations were unlikely to begin before 1991.

Homoeopathics

7. The Commission were informed that the EC Commission's proposals to harmonise the regulations for authorising the manufacture and marketing of homoeopathic medicinal products had been submitted by the EC Commission. The proposals allowed for a simple registration procedure for homoeopathic products for oral or external use, marketed without indications and containing less than 1 part per million of a substance.

8. The Commission felt that the proposed definition of the term "homoeopathic medicinal product" by reference to official pharmacopoeias, which would not be part of the Directive nor under direct legislature, was clearly controversial. There is no European Homoeopathic Pharmacopoeia and it seems unlikely that the European Pharmacopoeia Commission would agree to consider monographs concerned with homoeopathic products.

9. The simplified registration scheme avoided reference to the controversial question of efficacy. The Commission felt that the development of a method to establish efficacy should be considered further since in practice manufacturers liked to promote their products with indications. The Commission were concerned that any promotional material relating to a particular homoeopathic product or range of products should be regulated even if it were a general booklet available at point of sale.

Medical devices

10. The Commission received a report from the DH's Medical Devices Directorate on the progress of initiatives on medical devices. In particular the Commission noted the EC Commission's decision to have a combined Directive for non-active and all other active devices not covered by the Directive for active implants. The EC Commission had issued a first draft of this combined Directive in July and experts were discussing details including rules for a classification system based on the level of regulation appropriate to different kinds of devices. The Commission were assured by DH officials that the draft Directive addresses in its essential requirements the general question of the safety of devices.

Future system for authorisation of medicinal products within the EC

11. The Commission considered the EC Commission's draft proposals for a future licensing system. The proposals envisaged a three part system comprising:-
(i) centralised decisions for biotechnology and (optionally) other "high technology" products and new active substances;
(ii) decentralised decisions based on mutual recognition with provision for binding arbitration if necessary;and
(iii) national decisions for applications of purely national interest.

12. The proposals had been the subject of wide consultation. The major UK concerns were:

(i) scientific credibility of the decision making process;
(ii) pharmacovigilance;

(iii) the responsibilities of and relationships between the Committee on Proprietary Medicinal Products (CPMP), expert groups, rapporteurs, the EC Central Agency, its Executive Director and the Management Board;
(iv) timing and planning of implementation; and
(v) clarification of responsibility for decisions.

13. The Commission understood that the proposals for veterinary medicines were similar to those for medicines for human use.

14. The Commission regretted that the EC Commission had not taken the opportunity to propose a single EC wide licensing authority covering all medicinal products. The Commission expressed anxiety over a number of areas of particular concern. Rapporteurs could be appointed from any national competent authority.It would, therefore, be essential for the arrangements to include safeguards to ensure comparability of assessment, in particular that standards of assessment should be harmonised to a high standard. The role of experts and their relationship with the CPMP, and the procedures for appointing them required further thought. The Commission agreed that it was desirable for the CPMP to be reinforced with independent experts in addition to delegates appointed by member states.

15. The Commission particularly hoped that the procedure for appeals would be more fully developed to include some form of independent review if a decision were referred back to the CPMP to consider. In most member states there were no rights of appeal to an independent body so the UK might be in a minority in pressing for them. However, under the decentralised system a decision would be made by one member state and the intention was that the others should accept. In cases of disagreement a form of independent review would exist because the matter would be referred for arbitration to CPMP.

16. The Commission considered it was important that scientific principles should be applied to the new procedures. Ultimately the success of the system would be judged on whether it achieved the objective of getting good medicines to patients more quickly and efficiently than at present.

REPORT OF THE ADVISORY GROUP ON NURSE PRESCRIBING

17. The Commission were invited to comment formally on the Report of the Advisory Group on Nurse Prescribing. Ministers had accepted in principle the recommendations that certain groups of nurses working in the community should be authorised to prescribe from a limited list of items and to control dosage of

medicines within agreed guidelines.

18. The Commission generally welcomed the report. They recognised the role of community nurses in certain prescribing decisions and that the proposed changes would be more convenient for some patients. However, they foresaw considerable organisational problems and stressed the importance of ensuring the safety of patients.

19. In particular the Commission thought that care would be needed in drawing up the proposed Nurses' Formulary. The inclusion of items in the legal categories of Prescription Only Medicines and Pharmacy Medicines should be considered carefully. Nurse prescribers would need to be kept fully informed of changes relating to medicines on the list. On safety grounds the Commission considered that nurses should be restricted to prescribing only medicines which were licensed. They pointed out that pharmacists would need to be kept fully informed about the Nurses' Formulary and changes made to it.

20. Prescribing for a patient by both doctor and nurse raised concerns about possible drug interactions and the reporting of adverse drug reactions. The Commission felt it would be particularly important to establish effective collaboration and noted that nurses would hold their own professional records. The Commission were reassured to learn that the United Kingdom Central Council for Nursing, Midwifery and Health Visiting (UKCC) would ensure registration of named nurses authorised to prescribe. Pharmacists would be able to request confirmation of a nurse's authority to prescribe from the UKCC.

21. The Commission would be formally consulted under the statutory procedure for amending the POM Order if in due course any prescription only medicines were proposed for inclusion in the Nurses' Formulary.

HEARINGS

Human medicines

22. The Commission held six hearings in respect of applications for new product licences. In one case their advice was that a product licence should be granted and in a further three cases that a product licence should be granted subject to certain conditions being met. In two cases they advised that product licences should not be granted.

23. The Commission held two hearings and considered one written representation in respect of applications for reviewed product licences. In one case their advice was that a product licence should be granted for a limited range of indications and in another that a licence should be granted subject to amendment of the product particulars. In the third case they advised that a product licence should not be granted.

Veterinary medicines

24. The Commission also held a hearing concerning the proposed revocation of two product licences. Their advice was that the licences should not be revoked.

25. The Commission considered one written representation in respect of an application for a reviewed product licence. They advised that a product licence should not be granted.

OTHER MATTERS

Medicines Control Agency

26. The Commission were kept informed of progress on the reorganisation of the Medicines Control Agency on the lines recommended in the Evans and Cunliffe Report. Six multi-disciplinary "Businesses" were established: New Drugs, Abridged, Pharmacovigilance, Inspection and Enforcement, Executive Support, and Pharmacopoeia. Each was headed by a Business Manager, accountable for resources and performance, reporting to the Director. The Director, Business Managers, Legal Advisor and Finance Director comprise the Management Board.

27. The Commission were pleased to learn of the considerable improvements in the MCA's licensing performance in 1989/90 for New Chemical Entities, Abridged Licence Applications and Variations. They congratulated the MCA on being the first in Europe for licensing performance in relation to New Chemical Entities and noted with approval that backlogs in Abridged applications were being reduced and that the aim was to eliminate them by April 1992.

Veterinary Medicines Directorate

28. The Commission were also informed on the progress of the setting up of the VMD, a recommendation of the Cunliffe report. The Commission heard that all aspects of the licensing of animal medicines were now integrated into one unit in Weybridge. The VMD had been organised into three multi- disciplinary teams each with a professional and administrative team leader responsible for: pharmaceuticals, medicated feed activities, and biological and recombinant products. The VMD was seeking to increase public understanding of the rigorous nature of the licensing system through meetings with the press, consumer representatives and the agricultural industry.

Prescription Only Medicines Order

29. The Commission were consulted about proposals to amend the Prescriptions Only Medicines Order. They sought further information on the proposal that an anti-smoking preparation containing 2mg of nicotine should no longer be subject to prescription control. They advised that, subject to the product literature containing suitable warnings about the potential for misuse or abuse by children and to the product being responsibly advertised and promoted, pharmacists should be able to supply it without prescription. The Commission also endorsed the other proposals to amend the Prescription Only Medicines Order.

General Sales List Order

30. The Commission considered proposed amendments to the General Sales List Order. They considered unnecessary a proposed amendment to Schedule 3 adding to the classes of medicines which are not for general sale those for the treatment of peptic ulcers; although those products might contain ingredients in the General Sales List they believed that it was already generally understood that medicines for the treatment of peptic ulcers were unsuitable for general sale. They noted that products for this indication could not be promoted to the public. They advised against this amendment and endorsed the other proposed changes to the General Sales List Order.

General

31. The Commission recommended the following for publication:

British Pharmacopoeia 1988: Amendment No 4
Addendum 1991

British Pharmacopoeia(Veterinary) 1988:
Amendment No 4
Amendment No 5

British Approved Names 1990

British Approved Names 1990: Supplement No 1

European Pharmacopoeia: Approved Synonyms

REPORTS OF THE COMMITTEES

32. The Commission noted with interest the reports of the Committees established under section 4 of the Medicines Act 1968. They placed on record their appreciation of the work of the members of these committees.

APPENDIX I MEDICINES COMMISSION TERMS OF REFERENCE

1. The broad function of the Medicines Commission, as set out in Section 3(1) of the Medicines Act 1968 is to advise the Health and Agriculture Ministers of the United Kingdom "on matters relating to the execution of this Act or the exercise of any power conferred by it, or otherwise relating to medicinal products, where either the Commission consider it expedient, or they are requested by the Minister or Ministers in question to do so".

2. In Section 3(2) of the Act certain specific duties are placed upon the Commission and these include:

   a. making recommendations to Ministers with regard to the number of Committees to be set up under Section 4 of the Act, and the functions to be assigned to each such committee;

   b. recommending to Ministers persons well qualified to serve as members of a committee set up under section 4 of the Act;

   c. reviewing these committees from time to time and recommending any changes considered appropriate in their number and functions;

   d. undertaking functions of the kind normally assigned to one of these committees if at the time no appropriate committee exists;

   e. considering representations made (either in writing or at a hearing) by an applicant or licence holder where the licensing authority has been advised by a committee set up under Section 4 of the Act to refuse, suspend or revoke or vary a licence or certificate and reporting their findings and advice, and the reason for their advice, to the licensing authority.

3. Sections 99 to 101 of the Act confer on the Commission the function of recommending to Ministers that compendia (such as the British Pharmacopoeia), lists of names and other relevant works be published.

APPENDIX II

MEMBERSHIP OF THE MEDICINES COMMISSION 1 JANUARY 1991

† Professor Dame Rosalinde Hurley DBE LLB MD DUniv(Surrey) FRCPath (Chairman)
Professor of Microbiology, Royal Postgraduate Medical School's Institute of Obstetrics and Gynaecology, University of London

† Dr I D Aitken PhD BVMS MRCVS
Director of Animal Disease Research Association, Moredun Institute, Edinburgh

† Mr M J S Butler BSc (Econ)
Lecturer in Politics and Public Administration, University of Kent. Chairman of Canterbury and Thanet CHC and former Chairman of Association of CHCs for England & Wales

† Dr M G Carter MB ChB BPharm DipPharmMed FRPharmS MCPP
Director, ICI Pharmaceuticals

* Professor W I Cranston MA MD FRCP
Professor of Medicine, United Medical and Dental School, St Thomas' Hospital , London

† Professor P F D'Arcy OBE DSc BPharm PhD FRPharmS CChem FRSC FPSNI
Professor of Pharmacy, Queen's University, Belfast.

* Professor P Dawid MA ScD
Professor of Statistics, University College, London

† Professor A D Dayan MD FRCP FRCPath FIBiol FFPM
Professor of Toxicology, St Bartholemew's Hospital, London

* Professor M Drummond DPhil MCom BSc
Professor of Economics, Centre for Health Economics, University of York

† Miss Joan Greenleaf OBE BA FRPharmS
Former Regional Pharmaceutical Officer, North East Thames RHA

* Dr J C Gould MD BSc FRCP Ed FRCPath FRSE
Former Director of Central Microbiology Laboratories, Edinburgh

* B D Hoskin Esq BVMS MRCVS
Consultant to Veterinary Pharmaceutical Industry

† Mr C N Hudson MChir FRCS FRCOG FRACOG
Consultant, Obstetrics & Gynaecology, St Bartholomew's Hospital, London

† Professor T M Jones BPharm PhD FRPharmS CChem FRSC MCPP
Director, Research, Development and Medical, Wellcome Foundation Ltd

* Professor I Kennedy LLM
Professor of Medical Law and Ethics, King's College, London

* Dr M J Linnett OBE MD FRCGP
Former General Medical Practitioner, London

* Professor D McDevitt MD DSc FRCP FRCPEd FRCPI FFPM
Professor of Clinical Pharmacology, University of Dundee

* Dr P C Pietroni FRCGP MRCP DCH
General Medical Practitioner, London. Senior Lecturer in General Practice, Regent's College, Regent's Park, London

† Professor J Rhodes MD FRCP BSc ChB.
General Physician, University Hospital of Wales

* Professor J B Stenlake CBE DSc Hon DSc(Strathclyde) PhD FRPharmS CChem FRSC FRSE
Honorary Professor, University of Strathclyde, former Chairman of the British Pharmacopoeia Commission

† Gordon Tuck Esq LLB
Barrister, Legal Director for Europe and Africa, Miles Ltd

† Professor D W Vere MD FRCP FF PM(Hon)
Professor of Therapeutics, University of London

* Dr D R Williams BSc PhD CChem FRSC
Chief Chemist and Company Quality Manager, BOCM Silcock Central Laboratory

* H Cowan Wilson Esq BVMS FRCVS
General Veterinary Practitioner, Fife

* Term of office expires 31 December 1991

† Term of office expires 31 December 1993

APPENDIX III

REPRESENTATIONS CONSIDERED BY THE MEDICINES COMMISSION 1986-1990

	1986	1987	1988	1989	1990
Hearings	11	13	15	10	9
Written Representations	8	12	6	6	2

VETERINARY PRODUCTS COMMITTEE

ANNUAL REPORT 1990

TERMS OF REFERENCE

1. The Veterinary Products Committee was established in 1970 under Section 4 of the Medicines Act 1968. Its terms of reference are:
"To give advice with respect to safety, quality and efficacy in relation to the veterinary use of any substance or article (not being an instrument, apparatus or appliance) to which any provision of the Medicines Act is applicable.
To promote the collection of information relating to suspected adverse reactions for the purpose of enabling such advice to be given".

MEETINGS

2. The Committee held 11 meetings during 1990.

MEMBERSHIP

3.1 A list of members is provided at Appendix 1.
Professor Arbuthnott joined the Committee in July and Professor Blain resigned later in the year due to other commitments. Dr Calam attended as an occasional member and Professor Linton and Professor Jarrett were consulted as specialists in microbiology. Steps were being taken to strengthen the expertise still further from the beginning of 1991 by the appointment of additional members.

Declaration of Members' Interests

3.2 The Committee adopted a revised code of conduct requiring a declaration by members of their personal and non-personal interests on appointment: the code also requires that members' current interests should be published annually as an appendix to the Annual Report and this is provided at the Annex.

PRODUCTS AND PRODUCT GROUPS

Number of Applications 4.1 During 1990, the Licensing Authority received applications for 72 Product Licences 91 reviewed Product Licences and 103 Animal Test Certificates and Animal Test Certificate Exemptions. Of the Product Licence applications 10 were for new drug substances. Forty two applications were referred to the Committee for detailed consideration, of which 21 were recommended for refusal or revocation.
The Committee considered formal representations in respect of 28 applications, 20 of which were made orally, and refusal was recommended in 7 cases.

Anthelmintic Resistance 4.2 The Committee was informed of the potential dangers which might follow any further increase in anthelmintic resistance in the United Kingdom. It agreed the need for standard data sheet statements following review of this group of products, as well as the need for further research to be undertaken on anthelmintic resistance. The Chairman subsequently wrote to the Chief Scientist (MAFF) on this issue.

Aquagard 4.3 The Committee reviewed the Licence of a product containing dichlorvos for the treatment of sea lice infestation in salmon. It considered evidence concerned with environmental impact and agreed to a 2 year extension of the licence subject to provision by the company of an interim environmental report by June 1991.

