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ANNUAL REPORTS FOR 1989 OF:—

MEDICINES COMMISSION
COMMITTEE ON SAFETY OF MEDICINES
VETERINARY PRODUCTS COMMITTEE
BRITISH PHARMACOPOEIA COMMISSION
COMMITTEE ON THE REVIEW OF MEDICINES
COMMITTEE ON DENTAL AND SURGICAL MATERIALS

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MEDICINES COMMISSION ANNUAL REPORT FOR 1989

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 at Appendix I. A list of Members is at Appendix II.

2. There were 7 meetings of the Commission in 1989.

EUROPEAN COMMUNITIES

3. The Commission continued to receive reports from officials of the Department of Health (DH) and the Ministry of Agriculture, Fisheries and Food (MAFF) on the work of the Pharmaceutical Committee, the Committee on Proprietary Medicinal Products (CPMP) and the Committee on Veterinary Medicinal Products (CVMP).

4. The Commission also received consultative documents from the European Commission (EC) concerning proposals for the harmonisation of arrangements for the marketing of medicinal products in the European Community after 1992.

European Commission Consultation Document - III 3878/89 ('Outstanding White Paper proposals for the completion of the internal market in the pharmaceutical sector')

5. The Commission noted that the document carried forward points raised in the 'Cockfield' White Paper which had been published in 1985. We noted also that the document had been received by the UK authorities late in July 1989 with a closing date for comments of 30 September 1989. The document was considered by the Commission at the first available opportunity on 22 September. The document raised a number of important points of both principle and practice which would require very careful consideration. Members understood that the EC Commission were taking into account reactions to their July paper with a view to making formal proposals for directives dealing with marketing authorisation, classification, advertising, labelling, distribution and patient information in relation to medicinal products. It was the Commission's view that the time allowed by the EC for consultation about these important issues was wholly inadequate.

6. It was not clear to the Commission whether the purpose of the EC proposals relating to the classification of medicinal products was to harmonise trade in the pharmaceutical sector or the protection of public health. It seemed to the Commission that the proposals for the harmonisation of the classification and distribution arrangements for medicinal products within the Community, if adopted and implemented, would make little or no contribution to the free movement of medicinal products between member states. It appeared to us that the classification of medicinal products was a matter that could and should properly be left to each member state. We were not convinced that classifying a product as a prescription only medicine (POM) was a barrier to trade. In any case, we considered that the proposals relating to classification were premature; the first step, in our view, should be to reach agreement on the arangements for the cross-border marketing authorisation of medicines, a subject which we addressed in our report for 1988.

FOREWORD BY THE MINISTER FOR HEALTH

Published in this volume are the annual reports for 1989 of the Medicines Commission, the Committee on Safety of Medicines, the Veterinary Products Committee, the British Pharmacopoeia Commission, the Committee on the Review of Medicines and the Committee on Dental and Surgical Materials.

Modern pharmaceutical products have revolutionised the health and welfare of our people. These Committees play a major part in ensuring their safety, quality and efficacy. On behalf of all Ministers charged with responsibility for the administration of the Medicines Act, I am glad to place on record our thanks to the Members of these bodies, and of their sub-committees, for their help and advice: we much appreciate the time and effort they have each contributed.

Published also is the record of Members' interests in the pharmaceutical industry; this includes both personal interests and the interests of Members' departments (non-personal interests). Members follow the ethical standards set by the Code of Practice on such declarations to avoid conflicts of interest which might otherwise be held to impair the objectivity of the scientific and clinical advice they give. There is much benefit in intellectual cross-fertilisation between eminent practitioners and those concerned with the development of new treatments. And involvement in research sponsored by the pharmaceutical industry helps to keep members abreast of important aspects of drug development.

7. We noted from the EC's July paper that it was proposed to establish a minimal list of products which clearly came within the POM category and a list of products clearly suitable for non-prescription marketing, usually described as 'over the counter'(OTC) products. It was the intention thereafter that products which came within the grey area between POM and OTC would be considered and classified to one or other of the lists over a ten to fifteen year period. It was not clear to us who would carry out this work nor what criteria would be followed. We think that the primary consideration should be safety, both in relation to the product itself and the condition(s) for which it is indicated: some conditions are suitable for self-medication but others require a doctor's intervention and management. Other factors such as dosage, pack size and product literature would also need to be taken into account. The Commission were in no doubt that, for both human and veterinary medicines, socio-economic factors should not figure in the classification of medicines which should always be determined on medical/scientific grounds.