Bovine Somatotropin (B.S.T.) 4.4 The Committee completed its examination of two applications for Product Licences for BST products and concluded that they should be refused. The Committee was satisfied that the products were efficacious and posed no risk to either human or environmental safety. However, the Committee was not completely satisfied, on the basis of the data presented, with some aspects of the safety and welfare of treated animals. In addition, the Committee was not wholly satisfied with some pharmaceutical aspects of one of the products. Because of the public interest surrounding these applications the Committee agreed that its conclusions should be released to the press. The Committee was subsequently informed that both companies intended to appeal to the Medicines Commission.

The Committee was informed that in April the European Community Council of Ministers had adopted a moratorium on the use of BST except for authorised field trials until 31 December 1990. It was further informed in December that proposals to extend this moratorium until the end of 1991 had been tabled.

Guidelines 4.5 The Committee approved the following guidelines in connection with the review of veterinary medicines.

1. Guidelines on the Review of products containing Herbal Remedies.
2. Guidelines for products containing Levamisole. This includes a requirement for a maximum residue limit of 0.01mg/kg.
3. Guidelines for review of products containing Minerals and Vitamins. For these products it was agreed that detailed toxicological data would be necessary for potentially toxic substances such as selenium and where appropriate, for excipients.
4. Guidelines for Anti-diarrhoeals and Electrolytes. This includes a requirement that crystal violet must be removed from all products intended for use in food animals because of its carcinogenic properties. It also contained details of some substances for which toxicological data would be required, such as boric acid, and chlorocresol.
5. Guidelines for Non Steroidal Anti Inflammatory Products.
6. Guidelines on Production and Control of Veterinary Bacterial Vaccines.
7. Guidelines for the Review of Medicinal Disinfectants.

   This guideline was produced in conjunction with the National Office of Animal Health.

Mineral Hydrocarbons 4.6 The Committee was informed of the Committee on Toxicity's (COT) conclusions that mineral hydrocarbons should be reclassified as substances for which the available information indicates definite or probable toxicity and which ought not to be permitted for use in food. It noted the views of the Department of Health that the benefits to human health outweighed the risks and that products containing mineral hydrocarbons should continue in use as medicines for human use. The Committee noted that mineral hydrocarbons were present in over 130 veterinary products, including many

vaccines and all scab-approved sheep dips. It considered that if companies were prompted to withdraw products from the market there would be serious adverse effects on the health and welfare of animals, and expressed concern that the likely trend to prophylaxis using products derived from biotechnology could be inhibited if industry were discouraged from developing and making products containing oil adjuvants of mineral hydrocarbon origin. Nevertheless, it agreed with the COT that there are insufficient data for a satisfactory toxicological assessment of mineral hydrocarbons to be made. It therefore indicated that if the licences of all veterinary medicines containing mineral hydrocarbons were reviewed it could be argued that veterinary medicines might be exempted from the proposed regulations. It also asked the licensing authority to draw up appropriate guidelines and to press for the work necessary to establish maximum residue levels for mineral hydrocarbons used in veterinary medicine to be undertaken as a matter of urgency.

Nitrovin 4.7 The Committee consulted the Department of Health's Committee on Carcinogenicity and the Department of Health's Committee on Mutagenicity because of difficulty in interpreting poorly conducted carcinogenicity studies provided by industry. In the absence of evidence to refute the hypothesis that nitrovin was a genotoxic carcinogen and could therefore give rise to possible hazard to human health the Committee advised against UK support for the inclusion of nitrovin in annexes to the EC Feed Additive Directive 70/524.

Nitroxynil 4.8 The Committee agreed that because of the lack of existing toxicological data to support an adequate acceptable daily intake for the anthelmintic (flukicide) nitroxynil and because of recent work in Northern Ireland the existing withdrawal period was inadequate. It was therefore decided that nitroxynil should be regarded as a priority item for review. It was agreed that no immediate action was required on safety grounds.

Oxolinic Acid 4.9 The Committee similarly referred this substance to the Department of Health's Committees for advice on the grounds that oxolinic acid is a DNA gyrase inhibitor and no maximum residue level existed. The Committee accepted COT advice that licence holders should provide mutagenic and other toxicity data as well as residue data to modern

standards so that a realistic withdrawal period could be set. It was recommended that all existing Product Licences for use of the substance in fish should be varied to require a withdrawal period of 500 degree days.

Review of Veterinary Products

4.10 The Committee continued to provide advice on the review of veterinary medicinal products. The review is a requirement under the Veterinary Medicines Directive EC 81/851. Licences for products issued prior to implementation of the Directive are being reviewed to ensure that the scientific data meet the standards of Directive EC 81/852. All Product Licences issued before 1 January 1984 are being fully reviewed and those issued after 1 January 1984 are subject to review on safety under the provisions of the Medicines Act. The review has been conducted by issuing guidelines on the provision of data for each review group and by the assessment of individual applications. All product categories have now been called up for review, with a view to completion by 1992.

Vitamin A

4.11 The Committee was informed of the Chief Medical Officer's advice in respect of risks to pregnant women consuming high levels of Vitamin A. The Committee considered that the contribution to human consumption from the use of veterinary medicines was low but was in favour of the removal of recommendations for the treatment of "stress" from data sheets of veterinary injectable products containing Vitamin A. It also suggested that veterinarians and farmers should be advised to use Vitamin A preparations only where necessary and that farmers seek a veterinary opinion before administering such products.

RESIDUES

Establishment of Maximum Residue Levels (MRLs)

5.1 The Committee adopted principles for establishing future maximum residue levels for veterinary medicinal substances by accepting that they should be based solely on toxicological data, using no effect levels, appropriate safety factors and a knowledge of human food intake to determine an acceptable daily intake. Of particular concern was how to take account of injection site levels of residues and it was agreed that a differential MRL approach should be adopted.

Albendazole

5.2 The Committee agreed an MRL of 0.01 mg/kg for muscle, fat and milk, 0.5 mg/kg for liver and kidney for albendazole, a benzimidazole anthelmintic.

Spectinomycin 5.3 The Committee agreed an MRL of 2mg/kg for all edible tissues for spectinomycin, an aminocyclitol antibiotic.

Residues of Chlortetracycline 5.4 The Committee was informed of residue surveillance data indicating that approximately 10% of home produced and imported pig kidney samples contained residues of chlortetracycline at concentrations above the MRL set by the V.P.C. of 50 mcg/kg. The Committee recommended that once the results had been confirmed by further surveillance, a publicity campaign similar to that mounted for sulphonamides, on the necessity to adhere to withdrawal periods should be undertaken.

SUSPECTED ADVERSE REACTIONS SURVEILLANCE SCHEME

6. The Committee received quarterly reports of the Licensing Authority's activities under the Suspected Adverse Reactions Surveillance Scheme. Reports of suspected adverse reactions to licensed veterinary products or products undergoing trials in accordance with Animal Test Certificates were received from pharmaceutical companies and through voluntary reporting by veterinary surgeons and the general public under the Freepost "yellow form" arrangements.
A total of 317 reports were received during 1990 and investigated. Liaison with the Health and Safety Executive and with the Department of Health took place where suspected reactions occurred in humans. The Committee noted in particular the increase in incidents concerned with horses and cattle. Useful information is being gathered on possible drug and hypersensitivity reactions in the horse, while in cattle, subjects under investigation include problems associated with mineral and trace element products.

EUROPEAN DEVELOPMENTS

Developments in Community Licensing Law 7.1 The Committee was informed of progress in negotiations on draft directives updating the Community's licensing laws in the light of technological development, and extending them to cover veterinary vaccines and the distribution of veterinary medicines. It was informed that the Council of Ministers had adopted the two directives (as Directives 90/676 and 90/677) in December 1990. The Committee was also informed of a package of further Commission proposals, setting out a basis for the free movement of medicinal products in the European Community to apply from 1 January 1993. These would establish a new European Medicinal Agency linked to the creation of a new

Centralised Community procedure for assessing both human and veterinary products. This would be compulsory for all biotechnology products and veterinary medicines used as growth promoters. It would be available on an optional basis for other high technology products and medicines containing a new active substance. Consideration by the agency would lead to the issue of licences valid throughout the Community. Establishment of a Community wide adverse reaction reporting scheme is also proposed.

Feed Additives and Products Administered via Drinking Water

7.2 The Committee considered 7 applications for product licences; 1 was recommended for granting and 4 were recommended for refusal. Decisions on the remainder were deferred to enable further information to be obtained from the applicants. Two applications were for additives controlled by the feed additives Directive 70/524/EEC (as amended). The Committee also considered data in connection with the withdrawal period for a chlortetracycline product administered in pig feed and recommended that this period be extended by a compulsory variation to the product licence.

Validity of Council Directive 88/146 - prohibiting the use in livestock of certain substances having a hormonal action.

7.3 The Committee was informed of the European Court of Justice ruling on the challenge by the Féderation Santé Animale (FEDESA) which had sought judicial review of the United Kingdom's action in implementing the directive. The European Court of Justice found no factors affecting the legality of the directive.

OTHER MATTERS

Simplified Licensing Scheme

8.1 The Committee formally approved a simplified licensing scheme whereby approval may be given to the grant of licences to deal with particular problems. It was envisaged that these might include the treatment of disease conditions in minor species, the treatment of emergency or sporadic disease, subject to the product being designated P.O.M. The scheme is designed to alleviate problems of availability of such medicines but without compromising the licensing criteria required by the Medicines Act.

Tagamet

8.2 The Committee took note of the changes in licensing procedures implemented by the licensing authority in the wake of the House of Lords judgement in a case between Smith Kline and French, manufacturers of the drug known as Tagamet, and the Department of Health. The Court ruled that in certain circumstances when considering a licence application, the

Professor I K M Smith* MSc, PhD, MRCVS	*Department of Pathology Royal Veterinary College, London*
Dr S Venitt** BSc PhD	*Team Leader, Molecular Carcinogenesis Section Institute of Cancer Research*
Dr D H Calam MA, D.Phil, C Chem, FRSC	*Head of Chemistry Division National Institute for Biological Standard and Control Hertfordshire Attended as an occasional member*

* Term of office expires 31.12.91

** Term of office expires 31.12.93

BRITISH PHARMACOPOEIA COMMISSION

ANNUAL REPORT FOR 1990

Introduction

1. The British Pharmacopoeia Commission, appointed under Section 4 of the Medicines Act 1968, is responsible under Section 99(1) of the Act for preparing new editions of the British Pharmacopoeia and the British Pharmacopoeia (Veterinary) and for keeping these up to date. It provides advice to the United Kingdom delegation to the European Pharmacopoeia Commission (of which the United Kingdom is a member by virtue of its obligations under the Convention on the Elaboration of a European Pharmacopoeia, Treaty Series No 32: 1974) and it selects British Approved Names under Section 100 of the Medicines Act. The membership of the Commission during 1990 is given in Appendix I.

2. The Addendum 1990 to the *British Pharmacopoeia 1988* was published in April followed by publication of *British Approved Names 1990* together with its first supplement in September.

3. The British Pharmacopoeia Commission, which met five times during 1990, has appointed twelve Committees and seven Consultative Groups to assist it in its work. There were twenty meetings of Committees and Groups throughout the year and four additional *ad hoc* meetings on specialised topics. Membership of the Committees and Groups is given in Appendix II. The Commission expresses its gratitude for the invaluable contribution made by these members towards the maintenance and improvement of standards in the British Pharmacopoeia.

4. The Commission noted with pleasure awards that had been made to two former Chairmen. Sir Frank Hartley was elected a Fellow of the Imperial College of Science, Technology and Medicine, University of London. Professor J B Stenlake received the Charter gold medal for 1990 of the Royal Pharmaceutical Society of Great Britain. In addition, Mr G F Phillips was appointed as a Visiting Professor at Glasgow College and Dr M A Simmonds, a member of the nomenclature committee, was appointed Professor at The School of Pharmacy, University of London.

5. With regret the Commission noted the deaths of Professor Sir Edward Wayne (former Chairman of the Commission) and Dr H S Bean (former member of the erstwhile committees on sterile materials and tests for sterility).

British Pharmacopoeia 1988

6. The *Addendum 1990* to the *British Pharmacopoeia 1988* was published in April and came into effect on 1 September 1990. *Amendments No 4* were issued also with effect from 1 September 1990. The Addendum costs £23.00 and is available from HMSO Publications Centre, from Government Bookshops or from the Pharmaceutical Press (ISBN 0 11 321270 4). *Amendments No 4* are supplied free of charge to registered purchasers of the British Pharmacopoeia or may be purchased separately as above (ISBN 0 11 321310 7, price £1.95).

7. The Addendum includes seven monographs that are new to the British Pharmacopoeia and a considerable number of amended texts. Procedures for carrying out the test for uniformity of content of active ingredient have been added to a further number of monographs for capsules and tablets. In the interests of safety, the use of radioactive uranyl acetate as a reagent in identification tests for sodium has been deleted from many monographs.

8. During the year the Commission began a comprehensive review of the purpose and functions of the Pharmacopoeia and its place in the overall arrangements for ensuring the quality of medicines. This review will include all aspects of the Commission's approach to the elaboration of monographs and other texts.

Policy

9. A declared policy of the Commission is to reduce reliance on test methods involving animals wherever this is compatible with its primary objective of providing satisfactory pharmacopoeial standards. In pursuance of this policy the introduction of liquid chromatographic procedures for the assay of insulin has allowed removal of the biological assay from the eight monographs for insulin preparations.

British Pharmacopeia (Veterinary) 1985

10. Amendments Nos 4 and 5 to the *British Pharmacopoeia (Veterinary) 1985* were published with effective dates of 1 March 1990 and 1 September 1990 respectively. These amendments may be purchased from HMSO Publications Centre or from bookshops (ISBN 0 11 321278 X, price £1.40 and ISBN 0 11 321312 3, price £3.40 respectively).

11. A monograph for Amoxycillin Oily Injection was included for the first time in the British Pharmacopoeia (Veterinary) by means of *Amendments No 5.*

European Pharmacopoeia

12. The European Pharmacopoeia Commission met on three occasions during 1990. In addition, forty-four meetings of its Groups of Experts were held.

13. A list giving the current membership of the United Kingdom delegation and the names of British members of Groups of Experts is included in Appendix III. The British Pharmacopoeia Commission records its appreciation and gratitude to the delegation and to the Group members who generously and willingly devote their time, attention and expertise to this important task.

14. Monographs in the twelfth and thirteenth fascicules of the second edition of the European Pharmacopoeia were implemented on 1 January 1990 and appeared in edited form in the *British Pharmacopoeia 1988 Addendum 1990*. Notice was given that monographs and other texts in the fourteenth fascicule, which was published during the year, were to be implemented on 1 January 1991.

15. The European Pharmacopoeia Commission is seeking to shorten the time taken for the elaboration of monographs. To this end a procedure for adapting monographs from national pharmacopoeias has been established. The first five monographs so elaborated in this way were approved for publication at the 78th session of the European Pharmacopoeia Commission in November 1990.

16. During the year, discussions between representatives of the European Pharmacopoeia Commission, the *Conseil Européen des Fédérations de l'Industrie Chimique* (CEFIC) and the European Federation of Pharmaceutical Industries Associations (EFPIA) were held to encourage increased co-operation between the Pharmacopoeia and industry. In recognition that the European Pharmacopoeia should play an enhanced role in the European regulatory system, discussions were also held with drug regulators from the European Community and European Free Trade Association (EFTA) countries.

17. Secretaries of European national pharmacopoeial authorities now meet twice a year to discuss matters of mutual concern and to promote and further the harmonisation of standards.

List of Names

18. As provided for in Section 65(8) of the Medicines Act 1968, a supplementary list of *Approved Synonyms* for names at the head of monographs of the European Pharmacopoeia was prepared and this was published in December 1990 on the recommendation of the Medicines Commission.

19. In accordance with the provisions of Section 100 of the Medicines Act, the British Pharmacopoeia Commission has continued to select or devise nonproprietary names for medicinal substances suitable for use as titles of monographs should it be decided to include the materials in the British Pharmacopoeia or any other compendium prepared under Section 99 of the Act.

20. During the year, a new revised and consolidated edition of the list of names, *British Approved Names 1990*, was published together with *Supplement No 1* which contained a further 19 new names. The enlarged booklet restored the proprietary names cross-index omitted from the last edition and introduced a useful molecular formula index.

21. The British Pharmacopoeia Commission continued to participate in the work of the World Health Organization in issuing nonproprietary names for medicinal substances. It also co-operated with authorities engaged in nomenclature work in other countries, in particular with the United States Adopted Names Council. In April, the secretary to the Commission's Nomenclature Committee attended consultations that led to the publication during the year of a further list (No 63) of proposed International Nonproprietary Names.

Commission Laboratory

22. The main emphasis in the past year has been the laboratory assessment of new monographs. This has been greatly assisted by a better response to requests to manufacturers for information. The revision of existing British Pharmacopoeia monographs for both human and veterinary products continued. This was usually in response to changes brought about by the publication of a European Pharmacopoeia monograph or comments from users of the British Pharmacopoeia and British Pharmacopoeia (Veterinary).

23. As in the past, support has been provided to UK members of European Pharmacopoeia Groups of Experts. Laboratory staff are now directly involved through membership of three of these groups.

24. The demand for British Pharmacopoeia Chemical Reference Substances (BPCRS) after increasing for several years has levelled off. The price was increased from £30 to £35 in April.

25. To support the *Addendum 1990* an additional seven reference materials were established. This is in addition to the monitoring programme in which eleven current BPCRS were retested and thirty-six were replaced in order to maintain the stock.

International Harmonisation

26. Following preliminary discussion in 1989, the Secretary and Scientific Director now meets twice yearly with the chief executives of the European, Japanese and United States pharmacopoeias with the object of working towards international harmonisation of pharmacopoeial standards. A start is being made with the specifications for some pharmaceutical excipients, including lactose and magnesium stearate.

Liaision with other organisations

27. Co-operation continues with members of staff of the National Institute for Biological Standards and Control and the Central Veterinary Laboratory, Weybridge. The Commission is glad to acknowledge the significant contribution that these workers have made over a wide range of topics including antibiotics, hormones, immunological and other products. Staff of the Medicines Testing Laboratory, Edinburgh have once again provided a considerable amount of helpful advice and comment.

28. Important contact has also been maintained on a wide range of topics with various overseas authorities, in particular with the Japanese and United States pharmacopoeias, the United States Adopted Names Council, the Therapeutic Goods Administration Laboratories, Canberra, Australia, the Health Protection Branch, Health and Welfare, Canada and a number of official laboratories in countries party to the European Pharmacopoeia Convention.

29. Collaboration with the Pharmaceuticals Unit of the World Health Organization (WHO) continues to be an important aspect of the Commission's work. During the year two members of staff participated in WHO consultations.

APPENDIX I

MEMBERSHIP OF THE BRITISH PHARMACOPOEIA COMMISSION

* D Ganderton BPharm PhD FRPharmS *(Chairman)*
Visiting Professor in Pharmaceutics in the University of London

* P Turner MD BSc FRCP FFPM HonMRPharmS FIBiol *(Vice-Chairman)*
Professor of Clinical Pharmacology in the University of London

* W G Allen MRCVS
A Veterinary Surgeon

† A O Betts BSc MA PhD MRCVS
Professor Emeritus of the University of London; formerly Principal of The Royal Veterinary College, University of London

* D H Calam MA DPhil CChem FRSC
Head of Chemistry Division, National Institute for Biological Standards and Control

† A C Caws BSc CChem MRSC
A Senior Analyst in the Pharmaceutical Industry

† J F Chissell MSc CChem FRSC
A Manager of Regulatory Affairs in the Pharmaceutical Industry

† J M Dewdney BVSc MRCVS PhD CBiol FIBiol
A Director of Biotechnology in the Pharmaceutical Industry

† A F Fell BPharm PhD FRPharmS CChem FRSC FIQA
Professor of Pharmaceutical Chemistry in the University of Bradford

† F Fish OBE BPharm PhD FRPharmS
Professor Emeritus of the University of London; formerly Dean of The School of Pharmacy, University of London

† J A Goldsmith BSc PhD CChem FRSC FIQA
A Director of Technical Operations in the Pharmaceutical Industry; Visiting Professor to the University of Strathclyde

* E Griffiths BSc PhD DSc CChem FRSC
A Member of the Division of Bacteriology, National Institute for Biological Standards and Control

* J M Midgley BSc MSc PhD FRPharmS CChem FRSC
Professor of Pharmacy and Chairman and Head of the Department of Pharmacy in the University of Strathclyde

* G F Phillips OBE MSc CChem FRSC
Superintendent, Environmental and Forensic Services, Laboratory of the Government Chemist; Visiting Professor to Glasgow College

† L E Ramsay MB ChB FRCP
Consultant Physician, Royal Hallamshire Hospital; Reader in Clinical Pharmacology and Therapeutics, University of Sheffield

† N Randall PhD CChem FRSC FIQA
A Director of Quality Assurance in the Pharmaceutical Industry

* G D Rees BPharm PhD MRPharmS CChem MRSC FIQA
A Manager of Quality Assurance in the Pharmaceutical Industry

† B A Wills BPharm PhD FRPharmS CChem FRSC
Formerly Chief Pharmacist, Department of Health

† Term of office ends 31 December 1991
* Term of office ends 31 December 1993

APPENDIX II

BRITISH PHARMACOPOEIA COMMISSION

Membership of Committees and Groups

COMMITTEES

A: Medicinal Chemicals	A C Caws *(Chairman)*, N Randall *(Vice-Chairman)*, A L Barber, A G Davidson, C Ratcliffe, G D Rees, J R Slater, J B Stenlake, P R Wood
B: Medicinal Chemicals	A F Fell *(Chairman)*, J M Midgley *(Vice-Chairman)*, F Bailey, F Breslin, P H Cobb, H B Davis, B M Everett, A Holbrook, M Martin-Smith, B Midcalf, R N Thornhill (*Corresponding member* B Warren)
C: General Chemicals	G F Phillips *(Chairman)*, J M Midgley *(Vice-Chairman)*, P N Brittain, A Burbage, B M Everett, A F Fell, A Holbrook, R E King, S U Ruff, J M Sprake, C H Thorpe
D: Medicinal Chemicals	J A Goldsmith *(Chairman)*, J F Chissell *(Vice-Chairman)*, G P R Carr, L A Gifford, A Holbrook, J P Jefferies, D Moriau, W J Mossop, W J Poling, M Ray-Johnson, A A Wagland
E: Antibiotics	J F Chissell *(Chairman)*, D H Calam *(Vice-Chairman)*, D Adams, E Addison, A E Bird, A K Coulter, P J Duff, D Moriau, G D Rees, A H Thomas, I R Williams (*Corresponding member* R K Howard)
F: Pharmacy	B A Wills *(Chairman)*, D Ganderton *(Vice-Chairman)*, R Baird, D J G Davies, A L Davison, T Dott, J A Farwell, W L Hooper, W Lund, J M Padfield, W N Pitkethly, G Smith, D F Spooner, M P Summers, H E C Worthington
G: Crude Drugs and Galenicals	F Fish *(Chairman)*, A C Caws *(Vice-Chairman)*, L Anderson, D Griffin, K Helliwell, B P Jackson, P Linley, J D Phillipson, A R Rixon (*Corresponding member* J R Slater)
H: Biological Materials	D H Calam *(Chairman)*, D R Bangham *(Vice-Chairman)*, A F Bristow, K R Butterworth, J M Dewdney, B V Fisher, N Randall, J Tranter (*Corresponding member* G A Sabey)
J: Immunological Products	A O Betts *(Chairman)*, P A Knight *(Vice-Chairman)*, I G S Furminger, E Griffiths, A M T Lee, J Melling, P D Minor, D H Thornton, P W Wells (*Corresponding member* D I Magrath)
L: Surgical Dressings	F Fish *(Chairman)*, T D Turner *(Vice-Chairman)*, D T Britton, D A Conyers, D J Harris, D Metcalfe, P J Perry, R J M Smith, S Thomas
M: Nomenclature	G F Phillips *(Chairman)*, P Turner *(Vice-Chairman)*, D H Calam, E W Godly, P W Golightly, W Hancock, Sir Frank Hartley, G R Kitteringham, D F Lee, G P Moss, H McNulty, M A Simmonds, A Wade (*Corresponding member* A Wehrli)
N: Veterinary Medicine and Doses	A O Betts *(Chairman)*, W G Allen *(Vice-Chairman)*, R J Bywater, A R M Kidd, D G McBeath, D A Rutty

CONSULTATIVE GROUPS

K: Blood Products	K J Ayling *(Chairman)*, T W Barrowcliffe, R S Lane, R J Perry, T Snape, D P Thomas, L Vallet, J G Watt
S: Human Medicines	P Turner *(Chairman)*, M W Greaves, M H Lader, L E Ramsay, A Richens, G N Volans, J D Williams
T: General Analytical Methods	A F Fell *(Chairman)*, G F Phillips *(Vice-Chairman)*, F Bailey, J Berridge, G P R Carr, A G Davidson, L A Gifford, W I Stephen
U: Reagents	N Randall *(Chairman)*, E J Newman, L F Oughton, W I Stephen
V: Radioactive Materials	A F Fell *(Chairman)*, S R Hesslewood, D E Lovett, D Lui, A M Millar, R D Pickett, D J Silvester, T L Whateley
W: Surgical Sutures	F Fish *(Chairman)*, G G Pafford, T W Roylance
X: Plastics and Plastic Containers	B A Wills *(Chairman)*, J G Cook, M N Duncan, D J B Galliford, J E Pentelow, J L Sharp

APPENDIX III

EUROPEAN PHARMACOPOEIA COMMISSION

UNITED KINGDOM DELEGATION:		D Ganderton *(Head of delegation)*
		D H Calam
		A R Rogers
	Alternates:	M L Rabouhans
		B A Wills

MEMBERS OF GROUPS OF EXPERTS FROM THE UNITED KINGDOM:

Group 1	Biological Methods and Statistical Analysis	M L Rabouhans
	Sub-group on Microbial Contamination	A L Davison
	Sub-group on Limulus Amoebocyte Lysate Test	G A Sabey
Group 2	Chemical Methods	A Islam
Group 3	Nomenclature and Drafting	A R Rogers
Group 4	Physical and Physico-chemical Methods	A Islam
Group 5	Reagents	E J Newman
Group 6	Biological Substances	A F Bristow
	Sub-group on Blood and Blood Products	T Snape
	Sub-group on Insulin Preparations	B V Fisher
Group 7	Antibiotics	D H Calam
Group 8	Dressings and Ligatures	A R Rogers *(Chairman)*, T D Turner
Group 9	Inorganic Chemistry	A F Fell
Group 10A	Organic Chemistry (Synthetic Products)	A Islam
Group 10B	Organic Chemistry (Synthetic Products)	A R Rogers *(Chairman)*, A Holbrook
Group 10C	Organic Chemistry (Synthetic Products)	A C Caws
Group 11	Organic Chemistry (Natural Products)	A G Davidson
	Sub-group on Vitamin A	G F Phillips
	Sub-group on Cellulose Ethers	L J Blackwell
Group 12	Galenicals	D Ganderton
Group 13	Pharmacognosy	J D Phillipson
Group 13H	Fatty Oils and Derivatives	J D Phillipson
Group 14	Radioactive Compounds	R D Pickett
Group 15	Vaccines and Sera	I G S Furminger
Group 15V	Veterinary Vaccines and Immunosera	A M T Lee
Group 16	Plastics for Pharmaceutical Use	J G Cook

COMMITTEE ON THE REVIEW OF MEDICINES

ANNUAL REPORT FOR 1990

INTRODUCTION

1. The Committee on the Review of Medicines (CRM) was established in 1975 under Section 4 of the Medicines Act 1968. Its terms of reference are :

   "to consider and give advice on the safety, quality and efficacy, in relation to human use, of any substance or article to which any provision of the Medicines Act is applicable in connection with the review by the Licensing Authority of the safety, quality and efficacy of substances or articles in respect of which product licences granted under Part II of the Act are in force."

2. The CRM is concerned mainly with medicines which already were on the market when the Medicines Act came into force and which have Product Licences of Right (PLRs). Unless subject to one of the exemptions to the EEC pharmaceutical directives, all products with PLRs must be reviewed so as to ensure that they meet the standards imposed by those directives (of which the principal ones relevant to such products are 65/65/EEC, 75/318/EEC and 75/319/EEC.)

COMMITTEE MEMBERSHIP

3. The membership of the Committee is shown at Appendix I.

COMMITTEE ACTIVITIES

4. The Committee held five meetings in 1990. During the year the CRM held 10 hearings and considered 14 written representations against their provisional advice. The Committee also considered a further 28 applications referred to them. These figures reflect the imminent completion of the Review. Details are given at Appendix II.

5. During the year the Committee considered applications for reviewed licences for gripe water preparations and agreed general guidelines for their assessment, relating in particular to the level of alcohol and sodium bicarbonate content. They also recommended that these products should not be given to neonates or children over 1 year.

6. The Committee considered the continued use of podophyllum in some oral preparations and recommended that in view of its mutagenicity and carcinogenic potential, these products should be removed from the market.

7. The Committee considered the use of hexachlorophane in medicinal products and advised the Licensing Authority that the 2,3,7,8-TCDD level in hexachlorophane should be controlled to 2ppb.

8. The Committee completed their review of antacid suspensions in relation to preservative efficacy.

9. The Committee's concerns over the lack of efficacy and safety of ephedrine in suppositories led to the reformulation of the product concerned.

10. The professional staff resources were strengthened towards the end of 1989 enabling an increased rate of clearance of applications to be achieved. Statistics of the review progress are given at Appendix III. The number of applications remaining to be processed under the review programme is 576.

APPENDIX I

MEMBERSHIP OF THE COMMITTEE ON THE REVIEW OF MEDICINES

Professor D H Lawson MD FRCP (Ed) FRCP (Glasg) FFPM (Chairman),
Consultant Physician, Royal Infirmary, Glasgow. Visiting Professor, University of Strathclyde.

Mr A G Amias FRCS FRCOG
Consultant Obstetrician and Gynaecologist, St Georges Hospital, London.

Professor T H D Arie MA BM BCh FRCP FRCPsych FFPHM DPM (Eng)
Professor of Health Care of the Elderly, Queens Medical Centre, Nottingham.

Professor C J Bulpitt MD MSc FRCP
Professor of Geriatric Medicine, Royal Postgraduate Medical School, Hammersmith Hospital.

Professor J E Carless BPharm MSc PhD FRPharmS
Emeritus Professor of Pharmaceutics, University of London.

Mr W M Darling CBE FRPharmS
Pharmacist. Chairman, South Tyneside Health Authority.

Professor F Fish OBE BPharm PhD FRPharmS
Former Dean, School of Pharmacy, University of London.

Professor F Harris MD MMed (Paed) FRCP (Ed) FRCP (Lond)
Professor of Paediatrics and Dean, School of Medicine, University of Leicester.

Professor J G R Howie MD PhD FRCP (Ed) FRCGP
Professor of General Practice, University of Edinburgh.

Dr B J Kirby MB ChB FRCP
Deputy Director, Post Graduate Medical School, University of Exeter. Consultant Physician, Royal Devon and Exeter Hospital.

Professor Rona Mackie MD FRCP FRCPath FRSE
Professor of Dermatology, University of Glasgow.

Dr Agnes McKnight MD FRCGP DObst RCOG
Senior Lecturer, Department of General Practice, Queens University, Belfast.

Professor J M Midgley BSc MSc PhD CChem FRSC FRPharmS
Chairman and Head, Department of Pharmacy, Strathclyde University, Glasgow.

Dr A T Proudfoot MB ChB FRCP (Ed)
Consultant Physician, Royal Infirmary, Edinburgh, and Director of Scottish Poisons Information Bureau.

Dr L E Ramsay MB ChB FRCP
Consultant Physician, Royal Hallamshire Hospital, Sheffield.

APPENDIX II

1. COMMITTEE PROCEEDINGS 1990

1.1 Reference to CRM for advice under Section 20(3)* of the Act

a. applications	28
b. written representations (following notification under Section 21(1)*)	14
c. hearings (following notification under Section 21(1)*)	10
Total	52

1.2 Advice given to Licensing Authority following reference

a. licence should be granted without amendment to application	4
b. licence should be granted with amendment to the application (as accepted by the applicant)	19
c. CRM unable to recommend that a reviewed product licence should be granted	29
Total	52

2. COMMITTEE PROCEEDINGS 1986-1990

Referred to CRM for advice:	**1986**	**1987**	**1988**	**1989**	**1990**
Applications	93	52	45	51	28
Written Representations	34	22	19	23	14
Hearings	8	12	8	16	10
Advice:					
Licence should be granted	2	1	nil	11	4
Licence should be granted with amendment	47	29	40	24	19
Licence should not be granted	85	56	32	55	29

* Note: Section 20(3) of the Medicines Act provides that the licensing authority shall not refuse to grant a licence on any grounds relating to safety, quality or efficacy of the product except after consultation with the appropriate Committee. Section 21(1) makes provision for an applicant for a licence to make written representations to, or appear before the Committee before advice is given to the licensing authority. For this purpose the Committee is required to notify the applicant in writing of the grounds for any unfavourable advice.

APPENDIX III

PROCESSING OF APPLICATIONS FOR REVIEWED PRODUCT LICENCES

1. Applications in house, awaiting action at 1 January 1990 — 1687

2. Applications Processed

   i. reviewed licences granted in 1990 — 936

   ii. applications withdrawn — 172

   iii. applications refused — 3

   iv. total applications processed — 1119

3. Applications in-house awaiting assessment, advice or licensing action at 31 December 1990 — 576

4. Review Applications Processed from 1986 to 1990

	1986	1987	1988	1989	1990
Licences granted	435	639	565	719	936
Total number applications processed	704	831	735	910	1119

COMMITTEE ON DENTAL AND SURGICAL MATERIALS

ANNUAL REPORT FOR 1990

INTRODUCTION

1. The Committee on Dental and Surgical Materials was established by the Medicines (Committee on Dental and Surgical Materials) Order 1975 pursuant to the powers contained in Section 4 of the Medicines Act 1968. Its terms of reference are :

   a. to give advice with regard to the safety, quality and efficacy in relation to human or animal use of:

      (i) substances or articles for dental or surgical use being instruments, apparatuses or appliances to which any provision of the Medicines Act 1968 is applicable or medicinal products or other substances or articles (not being instruments, apparatuses or appliances) to which any provision of the Medicines Act 1968 is applicable and in respect of which neither the Committee on Safety of Medicines nor the Veterinary Products Committee is the appropriate Committee, whether or not used in conjunction with any other such substance, article, instrument, apparatus or appliance.

      (ii) substances and fluids described in paragraph 2 of Schedule 1 to the Medicines (Specified Articles and Substances) Order 1976 (substances and fluids for use with contact lenses or blanks).

   b. to promote the collection and investigation of information relating to adverse reactions for the purpose of giving such advice.

COMMITTEE MEMBERSHIP

2. A list of members of the CDSM is at Appendix I.

COMMITTEE ACTIVITIES

3. The CDSM held six meetings during the year and held seven hearings against their provisional advice. The number of cases referred to the Committee for advice is given in Appendix II.

4. A variety of topics were considered by the Committee during the year, on which they gave advice to the Licensing Authority. Several new chemical entities were considered including a new antibiotic for ophthalmic use, and a new antimicrobial agent for use as a contact lens disinfectant.

5. In addition, applications to the Committee for Proprietary Medicinal Products (CPMP) of the European Community in respect of a topical contraceptive agent and a novel local treatment for periodontitis were considered.

6. After consideration of several ophthalmic products indicated for use immediately after surgery, the Committee confirmed advice given on previous occasions that products for peri-operative use should be presented as unpreserved single use preparations.

7. The Committee considered several dental preventive products as part of the Review of Product Licences of Right, and advised that the inclusion of cariogenic sugars in such products was inappropriate.

8. Following the Committee's consideration of yellow card reports, the Committee reviewed adverse reactions in association with topical ophthalmic products for the treatment of glaucoma. A Current Problems article was published requesting further reports relating to ophthalmic beta-blocking agents.

9. The Committee noted that the introduction in the UK of licensing for contact lens care products had resulted in high standards of quality, safety and efficacy. The Committee reviewed the MAL 53 Guidelines as amended in 1988.

10. In view of their concerns over the safety of critical medical devices, the Committee continued to monitor closely the development of the EC Directive on Medical Devices, following the adoption of the Active Implantable Medical Devices Directive on 20 June 1990.

APPENDIX I

MEMBERSHIP OF THE COMMITTEE ON DENTAL AND SURGICAL MATERIALS

Professor C L Berry MD PhD FRCPath (Chairman)
Professor of Morbid Anatomy
London Hospital Medical College

Professor W Bonfield BSc Eng PhD DIC ARSM C Eng FIM MBES Hon MCORS
Head of Department of Materials
Dean of Engineering Queen Mary and Westfield College
University of London

Mr R J Buckley MA BM BCh FRCS
Consultant Ophthalmologist and Director of Contact Lens and Prosthesis Department
Moorfields Eye Hospital
London

Professor H D Edmondson BDS LDS FDSRCS MB ChB MRSC LRCP DARCPS DDS
Head of Department of Oral Surgery
University of Birmingham

Mr J A Elias FRCOG
Consultant Obstetrician and Gynaecologist
Greenwich Health District

Professor M Elstein MD MB ChB MSc FRCOG
Professor of Obstetrics and Gynaecology
University Hospital of South Manchester
Manchester

Mr J W Howe MB DO FRCS Ed FCophth
Consultant Ophthalmologist Royal Victoria Infirmary Newcastle-Upon-Tyne
Senior Lecturer in Ophthalmology
University of Newcastle-Upon-Tyne

Professor G C Jenkins PhD MB FRC Path
Professor of Haematology
University of London

Professor R B Johns PhD (London) LDSRCS (Eng)
Professor of Restorative Dentistry
University of Sheffield
Sheffield

Professor I D A Johnston MB MCh BAO FRCS
Professor of Surgery
The Medical School
University of Newcastle Upon Tyne

Dr J R Larke BSc PhD FBOA
Senior Lecturer in Ophthalmic Optics
Department of Optometry
University of Wales
Institute of Science and Technology

Mr B J Meakin B Pharm FRPharmS
Senior Lecturer in Pharmaceutics
School of Pharmacy & Pharmacology, and Principal, Centre for Drug Formulation Studies
University of Bath

Mr B Midcalf B Pharm MRPharmS
Principal Pharmacist (Quality Control)
St James University Hospital, Leeds

Professor C Scully PhD MD MDS FDS FFD MRCPath
Head of Department of Oral Medicine, Surgery and Pathology
Bristol Dental School and Hospital

Miss Ann B Sutherland MD (Edin) FRCSE
Retired Consultant Plastic Surgeon
Bangour General Hospital and The Royal Hospital for Sick Children
Edinburgh
West Lothian

Professor D E M Taylor TD MB ChB Ed FRCS FRCS Ed
Department of Mechanical Engineering
Brunell University
Uxbridge

Mr T D Turner OBE M Pharm FLS FRPharmS MCPP
Senior Lecturer Pharmacognosy
The Welsh School of Pharmacy
University of Wales College of Cardiff

Professor B Whiting MD FRCP
Professor of Clinical Pharmacology
Department of Materia Medica, University of Glasgow

Professor E G Woodward PhD FBCOA DCLP
Head of Department of Optometry and Visual Science
The City University
London

NOTE

1. Term of office for all members expires 31 December 1992.

Members appointed for specific meeting:-

May	-	Mr J D Brice FRCS *Consultant Neurosurgeon, Regional Neurological Centre, Southampton General Hospital*
July	-	Dr E Chantler BSc PhD *Senior Lecturer in Biochemistry, Department of Obstetrics and Gynaecology, University of Manchester*
		Mr F E Loeffler FRCS FRCOG *Consultant Obstetrician and Gynaecologist, St Mary's and Queen Charlotte's Hospitals, London*
November	-	Professor A M Breckenridge MSc MD FRCP *Professor of Clinical Pharmacology, Liverpool University*
		Professor L Symon TD FRCS *Professor of Neurosurgery, National Hospital for Neurology and Neurosurgery, London*

APPENDIX II

COMMITTEE ACTIVITIES	PRODUCT LICENCES +	CLINICAL TRIAL CERTIFICATES
A. APPLICATION FOR LICENCES AND CERTIFICATES		
Number of applications referred to Committee during the year	51	Nil
B. ADVICE ON APPLICATIONS		
Grant advised without hearing or representations:		
in accordance with applications	Nil	
other than in accordance with application	15	Nil
Grant advised following hearing or representations (Section 21(1) action) *	2	
Refusal advised	10	
Applications withdrawn	Nil	
C. APPLICATIONS OUTSTANDING		
Applications subject to Section 21(1) action * not yet complete	24	Nil
D. ADVICE ON EXISTING LICENCES AND CERTIFICATES		
Variations determined:	3	
Grant advised	1	
Refusal advised	2	
Revocation considered	5	

Notes:-

\+ Includes both "new" and Reviewed Licences.

* Section 21(1) makes provision for an applicant for a licence to make written representation to, or appear before, the Committee before advice is given to the Licensing Authority. For this purpose the Committee is required to notify the applicant of the grounds for any unfavourable advice.

APPENDIX III

COMMITTEE ON DENTAL AND SURGICAL MATERIALS

The Committee advises the Licensing Authority on applications for new licences and certificates, review cases, renewals and variations for the products medication below. CDSM also collects and interprets reports on adverse reactions associated with these products. The therapeutic classes of products dealt with by the Committee include:-

i. surgical materials such as bone cements, tissue adhesive etc;

ii. certain dressings etc in which the medicines is intended to have a curative function and is not limited to sterilising the dressing;

iii. intra-uterine contraceptive devices and any other instrument, apparatus or appliance inserted in the uterus (including the cervix) for the purpose of contraception: certain vaginal and tubal contraceptives;

iv. other surgical materials of the form of:-

a. Ligatures, sutures, binding materials etc prepared from the tissue of an animal and used wholly or partly in surgical operations

b. any other surgical ligature or suture etc prepared from any source which is capable of being absorbed by the body tissues

c. any absorbent or protective material capable of being absorbed by the body and used wholly or partly for use in surgical operations;

v. contact lens fluids and certain medicines placed in the eye;

vi. all licensable dental materials and medicines used specifically for the treatment and prevention of dental disease, including local anaesthetics used in dental practice.

COMMITTEE ON SAFETY OF MEDICINES

ANNUAL REPORT FOR 1990

TERMS OF REFERENCE

1. The Committee on Safety of Medicines (CSM) was established in 1970 under Section 4 of the Medicines Act 1968. Its terms of reference are:

   To give advice with respect to safety, quality and efficacy in relation to human use of any substance or article (not being an instrument, apparatus or appliance) to which any provision of the Medicines Act 1968 is applicable.

   To promote the collection and investigation of information relating to adverse reactions for the purpose of enabling such advice to be given.

MEMBERSHIP

2. A list of members of the Committee and Sub-Committees during 1990 is at the end of this report. Members are appointed for a three year period.

   The Committee wishes to record its appreciation of the valuable work of the Sub-Committees, and its professional and administrative secretariat.

MEETINGS

3. The Committee held 11 meetings during 1990. Two day meetings were held in February and July to enable the Committee to complete its business.

CONSIDERATION OF APPLICATIONS

4. The tables below provide a summary of applications and appeals for product licences (PLs) considered by the Committee during 1990:

The Committee considered and advised on a total of 232* product licence applications. Table A gives a breakdown between United Kingdom applications and those of the European Commission's Committee for Proprietary Medicinal Products (CPMP).

Table A

First Consideration by CSM

	Grant Advised	Grant not Advised
	Number of PLs	Number of PLs
New Active Substances (NAS)	35 (34)	65 (66)
Abridged	39 (41)	52 (36)

CSM Advice on CPMP Applications

	Number of PLs
New Active Substances (NAS)	28 (21)
Abridged	11 (2)

* In the case of two applications, the Committee deferred its decision in order to obtain further information from the Company.

Note: 1989 figures given in brackets

CSM - ADVICE FOLLOWING HEARINGS AND WRITTEN REPRESENTATIONS 1990

Table B

22 Hearings scheduled
9 Representations resolved with a hearing
18 Written Representations (includes 3 pre-hearings)

Hearings:

Analysis

New Active Substances	Yes	= 2 (8)
	Yes on condition	= 12 (11)
	No	= 5 (4)

Abridged	Yes	= 1 (1)
	Yes on condition	= 0 (1)
	No	= 1 (0)
Adverse Reactions	Yes	= 0 (0)
	Yes on condition	= 1 (0)
	No	= 0 (0)

Pre-Hearings: used on 4 occasions
The issues were resolved on 3 occasions and remained unresolved on 1.

Written Representations:

Analysis

New Active Substance	Yes	= 1 (4)
	Yes on condition	= 8 (9)
	No	= 1 (9)
Abridged	Yes	= 0 (3)
	Yes on condition	= 3 (0)
	No	= 5 (2)

Note: 1989 figures given in brackets

4.1 The total number of applications referred to the Committee in 1990 was 16% greater than in the preceding year. Of the product licence applications which were considered by the Committee in 1990 excluding CPMP applications, 31.8% were considered to be satisfactory for the grant of a licence at the first consideration.

4.2 Product licence (PL) applications for new active substances (UK and CPMP) accounted for 55% of all applications considered by the Committee in 1990.

4.3 The Committee noted a reduction in the average number of volumes of data submitted in support of an application from 58.9 volumes in 1989 to 52.3 volumes in 1990.

4.4 124 (80 NAS and 44 abridged) letters were written to companies informing them that the Committee was provisionally intending to advise against the grant of a PL. These detailed 1,274 (914 for NAS and 360 for abridged) points of issue; an average of 11 points per NAS application and 8 points per abridged application.

4.5 The Committee considered on average 21 applications per meeting compared to 16 per meeting in 1989.

4.6 The Committee was consulted and gave advice to the Licensing Authority and the CPMP on a number of variations to product licences.

4.7 During the year the Committee continued its policy of writing to Chief Executives of pharmaceutical companies to commend particularly good applications and express dissatisfaction with particularly bad ones. Six letters were sent, of which four were complimentary. Other comments about the quality of applications are regularly conveyed to companies by the Committee's Secretariat.

CONSIDERATION OF OTHER MATTERS

5. In addition to applications and appeals the Committee also considered and commented on papers of medical and pharmaceutical interest. The total number of such papers considered in 1990 was 88, of which 41 dealt with adverse reactions associated with medicinal products (ADRs), 7 dealt with CPMP matters and the remainder were general information items.

Bovine Spongiform Encephalopathy (BSE)

5.1 - see paragraph 17 of the 1989 Report

The Working Party under the chairmanship of Professor J G Collee, of the University of Edinburgh Medical School, met three times during 1990 to advise the Licensing Authority on issues involving BSE and human medicinal products.

Litigation

5.2 - see paragraph 31 of the 1989 Report

Litigation against the Committee continues in respect of opren, benzodiazepines and factor VIII blood products.

SAFETY OF MARKETED PRODUCTS

6. Newly introduced products (denoted by a black triangle symbol in data sheets, BNF, MIMS and advertisements) are under intensive surveillance by the Committee. At the beginning of 1990, 58 products were under intensive surveillance, over the year 21 drugs were removed from surveillance while 28 new products were added to surveillance. A list of these drugs was sent to all doctors with the August issue of "Current Problems" to provide ready reference when reporting adverse reactions to the Committee.

6.1 The Committee considered the safety of a number of marketed products including:

L-Tryptophan - see paragraph 19 of the 1989 Report

The Committee warned doctors in December 1989 of the association between L-tryptophan and eosinophilia-myalgia syndrome (EMS), first recognised in the USA. By April 1990 two UK reports of possible cases of EMS in association with L-tryptophan had been received. As a result, Pacitron and Optimax (oral preparations of L-tryptophan used in the treatment of depression) were withdrawn from general use voluntarily by the manufacturers. On 12 April the Chairman wrote to all doctors and pharmacists to explain the situation. No action was taken against the product licences, and Pacitron and Optimax remain available for use by named-patients in whom no other treatment is deemed suitable. No cases of EMS have been reported in association with parenteral products containing L-tryptophan and these remain fully available. By August 1990, 11 reports of possible cases of EMS had been received and doctors were informed of these cases in an article published in "Current Problems 29". Investigation into the cause of the syndrome is continuing and the Committee is closely monitoring the situation.

Human Insulin - see paragraph 19 of the 1989 Report.

This problem was reconsidered by the Committee in April 1990 when further information was available regarding the possible association of human insulin with impaired perception of hypoglycaemia and sudden death in young diabetics. Review of case reports, clinical studies and mortality data revealed no evidence of any problem associated specifically with human insulins. This view was communicated to doctors in an article published in "Current Problems 29". The Secretariat are in close communication with the British Diabetic Association and the Committee is continuing to monitor the situation as new evidence becomes available.

Chloraseptic Chloraseptic contains 1.4% phenol and is mainly used as a throat spray in the symptomatic treatment of sore throat. By May 1990 the Committee had received four reports of oedema of the epiglottis and/or larynx leading to respiratory difficulties associated with the use of Chloraseptic. One of the patients died, and two of the survivors required emergency hospital treatment. The Committee considered that Chloraseptic should not be used by patients with epiglottitis. Therefore the licence was varied to contra-indicate the product's use in children under the age of 6 years and appropriate label warnings were introduced. Doctors

were alerted to the problem in a Current Problems article published in May 1990, and since publication of the article a number of further reports have been received. The safety of this product remains under close surveillance.

Fenoterol (Berotec)

Fenoterol is a beta-2-agonist used in the treatment of asthma. Case-control studies from New Zealand have suggested that fenoterol may be implicated in the increase in asthma deaths which has been noted there during the last decade. The Committee reviewed these and other studies, and found them to be inconclusive. The Committee also reviewed evidence relating to the dosage of fenoterol and recommended that the product be reformulated at a lower dose. The manufacturer has submitted an application in respect of this and it will be considered by the Committee early next year.

Xamoterol (Corwin)

- see paragraph 19 of the 1989 Report

The safety of xamoterol continued to be reviewed during the year. It became evident that the distinction between moderate and severe heart failure was clinically difficult to make and inevitably as the disease progressed, patients moved to the high-risk group. As a consequence, the drug was further restricted to use in chronic mild heart failure only and contra-indicated in patients with moderate to severe heart failure. It was recommended that treatment with xamoterol should be initiated in hospital after careful objective assessment of the patient. The starting dose was reduced, advice given on regular follow up of patients and the side effect profile of the drug clarified to take into account its beta-blocking potential. These recommendations were included in "Current Problems 28" and in a letter in April 1990 from the Company marketing the product, highlighting the changes in the use of the drug.

Pimozide (Orap)

As a consequence of reports of sudden unexpected death and ECG abnormalities in patients receiving pimozide, the safety of the drug was reviewed by the Committee. Following assessment of all the relevant information, changes were made in the dose schedule of the drug and recommendations made for pre-treatment ECGs in all patients and periodic post treatment ECGs in those patients receiving pimozide in excess of 16mg daily. Detailed advice in the use of pimozide was given in "Current Problems 29" and by a letter from the Company to all doctors.

Vitamin A

The Chief Medical Officer cautioned women who are or who may become pregnant on the use of Vitamin A supplements because of evidence suggesting that high levels of Vitamin A may cause birth defects. The Committee therefore reviewed the teratogenic potential of Vitamin A and advised that medicinal products which contain Vitamin A should carry an appropriate warning on the label if the recommended daily dose exceeded the recommended daily allowance of Vitamin A (750 mcg).

Mesalazine (Asacol)

Nine reports of serious nephrotoxicity associated with the use of mesalazine in the UK had been received. As the data sheet stated that no renal toxicity had been reported in patients taking Asacol, an item on the nephrotoxic potential of Asacol would be included in the next Current Problems in early 1991, and the data sheet amended.

Communication with Doctors, Dentists and Pharmacists on matters of Drug safety

6.2 Three editions of "Current Problems", the Committee's drug safety information bulletin for doctors, dentists and pharmacists were issued as follows:

Current Problems 28 (May 1990) contained articles on:

1. Chloraseptic Throat Spray and oedema of the epiglottis and larynx.
2. Xamoterol (Corwin) - revised indications, contra-indications, dose schedule and warnings.
3. B_2-agonists, xanthines and hypokalaemia.
4. Bronchospasm associated with cardioselective and topical β-blockers.
5. Liquid paraffin - restricted indications and availability.
6. Heparin-induced thrombocytopenia.
7. Adverse reactions - what to report.

Current Problems 29 (August 1990) contained articles on:

1. Cardiotoxic effects of pimozide.
2. Human insulins: hypoglycaemia unawareness and sudden death.

3. Update on L-tryptophan and eosinophilia-myalgia syndrome.
4. Respiratory and neuromuscular effects of propafenone.
5. Glauline (metipranolol eye-drops) and uveitis.
6. Withdrawal of Propess controlled release PGE2.
7. New drugs under intensive surveillance.
8. The Yellow Card Scheme.

Current Problems 30 (December 1990) contained articles on:

1. Fatalities following intrathecal vinblastine and vincristine.
2. Clozaril induced neutropenia and the Clozaril Patient Monitoring Services.
3. Nephrotoxicity associated with mesalazine (Asacol).
4. Zopiclone (Zimovane) and neuro-psychiatric reactions.
5. How can we help you report suspected adverse drug reactions?
6. Current Problems index.
7. Information on Bjork-Shiley heart valves from the Medical Devices Directorate.

Reporting of suspected Adverse Reactions

6.3 Adverse reactions to medicinal products are reported to the Committee on a voluntary basis by doctors, dentists and coroners under the yellow card scheme. Reports are also received from pharmaceutical companies as a requirement of their product licences. The Committee very much appreciates the co-operation of those who submit reports.

The table below shows the number of reports received since 1980:

Reports of Suspected Adverse Reactions Received for Registration

1980	10,179
1981	13,032
1982	10,922

1983	12,689
1984	12,163
1985	12,652
1986	15,527
1987	16,431
1988	19,022
1989	19,246
1990	18,084

There has been a fall in the number of reports received this year in comparison with recent previous years. There are probably a number of reasons for this. They may include the increasing use of GP computer systems for prescribing which limit the use of FP10 pads which contain reporting forms, but the reasons for the reduced use of yellow cards are unclear. The Committee is actively examining ways of encouraging reporting.

Currently, yellow slips can be found in the British National Formulary, the ABPI data sheet compendium and MIMS as well as the FP10 prescription pads. An analysis of all reports received in 1990 is set out in the following table:

Reports of Suspected Adverse Reactions Received in 1990

Figures for 1989, where appropriate are shown in brackets

	TOTAL	% OF TOTAL
Yellow Cards	5723 (7811)	33.0 (40.6)
BNF Slips	5621 (5116)	32.4 (26.6)
FP10 Slips	3098 (3896)	17.9 (20.2)
Data Sheet Slips	287 (59)	1.6 (0.3)
Industry Reports	1809 (1870)	10.4 (9.7)

Red Alert	0 (35)	0.0 (0.2)
Anaesthetists Reports	85 (98)	0.5 (0.5)
Cutaneous Reports	6 (47)	0.0 (0.2)
MIMS Slips	485 (169)	2.8 (0.9)
Others	217 (-)	1.2 (-)

Yellow Card for Anaesthetists

6.4 - see paragraph 27 of the 1989 Report

The pilot project to encourage reporting of drug reactions to anaesthetic agents, launched in September 1988 by the Committee, the College of Anaesthetists, and the Association of Anaesthetists, was reviewed in 1990. The findings were most encouraging and the Committee agreed to the anaesthetic reporting form being included permanently in the range of reporting forms.

Hospital Pharmacists Reporting scheme

6.5 - see paragraph 28 of the 1989 Report

Following the success of a number of schemes in which pharmacists have encouraged doctors to report suspected ADRs, the Committee have recognised the skills of hospital pharmacists in identifying ADRs and have endorsed a pilot scheme of direct ADR reporting by hospital pharmacists to the Committee which will be carried out in Newcastle.

New design of Yellow Card Reporting form

6.6 A new design of the yellow card was introduced in December 1990 and distributed in the Lancet and BMJ accompanied by an editorial in the latter.

ADROIT Adverse Reactions computer system

6.7 - see paragraph 30 of the 1989 Report

The development of the new computer system, ADROIT (Adverse Drug Reaction Online Information Tracking) to support the monitoring of adverse drug reactions was continued in 1990. The new system combines image storage on laser disk of ADR reports linked with a relational data base and will go live in early 1991. It will increase the speed of handling ADR reports and greatly facilitate the analysis and assessment of these reports.

APPENDIX I

MEMBERSHIP OF THE COMMITTEE ON SAFETY OF MEDICINES

Professor A W Asscher BSc MD FRCP (Chairman)
Dean of St George's Hospital Medical School, London

Professor C L Berry MD PhD FRCPath
Professor of Morbid Anatomy, University of London

Professor S S Bleehen BA MB BChir FRCP
Professor of Dermatology, Sheffield University and
Consultant Dermatologist, Royal Hallamshire Hospital

Professor T G Booth OBE BPharm PhD FRPharmS MCPP
Professor of Pharmacy Practice, University of Bradford

Professor A M Breckenridge MD MSc FRCP FRCPE FRS (Ed)
Professor of Clinical Pharmacology, University of Liverpool

Dr R G Finch FRCP FRCPath
Consultant and Senior Lecturer in Microbial Diseases, City Hospital, Nottingham

Professor A T Florence PhD DSc FRSC FRSE FRPharmS
Dean of the School of Pharmacy, University of London

Professor E C Gordon-Smith MA MSc FRCP FRCPath
Professor of Haematology, St George's Hospital Medical School, London

Professor F Harris MD MMed(Paed) FRCP (Ed) FRCP
Professor of Paediatrics and Dean of the Faculty of Medicine, University of Leicester

Professor H S Jacobs MD FRCP
Professor of Reproductive Endocrinology, The University College and Middlesex Hospital School of Medicine, London

Dr W A Jerrett MB BCh FRCGP
General Practitioner, Glamorgan

Professor M J S Langman MD FRCP
Professor of Medicine, University of Birmingham

Professor D H Lawson MD FRCP FFPM
Consultant Physician, Glasgow Royal Infirmary,
Visiting Professor, University of Strathclyde, Glasgow

Mr F E Loeffler FRCS FRCOG
Consultant Obstetrician and Gynaecologist, St Mary's & Queen Charlotte's Hospitals, London

Professor A E M McLean BM PhD FRCPath
Professor of Toxicology, The University College and Middlesex Hospital School of Medicine, London

Professor J M Midgley BSc MSc PhD CChem FRSC FRPharmS
Head of Department of Pharmacy, University of Strathclyde

Dr S A Montgomery MD BSc FRCPsych
Reader in Psychiatry, St Mary's Hospital, London

Dr Celia M Oakley MD FRCP FACC FESC
Consultant Cardiologist, The Royal Post Graduate Medical School, London

Professor M D Rawlins BSc MD FRCP(Lon) FRCP(Edin) FFPM
Professor of Clinical Pharmacology, Wolfson Institute of Clinical Pharmacology, University of Newcastle

Dr D A J Tyrrell CBE MS DSc FRCP FRCPath FRS

Professor M P Vessey MA MD FRCP FRCGP FFPHM FRCOG FRS
Professor of Social and Community Medicine, Radcliffe Infirmary, Oxford

APPENDIX II

SUB-COMMITTEE ON CHEMISTRY, PHARMACY AND STANDARDS (CPS)

Professor A T Florence PhD DSc FRSC FRSE FRPharmS (Chairman)

Professor J R Brown BSc MSc PhD FRPharmS CChem FRSC CBiol FIBiol

Dr D H Calam MA DPhil CChem FRSC

Dr R T Calvert BSc PhD FRPharmS

Professor J E Carless BPharm MSc PhD MRPharmS

Dr A G Davidson BSc PhD MRPharmS

Professor D J Davies MSc PhD FRPharmS

Dr A L Davison PhD FIBiol

Professor F Fish OBE BPharm PhD FRPharmS

Professor D Ganderton BPharm PhD FRPharmS

Mr B Midcalf BPharm MRPharmS

Professor J M Midgley BSc MSc PhD CChem FRSC FRPharmS

Professor J M Newton BPharm PhD FPS

Professor M S Parker BSc MSc PhD FRPharmS MCPP FRSA

Professor J E Rees BPharm PhD FRPharmS

Professor G T Tucker BPharm PhD

APPENDIX III

SUB-COMMITTEE ON SAFETY, EFFICACY AND ADVERSE REACTIONS (SEAR)

* Professor M D Rawlins BSc MD FRCP(Lon) FRCP(Edin) FFPM (Chairman)

* Dr Linda Beeley MA FRCP

Professor A T Birmingham BSc MB BS MRCS LRCP

* Professor A M Breckenridge MD MSc FRCP FRCPE FRS (Ed)

Dr R L Carter MA DM DSc FRCPath

Professor D S Davies BSc PhD CChem FRSC

Dr P B Farmer MA DPhil

Dr R Finch FRCP FRCPath

Professor S T Holgate BSc MD FRCP

* Professor C J Hull MBBS DA FCAnaes

Professor D R Jones BA MSc PhD

Dr B J Kirby MB FRCP

* Professor M J S Langman MD FRCP

Dr A V P MacKay MA BSc PhD MBChB FRCPsych FRCP

Professor A E M McLean BM PhD FRCPath

Professor B K Park BSc PhD

* Professor P A Routledge PhD FRCP

Professor C G Swift PhD FRCP

Dr G N Volans BSc MD FRCP

Dr D W Wall MB ChB(Hons) MRCP FRCGP

* Members of the Adverse Reactions Group (ARGOS) of SEAR

APPENDIX IV

SUB-COMMITTEE ON BIOLOGICALS

Dr D A J Tyrrell CBE MD DSc FRCP FRCPath FRS (Chairman)

Professor J W Almond BSc PhD - resigned 29 October 1990

Professor J E Banatvala MA MD FRCPath DCH DPH

Dr E B Gingold BSc(Hons) MSc PhD

Professor K Gull BSc PhD - appointed 31 July 1990

Professor G Janossy MD PhD MRCPath DSc

Dr S L Jeffcoate MB BChir PhD FRCPath

Professor J Melling MSc PhD FIBiol FRPharmS

Professor C Mims MD FRCPath - resigned 12 March 1990

Dr P Minor BA PhD

Dr R J Perry BSc PhD MRSC CChem

Dr G C Schild BSc PhD FIBiol

Dr T J Snape BA PhD CChem MRSC

Dr E Tuddenham MD FRCP FRCPath - resigned 12 March 1990

APPENDIX V

JOINT CSM / JCVI SUB-COMMITTEE ON ADVERSE REACTIONS TO VACCINES AND IMMUNOLOGICAL PRODUCTS (ARVI)

Professor A M Breckenridge MD MSc FRCP FRCPE FRS (Ed) (Chairman)

Professor J E Banatvala MA MD MRCP FRCPath

Dr C Bowie MRCP MFCM

Dr N Cavanagh MD MRCP

Dr P E M Fine VMD PhD

Professor F Harris MD MMED(Paed) FRCP FRCP(Ed)

Dr C R Kennedy MD MRCP BA MBBS

Professor D G McDevitt DSc MD FRCP(Ed) FRCPI

Dr B W McGuiness MD FRCP DObst RCOG DCH RCPS

Professor S R Meadow MA DCh FRCP

Professor D L Miller MA FRCP FFCM DPH MD

Dr E Miller MB BS BSc

Dr P Minor BA PhD

Dr D Reid MD FRCP FFCM DPH

Dr D A J Tyrrell CBE MD DSc FRCP FRCPath FRS

DECLARATION OF INTERESTS: A CODE OF PRACTICE FOR MEMBERS OF THE MEDICINES COMMISSION AND SECTION 4 COMMITTEES* AND SUB-COMMITTEES

INTRODUCTION

1. This code of practice guides members of the Medicines Commission and associated committees (see below) as to the circumstances in which they should declare an interest in the pharmaceutical industry.

2. The advice of the Commission and the Committees concerns matters which are connected with the pharmaceutical industry and it is therefore desirable that members should have a good understanding of the work of the industry. It is also desirable that some members should have practical experience of the scientific problems of product development. The pharmaceutical industry relies heavily on the advice of doctors and pharmacists outside the industry in, for example, the universities. To avoid any public concern that commercial interests might affect the advice of the Commission and Committees, Ministers have decided that the arrangements which govern relationships between members and the pharmaceutical industry and information on significant and relevant interests should be on public record.

SCOPE AND DEFINITIONS

3. This code applies to members of the following bodies:

   a. Medicines Commission Under Section 2 of the Medicines Act 1968, the Chairman and members of the Medicines Commission are appointed by Ministers after consultation with such organisations as they consider appropriate. The membership must include persons who appear to Ministers to have wide and recent experience of, and to have shown capacity in, the practice of medicine, the practice of veterinary medicine, the practice of pharmacy, chemistry and the pharmaceutical industry. Appointments to the Medicines Commission are for a term of 4 years.

* Excluding the British Pharmacopoeia Commission and its Committees

b. Section 4 Committees The Committee on Safety of Medicines, the Committee on the Review of Medicines, the Veterinary Products Committee and the Committee on Dental and Surgical Materials are Committees established under Section 4 of the Medicines Act 1968. Ministers appoint the Chairmen and members of the Section 4 Committees. The term of office is usually 3 years.

c. Sub-Committees Section 4 Committees may establish sub-committees, and appoint their Chairmen and members. The following Sub-Committees are currently functioning: Sub-Committee on Safety, Efficacy and Adverse Reactions; Sub-Committee on Biologicals; Sub-Committee on Chemistry, Pharmacy and Standards; Sub-Committee on Adverse Reactions to Vaccines and Immunisation.

4. In this code, "pharmaceutical industry" means

a. companies, partnerships or individuals who are involved with the manufacture,sale or supply of medicinal products subject to the licensing provisions in the Medicines Act;

b. trade associations representing companies involved with such products;

c. companies, partnerships or individuals who are directly concerned with research, development or marketing of a medicinal product which is being considered by the Commission or one of the Committees or Sub-Committees.

References to "the pharmaceutical industry" include cases involving a single company.

5. In this code, "the Department" means the Department of Health.

DIFFERENT TYPES OF INTEREST

6. The following is intended as a guide to the kinds of interests which should be declared. Where a member is uncertain as to whether an interest should be declared he or she should seek guidance from the Department or, where it may concern a particular product which is to be considered at a meeting, from the Chairman at that meeting. If members have interests not specified in these notes but which they believe could be regarded as influencing their advice they should declare them. However, neither members nor the Department are under an obligation to search out links between one company and another, for example where a company with which a member is connected has an interest in a pharmaceutical company of which the member is not aware and could not reasonably be expected to be aware.

Personal interests

7. A personal interest involves payment to the member personally. The main examples are:-

a. Consultancies: any consultancy, directorship, position in or work for the pharmaceutical industry which attracts regular or occasional payments in cash or kind.

b. Fee-Paid Work: any work commissioned by the pharmaceutical industry for which the member is paid in cash or kind.

c. Shareholdings: any shareholding in or other beneficial interest in shares of the pharmaceutical industry. This does not include shareholdings through unit trusts or similar arrangements where the member has no influence on financial management.

Non-personal interests

8. A non-personal interest involves payment which benefits a department for which a member is responsible, but is not received by the member personally. The main examples are:-

a. Fellowships: the holding of a fellowship endowed by the pharmaceutical industry.

b. Support by the Pharmaceutical Industry: any payment, other support or sponsorship by the pharmaceutical industry which does not convey any pecuniary or material benefit to a member personally but which does benefit his/her position or department eg

i. a grant from a company for the running of a unit or department for which a member is responsible;

ii. a grant or fellowship or other payment to sponsor a post or a member of staff in the unit for which a member is responsible. This does not include financial assistance for students;

iii. the commissioning of research or other work by, or advice from, staff who work in a unit for which the member is responsible.

Members are under no obligation to seek out knowledge of work done for or on behalf of the pharmaceutical industry within departments for which they are responsible if they would not normally expect to be informed.

DECLARATION OF INTERESTS

Declaration of interests to the Department

9. Members of the Commission, the Committees and Sub-Committees should inform the Department in writing when they are appointed of their current personal and non-personal interests. Only the name of the company and the nature of the interest is required; the amount of any salary, fees, shareholding, grant etc need not be disclosed to the Department. An interest is current if the member has an on-going financial involvement with the pharmaceutical industry, eg. if he or she holds shares in a pharmaceutical company, has a consultancy contract with the pharmaceutical industry, or if the member or the department for which he or she is responsible is in the process of carrying out work for the pharmaceutical industry. Members are asked to inform the Department at the time of any change in their personal interests, and will be invited to complete a declaration form once a year. It would be sufficient if changes in non-personal interests are reported in the annual declaration form following the change. (Non-personal interests involving less than £1000 from a particular company in the previous year need not be declared to the Department.)

Special position of Chairmen

10. It is not appropriate for the Chairmen of the Medicines Commission and the Section 4 Committees to have any current personal interests in the pharmaceutical industry. The position of Sub-Committee Chairmen is the same as for all other members, since Sub-Committees report to the main Committee rather than giving advice in their own right.

Declaration of interests at meetings and participation by members

11. Members are required to declare relevant interests at Commission, Committee or Sub-Committee meetings, and to state whether they are personal or non-personal interests and whether they are specific to the product under consideration or non- specific.

a. A member must declare a personal specific interest if he or she has at any time worked on the product under consideration and has personally received payment for that work, in any form, from the pharmaceutical industry. The member shall take no part in the proceedings as they relate to the product, except, at the Chairman's discretion to answer questions from other members. If the interest is no longer current, the member may declare it as a lapsed personal specific interest.

b. A member must declare a personal non-specific interest if he or she has a current personal interest in the pharmaceutical company concerned which does not relate specifically to the product under discussion.

The member shall take no part in the proceedings as they relate to the product, except, at the Chairman's discretion, to answer questions from other members.

c. A member must declare a non-personal specific interest if he or she is aware that the department for which he or she is responsible has at any time worked on the product but the member has not personally received payment in any form from the pharmaceutical industry for the work done. The member may take part in the proceedings unless he or she has personal knowledge of the product through his or her own work or through direct supervision of other people's work, in which case he or she should declare this and not take part in the proceedings (except to answer questions).

d. A member must declare a non-personal non-specific interest if he or she is aware that the department for which he or she is responsible is currently receiving payment from the pharmaceutical company concerned which does not relate specifically to the product under discussion. The member may take part in the proceedings unless, exceptionally, the Chairman rules otherwise.

12. The examples of "personal", "non-personal" and "current" interests given in the previous paragraphs should be read in the context of paragraphs 6,7, and 8. "Taking part in the proceedings" includes both speaking and voting. A member who is in any doubt as to whether he or she has an interest which should be declared, or whether to take part in the proceedings, should ask the Chairman for guidance. The Chairman has the power to determine whether or not a member with an interest shall take part in the proceedings.

13. If a member is aware that a product under consideration is or may become a competitor of a product manufactured, sold or supplied by a company in which the member has a current personal interest, he or she should declare the interest in the company marketing the rival product. The member should seek the Chairman's guidance on whether to take part in the proceedings.

RECORD OF INTERESTS

14. A record is kept in the Department of

a. names of members who have declared interests to the Department on appointment, as the interest first arises or through the annual declaration, and the nature of the interest.

b. names of members who have declared interests at meetings of the Medicines Commission, Section 4 Committees and Sub-Committees, giving dates, names of relevant products and companies, details of the interest declared and whether the member took part in the proceedings.

PUBLICATION

15. Information about interests declared by members to the Department will be published each year with the Annual Reports of the Medicines Commission and Section 4 Committees (normally published in July).

MEDICINES COMMISSION

MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS AS FOLLOWS:

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
PROFESSOR DAME ROSALINDE HURLEY (CHAIRMAN)	NONE	NONE			
DR I D AITKEN	MOREDUN ANIMAL HEALTH LIMITED	DIRECTOR AND FEE	NONE		
MR M J S BUTLER	NONE		NONE		
DR M G CARTER	ICI PLC	SALARY AND SHAREHOLDER			
PROFESSOR W I CRANSTON	NONE		SERVIER LIMITED ELI LILLY DUNCAN FLOCKHARD LILLY BAYER EFAMOL ICI KABI VITRUM AYERST LABORATORIES LTD SQUIBB PHARMACIA	RESEARCH FUNDING	YES

Note - Members are invited at each meeting to declare any interest in applicant companies, and the Chairman, with the help of legal advisers where necessary, rules on the propriety of attendance

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMP ANY	NATURE OF INTEREST	WHETHER CURRENT
PROFESSOR W I CRANSTON (CONT'D)			BEECHAM PHARMACEUTICALS FISONS PLC GLAXO RESEARCH LTD ROUSSEL UCLAF (PARIS) RECKITT AND COLMAN SYNTEX DUPHAR SEARLE MSO MAY AND BAKER PFIZER SANDOZ STERLING WINTHROP (HG) TRAVENOL (BAXTER'S) CIBA-GEIGY WYETH LABS SCHERING HEALTH CARE LTD UPJOHN PLC ABBOT PHARMACEUTICALS NAPP ALLEN AND HANBURYS BOEHRINGER/SMITH KLINE AND FRENCH	} } } } } } } } } } } } RESEARCH } FUNDING } } } } } } } } }	YES
PROFESSOR P D'ARCY	NONE		NONE		

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
PROFESSOR A P DAWID	GLAXO GROUP RESEARCH LTD	CONSULTANCY/ GRANT	NEUROENDOCRINOLOGY AND OPTHALMOLOGY RESEARCH TRUST	TRUSTEE	YES
	FASTMALT LTD	DIRECTOR/ SHAREHOLDER	IPSEN BEAUFOUR	SUPPORT FOR ABOVE TRUST	YES
PROFESSOR A D DAYAN	BIOGEN INC	ADVICE ON A PRODUCT	GLAXO PLC	RESEARCH GRANT	NO
	BOOTS COMPANY ICI	} SHARE HOLDING	SMITH KLINE BEECHAM	RESEARCH GRANT	NO
	MERCK, SHARPE & DOHME	TOXICOLOGICAL ADVICE			
	ML LABORATORIES PLC ROCHE PRODUCTS LTD SMITH KLINE BEECHAM SYNTEX	} TOXICOLOGICAL } ADVICE } ON A } PRODUCT			
	WELLCOME	TOXICOLOGICAL ADVICE			
	JOHN WYETH & BROTHER LTD	TOXICOLOGICAL ADVICE ON A PRODUCT			

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
PROFESSOR M F DRUMMOND	MERCK, SHARP & DOHME ICI UPJOHN LTD THE WELLCOME FOUNDATION LTD	CONSULTANCY, GROUP OF PRODUCTS	LIPHA RHONE-POULENCE THE WELLCOME FOUNDATION	RESEARCH GRANT	NO YES YES
	SANDOZ LTD	CONSULTANCY PARTICULAR PRODUCT	MERCK COMPANY FOUNDATION	GIFT TO MY DEPT	YES
DR J C GOULD	SMITH KLINE BEECHAM RESEARCH DIVISION	AD HOC CONSULTANCY	NONE		
MISS J C V GREENLEAF	INNOVEX LIMITED DAVID BULL LABORATORIES	CONSULTANCY CONSULTANCY	NONE		
MR B HOSKIN	ICI PLC WELLCOME PLC	SHAREHOLDING SHAREHOLDING, PENSION	NONE		
MR C N HUDSON	NONE		NONE		
PROFESSOR T M JONES	WELLCOME PLC	BOARD MEMBER SHARE HOLDER	NONE		

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
PROFESSOR I KENNEDY	NONE		SMITH KLINE BEECHAM THE WINTHROP FOUNDATION GLAXO APPEAL TRUST	SUPPORT OF RESEARCH	YES YES YES
DR M J LINNETT	ICI	SHARE HOLDER	NONE		
PROFESSOR D G MCDEVITT	DRUG DEVELOPMENT SCOTLAND LTD	DIRECTOR (EX-OFFICIO)	BAYER BEECHAM BOEHRINGER INGELHEIM BOOTS BRISTOL-MYERS SQUIBB CYANAMID GLAXO HOESCHT ICI JANSSEN LEDERLE MERCK, SHARP & DOHME MERRELL-DOW ORGANON PARKE-DAVIS PFIZER ROTHMANS RHONE-POULENC (RORER) ROUSSELL G D SEARLE SMITH KLINE BEECHAM SQUIBB	RESEARCH GRANT	YES YES YES YES YES YES YES YES YES YES YES YES YES YES YES YES YES YES YES YES YES
	WARNER-LAMBERT	MEDICAL REFEREE			
	3M HEALTH CARE LTD	CONSULTANCY			
	BOEHRINGER INGELHEIM LTD	CONSULTANCY REPORT			

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
DR P C PIETRONI	NONE		NONE		
PROFESSOR J RHODES	SMITH KLINE BEECHAM TILLOTTS PHARMA AG NORWICH EATON (USA) FARMITALIA CARLO ERBA LTD	CONSULTANCY	SMITH KLINE BEECHAM TILLOTTS PHARMA AG NORWICH EATON (USA) FARMITALIA CARLO ERBA LTD CEDONA (HOLLAND) ELAN CORPORATION	FINANCE FOR RESEARCH STAFF	YES YES YES YES YES YES
			GLAXO LABORATORIES	GRANT FOR RADIOLOG-ICAL EQUIPMENT	YES
PROFESSOR J B STENLAKE	AMERSHAM INTERNATIONAL BOOTS ICI SMITH & NEPHEW	SHARE HOLDER	NONE		
	WELLCOME FOUNDATION LTD	1. SHARE HOLDER 2. ROYALTY INCOME FROM TRACRIUM (ATRACURIUM) 3. RESEARCH CONTRACT			

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
MR G C TUCK	MILES LTD	COMPANY SECRETARY AND LEGAL DIRECTOR (SALARIED)	NONE		
PROFESSOR D W VERE	RHONE-POULENC RORER LTD	CONSULTANCY (NOT LIMITED)	SANDOZ, BASEL	GRANT TO DEPARTMENT	NO
DR D R WILLIAMS	NONE	NONE			
MR H C WILSON	NONE	NONE			

VETERINARY PRODUCTS COMMITTEE

MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS AS FOLLOWS:-

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
PROFESSOR J ARMOUR (CHAIRMAN)	MERCK RESEA.RCH LABORATORIES	PARASITOLOGY CONSULTANCY	NONE		
PROFESSOR J P ARBUTHNOTT	S.K.B.	CONSULTANCY:FEES, ANTI-INFECTIVES	SKB KIMBERLEY CLARK UNILEVER	} RESEARCH } GRANT DONATION TOWARDS RESEARCH	YES YES YES
PROFESSOR P M BIGGS	HOECHST UK LTD	CONSULTANCY	NONE		
PROFESSOR P G BLAIN	ICI PLC	CONSULTANCY	MSD	CLINICAL TRIAL	NO
	STERLING WINTHROP	MEMBER OF CLINICAL COMMITTEE	ICI PLC	RESEARCH GRANT	YES
PROFESSOR J W BRIDGES	NONE		NONE		
PROFESSOR J BROWN	MERCK SCHERING PL.OUGH	CONSULTANCY CONSULTANCY	SERONO	CONSULT-ANCY	NO
	JOUVEINAL	CONSULTANCY	GLAXO	GRANTS	YES

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
MR D S COLLINS	NONE		NONE		
MR P J CROSSMAN	S.K.B	FEES FOR CLINICAL TRIALS	NONE		
DR S DENYER	AMERSHAM INTERNATIONAL	CONSULTANCY			
	BEECHAM PHARMACEUTICALS	CONTRACT RESEARCH AND CONSULTANCY	NONE		
	GLAXO PHARMACEUTICALS	CONTRACT RESEARCH AND CONSULTANCY			
MISS K GIBSON	NONE		NONE		
PROFESSOR D E JACOBS	SOREX LTD	CONSULTANCY	BAYER COOPERS PITMAN-MOORE HOECHST PFIZER SMITHKLINE & BEECHAM TEMANA	)))))	RESEARCH/ CONSULTANCY	YES
PROFESSOR O JARRETT	NONE		NONE		

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
PROFESSOR LAMMING	NONE		ABBOTT LABORATORIES CIBA-GEIGY HOECHST SERONO	SUPPORT FOR RESEARCH	YES
PROFESSOR P LEES	NORBROOK LABORATORIES LTD	CONSULTANCY	RYCOVET (GRAMPIAN HOLDINGS) INTERVET INTERVET NORBROOK LABORATORIES VETOQUINOL LTD PANAPHARMA LTD AMERICAN CYANAMID SCHERING PLOUGH/ESSEX BOEHRINGER INGLEHEIM	SUPPORT FOR RESEARCH	NO NO YES YES YES YES YES YES YES
DR K A LINKLATER	NONE		COOPERS ANIMAL HEALTH PITMAN-MOORE HOECHST (UK) LTD JANSSEN ANIMAL HEALTH MSD AGVET PFIZER LTD INTERVET UK LTD	COMMERCIAL CONSULTANCY	YES YES YES YES YES YES YES
PROFESSOR A J LINTON	NORBROOK LABORATORIES LTD	CONSULTANCY	NONE		

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
PROFESSOR I SMITH	DUPHAR	CONSULTANCY	DUPHAR BAYER	RESEARCH	YES YES
DR S VENITT	NONE	NONE			

COMMITTEE ON THE REVIEW OF MEDICINES

MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON PERSONAL INTERESTS AS FOLLOWS:

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
MR A G AMIAS	NONE		NONE		
PROFESSOR T H D ARIE	BOOTS ICI	} SHARE-HOLDER	NONE		
PROFESSOR C J BULPITT	WELLCOME FOUNDATION LTD	WELLCOME PROTOCOL REVIEW COMMITTEE CONSULTANCY FEE	ICI LIMITED E MERCK LTD PFIZER LTD MERCK SHARP & DOHME LTD	} DEPARTMENTAL GRANTS	YES
PROFESSOR J E CARLESS	NONE		NONE		
MR W M DARLING	NONE		NONE		
PROFESSOR F FISH	NONE		NONE		

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
PROFESSOR F HARRIS	NONE		SQUIBB EUROPE GLAXO GROUP RESEARCH LTD FISONS PHARMACEUTICAL BAYER UK LTD SHIRE PHARMACEUTICALS BEECHAM WULFING GIST BROCADES DELFT UNILEVER RESEARCH LTD UPJOHN LTD CIBA GEIGY SANDOZ JANSSEN PHARMACEUTICALS LTD AMERSHAM INTERNATIONAL BOEHRINGER MANNHEIM PHARMACIA LTD ALLEN & HANBURY'S MERCK SHARP & DOHME NEUROSCIENCE RESEARCH CENTRE LEO LABS LTD SMITH KLINE 1982 FOUNDATION PFIZER LTD ICI SCHWARZ PHARMACEUTICALS ABBOTT LABORATORIES UCB PHARMACEUTICALS MERRELL DOW VOX HEALTHCARE	Research grants to Departments in the University of Leicester School of Medicine of which the member is Dean	Yes

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
PROFESSOR F HARRIS (CON'T)			MEDISURE } FARMITALIA CARLO ERBA } BRISTOL MYERS } ASTRA PHARMACEUTICALS } ROUSSEL LABORATORIES } DELTA BIOTECH }		
PROFESSOR J G R HOWIE	GLAXO	OCCASIONAL LECTURING FEES - NOT PRODUCT RELATED	NONE		
DR B J KIRBY	NONE		NONE		
PROFESSOR D H LAWSON (CHAIRMAN)	NONE		NONE		
PROFESSOR R M MACKIE	NONE		NONE		
DR A MCKNIGHT	SCHERING HEALTH CARE LTD	RESEARCH FUNDING	NONE		
PROFESSOR J M MIDGLEY	CONVATECH (BRISTOL-MEYERS SQUIBB)	CONSULTANCY GRANUFLEX DRESSING	RHONE-POULENC LTD ROCHE PRODUCTS LTD	RESEARCH SUPPORT VISITING PROFESSOR	YES YES

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
DR A T PROUDFOOT	NONE		NONE		
DR L E RAMSAY	NONE		SERVIER LABORATORIES ABBOTT LABORATORIES BEECHAMS LABORATORIES	RESEARCH	YES

COMMITTEE ON DENTAL AND SURGICAL MATERIALS

MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON PERSONAL INTEREST AS FOLLOWS:-

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
PROFESSOR C L BERRY (CHAIRMAN)	NONE		NONE		
PROFESSOR W BONFIELD	SMITH & NEPHEW	RESEARCH	NONE		
	JOHNSON & JOHNSON ORTHOPAEDIC	RESEARCH			
	BIOMET LTD	RESEARCH			
MR R J BUCKLEY	FISONS PLC	INTERNATIONAL CONGRESS ALLERGOLOGY AND CLINICAL IMMUNOLOGY KYOTO JAPAN (TRAVEL GRANT)	FISONS PLC	RESEARCH SUPPORT	YES
PROFESSOR H D EDMONDSON	ASTRA PHARMACEUTICALS LTD	EXPERT OPINION AT ANNUAL CONFERENCE (PARTIAL GROUP SPONSORSHIP)	ASTRA PHARMACEUTICALS LTD STRAUMANN CORVENT BRITCAIR (SKF LTD)	EXPERT OPINION	YES YES YES
			SYNTEX	CLINICAL TRIALS	YES

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
MR J A ELIAS	NONE		NONE		
PROFESSOR M ELSTEIN	SCHERING HEALTHCARE	EDITORSHIP AND	SCHERING HEALTHCARE		YES
	SCHERING AG	LECTURE FEES			
	ORTHO CILAG	ADVISORY PANEL, FEES	ORGANON INTERNATIONAL		YES
			LONDON INTERNATIONAL		YES
	WYETH LABORATORIES	FEES			
			FEMCARE		YES
			LEIRAS		YES
				RESEARCH	
			CONRAD USA / AID	STUDIES AND	YES
				CLINICAL	
			ORTHO CILAG	TRIALS	YES
			WYETH - AYERST		YES
			MEDGENIX		YES
			COLOMBIA		YES
			ROUSSEL LABORATORIES		YES
			NORWICH-EATON		YES
MR J HOWE	NONE		NONE		
PROFESSOR G C JENKINS	NONE		NONE		
PROFESSOR R B JOHNS	NONE		NONE		

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
PROFESSOR I D A JOHNSTON	NONE		COW & GATE KABI VITRUM CIBA GEIGY	RESEARCH	YES
DR J R LARKE	PILKINGTON VISION CARE	CONSULTANCY	ALLERGAN HYDRON BAUSCH & LOMB	PROVISION OF TEACHING MATERIALS	YES
MR B J MEAKIN	CO-ORDINATED DRUG DEVELOPMENT	DIRECTOR, SHARE HOLDER	BAUSCH & LOMB INTERNATIONAL USA	RESEARCH CONTRACTS TO UNIVER-SITY OF BATH	YES
	POLYMER TECHNOLOGY USA	CONSULTANCY	SAUFLON PHARMACEUTICALS		YES
	ALLERGAN OPTICAL	CONSULTANCY	MARKET ACCESS INTERNATIONAL	INVOLVEMENT IN DIRECTION OF WORK CARRIED OUT BY UNIVER-SITY EMPLOY-EES	YES
	SMITH & NEPHEW	FEES	ABATRON HARRIS PHARMACEUTICALS		YES
	GLAXO GROUP RESEARCH	CONSULTANCY			
	AMBASSADOR HOLDINGS (SINGAPORE)	CONSULTANCY			
	CONTROLLED THERAPEUTICS	PATENT HOLDER FOR UNIVERSITY OF BATH			

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
MR B MIDCALF	NONE		NONE		
PROFESSOR C SCULLY	BLENDAX/ PROCTOR & GAMBLE	CONSULTANCY/ RESEARCH GRANT	NONE		
	VITABIOTICS	GRANT			
	3M HEALTH CARE	GRANT			
	WYETH LABORATORIES	GRANT			
MISS A B SUTHERLAND	NONE		NONE		
PROFESSOR D E M TAYLOR	GEISTLICH SONS PHARMACEUTICAL	CONSULTANCY	DAVIS & GECK (CYANAMID)	GRANT IN KIND (TEACHING)	YES
MR T D TURNER	JOHNSON & JOHNSON	CONSULTANCY	NONE		
	SETON	CONSULTANCY			
	COURTAULDS	RESEARCH GRANT			
PROFESSOR B WHITING	WARNER-LAMBERT	CONSULTANCY	GLAXO	GRANT	YES
PROFESSOR E G WOODWARD	NONE		NONE		

COMMITTEE ON SAFETY OF MEDICINES

MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS AS FOLLOWS:

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
Professor A W Asscher (Chairman)	None		ACRAF Ltd (Angelini Pharms) Abbott Laboratories Ltd Advisory Services (Clinical & General) Ltd Astra Pharmaceuticals Ltd Bayer (UK) Ltd Beechams G H Besselaar Associates Ltd Boots Bristol Mayers Pharmaceuticals British Technology Group British Telecom Celltech Ciba-Geigy Du Pont (UK) Ltd Farmitalia Carlo Erba Ltd Ferring Pharmaceuticals Fisons Glaxo Hoechst Ltd ICI Janssen Pharmaceuticals Johnson & Johnson Knoll Leo Laboratories Lilly Industries Ltd	The Dean (Professor Asscher) is Chief Executive of the Medical School, which has 23 departments. The grants listed refer to grants made to individual departments. None of them is payable to the Dean since he heads the Schools's administration	Yes

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor A W Asscher (continued)			May & Baker } Merck, Sharp & Dohme } Merrell Dow Pharmaceuticals } Milupa Ltd } Oxford Virology Ltd } Paines & Byrne } Pfizer } Pharmax Ltd } Priory Hospital } Prudential } A H Robins } Roche Products Ltd } Sandoz Pharmaceuticals } Sanofi (UK) Ltd } G D Searle & Co. Ltd } Seven Seas Ltd } Shell (UK) Ltd } Speywood Laboratories (Porton) } Squibb & Sons } Sterling Winthrop } Zyma (UK) Ltd }		
Professor C L Berry	None		None		
Professor S S Bleehen	Steifel Labs (UK)	Skin Forum Advisory Board (Fee)	Unilever Research	Research Grant	Yes
	Sandoz	Research Grant	Roche	Grant to Department	Yes
			Galderma	Grant to Department	No

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
Professor T G Booth	Wellcome PLC	Share Holder	Boots PLC	Staff Funding	Yes
	Scholl (UK) Ltd Nicholas Labs Ltd Convatec Ltd	Consultancy and Fee Paid Work	AAH Pharmaceuticals Ltd Glaxo Pharmaceuticals Ltd Janssen Pharmaceuticals Ltd Lilly Industries Ltd	Grant, Support for Chair/Staff, Fellowship Support, Research Support	Yes
Professor A M Breckenridge	Smith Kline & Beecham	Consultancy	Boehringer Mannheim Boots Duncan Flockhart & Co. Ltd Glaxo Pharmaceuticals ICI Kirby Warrick Organon Labs Ltd Parke Davis Research Labs Pfizer Ltd Sandoz Pharmaceuticals Schering Health Care Ltd G D Searle Smith Kline Beecham	Research Grants to Members of Department to support their research.	Yes
Professor A T Florence	Napp Controlled Therapeutics Syntex Research	Consultancy	L'Oreal Syntex	Research Studentship supervised by Professor Florence	Yes

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
Professor A T Florence (Cont'd)			Bayer Beecham Blomos (Holland) Boehringer Boots PLC CIS Pharmaceuticals Ciba-Geigy Daiichi Seiyaku (Japan) FMC Corporation (Philadelphia) Glaxo Hoechst (UK) ICI Janssen Pharmaceuticals John Wiley & Sons Lilly Industries MSD Pfizer Lipha Reckitt & Colman Rhone-Poulenc Roche Syntex R P Scherer Takeda Chemicals (Japan) Upjohn Wellcome Wyeth Research (UK)	Research Grants, to departments and individuals in the School of Pharmacy, University of London, of which Professor Florence is Dean.	Yes
Dr R G Finch	Bristol Myers/Squibb Rhone-Poulenc	Consultancy	ICI Merrell Dow/Marion	Departmental Research	Yes

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Dr R G Finch (Cont'd)	Pfizer ICI Centocor	Consultancy	Wellcome Trust	Grants	
	Bayer	Honorarium: Quinolone Board Member			
Professor E C Gordon-Smith	None		Chugai/Rhone Poulenc Glaxo	Clinical Trials	Yes
			Sandoz Schering-Plough	Clinical Trials	No
Professor F Harris	None		Abbott Laboratories Allen & Hanbury's Amersham International Astra Pharmaceuticals Bayer (UK) Ltd Beecham Wulfing Boehringer Mannheim Bristol Myers Ciba Geigy Delta Biotech Farmitalia Carlo Erba Fisons Pharmaceutical Gist Brocades Delft Glaxo Group Research Ltd ICI Janssen Pharmaceuticals Ltd Leo Labs Ltd Medisure	Research Grants, and Student-ships to Depart-ments of the School in the University of Leicester for which Professor Harris is Dean.	Yes

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor F Harris (Cont'd)			Merck Sharp & Dohme } Merrell Dow } Neuroscience Research Centre } Pfizer Ltd } Pharmacia Ltd } Roussel Laboratories } Sandoz } Schwarz Pharmaceuticals } Shire Pharmaceuticals } Smith Kline 1982 Foundation } Squibb Europe } UCB Pharmaceuticals } Upjohn Ltd } Unilever Research Ltd } Vox Healthcare }		
Professor H S Jacobs	Ares-Serono } Novo-Nordisk }	Consultancy	Ares-Serono } Novo-Nordisk } Organon } Sandoz }	Grants to Department	Yes
	Glaxo	Shareholder			No
Dr W A Jerrett	None		None		
Professor M J S Langman	Sandoz } Wellcome }	Consultancy	Astra } Glaxo } Merck Sharpe & Dohme } Norsk Hydro } Smith Kline Beecham } Squibb } Upjohn }	Support for Departmental Research Activities	Yes

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor M J S Langman (Cont'd)			Hoechst		No
Professor D H Lawson	None		None		
Mr F E Loeffler	None		None		
Professor A E M McLean	Delta Biotechnology Booker Nutritional Products Pharmax Ltd Riker 3M Healthcare Roussel Ltd Smith & Nephew Ltd Warner Lambert Ltd	Consultancy	Sterling Winthrop	Research Grant	Yes
	British Technology Group	Patent Royalties			
Professor J M Midgley	Convatec Wound Healing Research Institute (Bristol Myers-Squibb)	Consultancy	None		
	Rhone-Poulenc Allergan	Research Grants			

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
Dr S A Montgomery	Beecham Novo Jouveinal Organon Duphar	Lectures/Advice	Bayer Janssen Lilly Lundbeck Merrill Dow Wyeth	Contributions to Support Research Staff Costs	Yes
			Glaxo Merck Sanofi	Contributions to Support Research Staff Costs	No
Dr C M Oakley	None		None		
Professor M D Rawlins	None		Bayer (UK) Boots Bristol Myers Byk Gulden (Germany) Janssen Sandoz	Departmental Research Grants and Lectureships	Yes
Dr D A J Tyrrell	Proctor & Gamble	Consultancy	None		
Professor M P Vessey	Novo-Nordisk	Consultancy	Bristol Myers/Squibb Ciba-Geigy Smith Kline Beecham Sterling Health Upjohn	Research Grants	Yes

COMMITTEE ON SAFETY OF MEDICINES

SUB COMMITTEE ON SAFETY, EFFICACY AND ADVERSE REACTIONS

MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS AS FOLLOWS:

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
Dr L Beeley	None		None		
Professor A T Birmingham	Wellcome Research Labs, Beckenham	Honorarium: Member of Protocol Review Committee	Alza, Abbott/MRC, Amersham, Beechams, Boehringer, Boots/MRC, British Technology, Celltech, Glaxo, Pharmafood, ICI, Johnson & Johnson, Janssen, Merck, Sharp & Dohme, Merrell-Dow, Proctor & Gamble, Reckitt & Colman, Roussel, Serc/Beechams, Smith Kline, Squibb, Syntex	Support of Research in the Department by Grants, Contracts or Studentships	Yes

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
Professor A T Birmingham (Cont'd)			Syntex/Serc Upjohn Wyeth/Serc	}	
Professor A M Breckenridge	(see entry under Committee on Safety of Medicines}				
Dr R L Carter	ICI	Shareholder	None		
Professor D S Davies	ICI	Shareholder	Abbott Astra/Draco Bayer (UK) Boehringer Ingelheim Bristol Myers David Bull Labs Eisai Farmitalia Carlo Erba Fisons Glaxo Hoechst ICI M L Laboratories Merck Sharp & Dohme Rhone-Poulenc Rorer Roche S K Beecham Squibb Schering Wellcome Research Labs	} Commissioned Research, Fellowships, Grants & Consultancy	Yes
	M L Laboratories	Non Executive Director			
	Clinical & Biochemical Pharmacology Limited	Director			

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
Dr P B Farmer	Laboratories Fournier	Travel and Subsistence	Laboratories Fournier	Analysis of Drug Metabolites	Yes
Dr R G Finch	(see entry under Committee on Safety of Medicines)				
Professor S T Holgate	Almiral (Spain) Fisons (UK) ICI (UK) 3M Riker (UK/USA) Labs Roche (UK) Upjohn (USA) Wellcome (UK)	Consultancy	Almiral (Spain) Draco (Sweden) ICI (UK) Schering-Plough (USA)	Research Grants & Clinical Trials	No
			UCB (Belgium) Allen / Hanbury's (UK) Astra (Pharma) AG (Germany) Boehringer Ingelheim Boehringer Mannheim (Germany) Bristol Myers-Squibb Ferring Peptide Research Glaxo (UK) Harris (UK) Merrell Dow (UK) Napp (Cambridge) Roche (UK) Roussel (UK) Sandoz (Switzerland) Servier (France)	Research Grants & Clinical Trials	Yes

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor C J Hull	Janssen Pharmaceuticals Wellcome Foundation	Consultancy	Janssen Pharmaceuticals	Sponsored Research Project	No
			ICI	Sponsored Research Project	Yes
Professor D R Jones	Wellcome Foundation	Member of Trial Monitoring Committee (Exosurf)	None		
Dr B J Kirby	None		Sterling-Winthrop	Research Support	No
Professor M J S Langman	(see entry under Committee on Safety of Medicines)				
Dr A V P Mackay	Glaxo Group Research Limited	Consultancy	Efamol / Scotia	Research Grant to a Colleague	Yes
			Sandoz	Revenue from Drug Trial	No
Professor A E M McLean	(see entry under Committee on Safety of Medicines)				

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor B K Park	None		Beecham Boots Park-Davis	} Postgraduate } Studentships & } Research Grants	No Yes Yes
Professor M D Rawlins (Chairman)	(see entry under Committee on Safety of Medicines)				
Professor P A Routledge	None		Glaxo	Volunteer Research on Drug	Yes
			Pfizer (UK)	Research on Compound in Volunteers	No
			Wellcome	Drug Analysis	No
			Cardiff Clinical Trials Unit	Sub-Contract assay work for several companies: Abbot (USA) Bayer (UK) Syntex	No

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor C G Swift	None		Astra Boots ICI Labs for Applied Biology Rhone-Poulenc - Rorer Searle Ltd Shire Pharm Ltd Park-Davis Ltd Sode Pharm Ltd	Departmental Research Grants	Yes
Dr G N Volans	Boots	Expert Reports	Bayer Glaxo LERS-Synthilabo Lilly E Merck Pharmacia Leo	Research	Yes
			Boots Dista Duphar Glaxo Sanofi Servier	Assays for Various Drugs	Yes
			Boots ICI May & Baker Schering-Plough Squibb Servier	Information Searches & Report Preparation	Yes
Dr D W Wall	None		None		

COMMITTEE ON SAFETY OF MEDICINES

SUB COMMITTEE ON CHEMISTRY, PHARMACY AND STANDARDS

MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS AS FOLLOWS:

	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
MEMBER	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor J R Brown	Merck Schering-Plough Jouveinol	} } Consultancy }	Serono	Consultancy	No
			Glaxo	Grants	Yes
Dr D H Calam	None	None			
Dr R T Calvert	Boots	Share Holder	None		
Professor J E Carless	None		None		
Dr A G Davidson	None		None		
Professor D J G Davies	Smith & Nephew Pharms	Royalty Payment on Pryme Care Product & Fees for occasional Development Work	Abatron Ltd A K G Westalia Allergan Inc Allergan Optical Bausch & Lomb Boots	} } } } } }	
	Co-ordinated Drug Development Ltd	Director and Shareholder	Celltech Contactasol	} }	

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor D J G Davies (Cont'd)	Controlled Therapeutics Ltd	Royalty Payments	Controlled Therapeutics Cyanamid Eschmann Bros & Walsh Glaxo Group Research Harris Pharmaceuticals Hickson & Walsh Hoechst Hydropharma ICI PA Consultants Pitman Moore Inc Rhone-Poulenc Roche Roussel Uclaf (France) Sanflon Serono Shield Diagnostics Smith & Nephew Squibberm Sterling Vista Optics Wellcome	Research Projects, Studies and Studentships	Yes
	Allergan Inc	Hold Licence option on one potential Contact Lens Product Fees for occasional Development Work			
	Vista Optics Ltd	Hold Licence option on potential Contact Lens Products			
	Bausch & Lomb Glaxo Group Research	Marketing Agreement Occasional Fees			
Dr A L Davison	Glaxo PLC	Shareholder	Fisons Healthcare	Contract Testing of Medicines	Yes
Professor F Fish	None		None		
Professor A T Florence (Chairman)	(see entry under Committee on Safety of Medicines)				

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
Professor D Ganderton	Co-ordinated Drug Development ICI Celltech	Director and Share Holder Share Holder Consultancy	None		
Mr B Midcalf	None		None		
Professor J M Midgley	(See entry under Committee on Safety of Medicines)				
Professor J M Newton	None		Beecham Laboratories Glaxo Group ICI Pharmaceuticals May & Baker Wellcome Foundation Harris Pharmaceuticals	Research Grants and Studentships	Yes
			WHO	Adviser to Task Force	Yes
Professor M S Parker	None		Ciba-Geigy Controlled Therapeutics Corp Convatec (UK) Ethical Pharms Ltd Glaxo Research Group Pall Filtration Ltd Pfizer Central Research Ltd Rorer Health Care Reckitt & Colman Seaford Labs Ltd Squibb Derm	Research and Project Funding in Department of Pharmacy including Case Awards and Undergraduate Studies	No

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
Professor J E Rees	Abbott Glaxo	Share Holder	Syntex AKG Westalia Allergan Inc Bausch & Lomb Controlled Therapeutics Co-ordinated Drug Development Cyanamid Eschmann Bros & Walsh Finn Sugar Glaxo Research Harris Hickson & Walsh Hoechst Sauflan Pharm Shield Diagnostics Smith & Nephew Squibbderm Sterling Research Serno Diagnostics Rhone Poulenc Unipath	Research & Study Grants and Consultancies to Departments	Yes
	Smith Kline Beecham	Share Holder until 7 June 1990			
	Controlled Therapeutics Inc. Allergan Optical	Licence agreement relating to a new contact lens disinfection system			
	Pfizer	Fee as advisor for annual Pfizer academic awards			
	Hadley-Hutt	Research Grant			
	Duphar (Holland)	Personal Consultancy in relation to a specific research product 10/12/1990 to 01/02/1991			
Professor G T Tucker	Napp S K Beecham Upjohn	Consultancy	Hoffman La Roche (Basle) S K Beecham Klinge Pharms (Munich) Innovata Biomedica	Grants to Departments	Yes

COMMITTEE ON SAFETY OF MEDICINES

SUB COMMITTEE ON BIOLOGICALS

MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS AS FOLLOWS:

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
Professor J E Banatvala	Smith Kline Beecham Roche Products	Research Studies	Abbot Diagnostics Amerlite Diagnostics British Biotechnology Merieux Smith Kline Beecham Wellcome Foundation	Sponsorship Costs	Yes
			Cytobrush Unipath	Clinical Trials	No
Dr E B Gingold	None		None		
Professor K Gull	British Biotechnology	Consultancy	Wellcome Diagnostics Proteus	Studentship & Lectureship	Yes
	Kent Life Science	Director			
Professor G Janossy	None		Sandoz	Grant	Yes
Dr S L Jeffcoate	None		None		

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor J Melling	None		Agen Biomedical	Patent	
			Amersham International	Contract	
			Akzo (Organon) Ltd	Contract/Patent	
			Bayer	Patent	
			BASF	Patent	
			Beechams	Supply/Contract	
			Behringwerke	Patent/Contract	
			Beki Barn AB	Patent	
			Bioscot	Safe Deposit	
			Bioferon	Patent	
			Boehringer Mannhein	Patent	Yes
			Boots	Supply	
			British Biotechnology	Supply	
			British Novo	Safe Deposit	
			Bunge (Australia) (Pty) Ltd	Patent	
			C L Pharma AG	Patent	
			Cambridge Research Biochemicals	Supply	
			Celltech	All Services	
			Convatec	All Services	
			Ciba-Geigy AG	Patent	
			Delta Biotechnology	All Services	
			Diosynth SA (Organon)	Contract/Patent	
			Degussa	Patent	
			Evans Biologicals	Contract	
			Farmitalia Carlo Erba	Patent/Supply	
			Fisons	Training/Supply	
			Glaxo	All Services	
			Genzyme	Contract	

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor J Melling (continued)			Hoechst AG	Patent	
			Hoffman La Roche	Patent/Supply	
			Immuno	Sales	
			Immunotech	Contract	
			Innogenetics	Patent	
			Intervet	Patent	
			Ire Medgenix	Patent/Supply	
			Ire Celltarg	Patent	
			Johnson & Johnson	Contract	
			Nordisk Gentofte	All Services	
			Novo (Denmark)	Patent	
			Novo (UK)	Safe Deposit	
			Orpegen	Patent	
			Otto Nordwald AG	Supply/Patent	Yes
			Oxford Glycosystems	Contract	
			Oxford Virology	Contract	
			Oxoid	Contract	
			Peptide Technology	Patent	
			Pfizer	Contract	
			Pharmacia AG	Patent	
			Pitman Moore	Contract/Safe Deposit/Supply	
			Pharma Biotechnologie	Patent	
			Porton Products	All Services & Sales	
			Progen Biotechnik	Patent/Contract	
			Quadrant Bioscience	Contract/Patent	
			Rhone Poulenc	Supply	
			Sandox	All Services	
			Sanofi	Contract/Supply	
			Schebo Tech	Patent	
			Schering AG	Patent	
			Serotec	Contract	
	Serono		Contract		

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor J Melling (Cont'd)			Shield Diagnostics	Contract/Patent	
			Smith Kline French	Supply	
			Smith Kline Beckham	All Services	
			Smith Kline Rit	Contract	
			Squibb Surgicare	Supply	Yes
			Stabilgen	Patent	
			Upjohn	Training/Supply	
			Wellcome	All Services & Sales	
			Vuman Ltd	Safe Deposit	
			Xenova	All Services	

DEFINITIONS

1. Patent — Logging a 30 year culture deposit in ECACC in accordance with the Budapest Treaty. The company pay a fee to PHLS/CAMR.

2. Supply — The supply of cultures from ECACC. The company pay a fee to PHLS/CAMR.

3. Safe Deposit — Logging a culture deposit in ECACC for safe keeping with access only by the company. The company pay a fee to PHLS/CAMR.

4. Contract — Laboratory and R and D work including technical consultancy. The company pay a fee to PHLS/CAMR.

5. Training — Company staff spending time at CAMR for training. The company pay a fee to PHLS/CAMR.

6. All Services — All of the above, 1- 5.

7. Sales — Sale of products produced by CAMR

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Dr P D Minor	None		None		
Dr R J Perry	Scottish National Blood Transfusion Service	Operational Director	Cell Tech Limited	Research Grant	Yes
Dr G C Schild	None		None		
Dr T J Snape	Central Blood Labs Authority	Salaried Employment Full Time	None		
Dr E G D Tuddenham	Delta Biotechnology Limited	Consultancy	Ciba-Geigy	Sponsored PhD Studentship	Yes
Dr D A J Tyrrell (Chairman)	(see entry under Committee on Safety of Medicines)				

COMMITTEE ON SAFETY OF MEDICINES

SUB COMMITTEE ON ADVERSE REACTIONS TO VACCINES AND IMMUNISATION

MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS AS FOLLOWS:

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
Professor J E Banatvala	Smithkline Beecham Roche Products Ltd	Research Studies	Abbot Diagnostics Amerlite Diagnostics British Biotechnology Merieux Smith Kline Beecham Wellcome Foundation	Sponsorship Costs	Yes
			Cytobrush Unipath	Clinical Trials	No
Dr C Bowie	None		Smith Kline & French	Research Grant	No
Professor A M Breckenridge (Chairman}	(see entry under Committee on Safety of Medicines)				
Dr N Cavanagh	None		None		
Dr P Fine	None		None		
Professor F Harris	(see entry under Committee on Safety of Medicines)		None		

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Dr C R Kennedy	None		None		
Professor D G McDevitt	Drug Development, Scotland	Director (Ex-officio)	Bayer Beecham Boehringer Ingelheim Boots Bristol-Myers Squibb Glaxo Hoechst ICI Janssen Lederle Merck Sharp & Dohme Merrell-Dow Organon Parke-Davis Pfizer Rothmans Rhone-Poulenc (Rorer) Roussel G D Searle Smith Kline Beecham Squibb Cynamid	Research Grants	Yes
	Warner-Lambert	Medical Referee			
	3M Health Care	Consultancy			
	Boehringer Ingelheim	Consultancy Report			
Dr B W McGuinnes	None		Leo Laboratories	Student Research	Yes
			Stuart Laboratories	Research Support	Yes

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor S R Meadow	Boots Ferring	Share Holder Consultancy	Ferring	Research Grant	Yes
Professor D L Miller	None		None		
Dr E Miller	None		None		
Dr P Minor	None		None		
Dr D Reid	Smith Kline & Beecham	Research Grant	None		
Dr D A J Tyrrell	(see entry under Committee on Safety of Medicines)				