8. The Commission were concerned that a phased approach to the harmonisation of the classification of medicinal products in the EC could lead to confusion and uncertainty. It was apparent that the EC were prepared to tolerate a non-harmonised system for many years after 1992. This suggested to us that our reservations about the need to harmonise at all in the field of classification for the purposes of trade were well-founded. We thought that if there were to be common EC classification this should be a one-step exercise.

Future System for Authorisation of Medicinal Products in EC

9. The Commission noted with interest a report concerning proposals from the EC Commission about the future arrangements for the marketing authorisation of medicinal products in the EC. The proposals envisaged the establishment of a European Medicines Agency on which all member states would be represented. There would be a Director with technical and administrative staff and a representative Board. CPMP and CVMP would be strengthened and form the two main professional advisory bodies within the agency, responsible for formulating "opinions" on licence applications.

10. There would be centralised and decentralised licensing procedures. The centralised procedure would be mandatory for all biotechnology products and it would be open to companies to use it for other high technology applications and new active substances generally. Assessors from the national authorities could provide an assessment for CPMP to consider. Before this, it would go before working groups for discussion. The centralised opinion would be binding. Provision for an appeal procedure would be made but details were not yet clear.

11. A decentralised procedure would operate in respect of applications not subject to the centralised procedure when a Company wanted to register a drug in more than one country. Mutual recognition would operate unless a member state had a serious reservation. If the objections could not be resolved, the case would go before CPMP with the country where the product was registered acting as rapporteur.

12. Members noted that the proposals although generally in line with the views they had previously expressed, lacked sufficient detail to ensure that an efficient new system could be developed. We look forward to receiving further reports in due course.

Good clinical practice guidelines for trials on medicinal products in the EC (III/3976).

13. The Commission received reports and were consulted about the development of EC guidelines, under the Directives on medicinal products, to establish the reliability of data from clinical trials and to establish standards of good practice for clinical trials on medicinal products. Members noted that, although later the guidelines might be the subject of a Directive, it was the intention that they would have the status of Recommendations in European law and accordingly would not be legally enforceable. It was our view that the primary purpose of the guidelines should be the protection of the individual. If the guidelines were not complied with trial subjects could be harmed. This suggested to us that proposals for trials should be closely scrutinised by local research ethics committees and that there should be sanctions for non-compliance. The Commission understands that discussions within the EC on the final form of the guidelines are continuing and we await further developments.

Active implantable medical equipment

14. The Commission received a report from the Department of Health's Procurement Directorate about a series of Directives planned by the EC with the aim of removing barriers to trade in medical devices throughout the Community. We understood that there were to be four Directives covering active implantable devices, active non-implantable devices, non-active devices and in-vitro diagnostics. Members recalled that both the Commission and the Committee on Dental and Surgical Materials (CDSM) had frequently referred to their concern about the lack of regulation of certain critical implantable medical devices and we noted that the UKs response to the draft directive on active implantable devices had taken into account the views we expressed in our 1987 report. Important points had still to be settled including drawing a clear distinction between medicinal products and devices and making adequate provision for drug/device combinations, ensuring that proper weight was given to pre-market clinical investigation and that provision was made for post-market surveillance. In general, the Commission endorsed the approach adopted by the Procurement Directorate and looked forward to receiving further reports on progress in due course.

DRUG TRIALS IN HEALTHY VOLUNTEERS

15. In 1986 the Commission reported to Ministers their views on the adequacy of safeguards for healthy volunteers participating in trials associated with the development of new drugs. The Commission exressed the view at that time that the role and constitution of Ethics Committees should be clarified and codified. We noted that the Department of Health had now produced draft guidelines for local clinical research ethics committees, and that these would be published as a Health Circular in due course.

16. The Commission generally welcomed the guidelines which we saw as a significant contribution to the proper conduct of the development of new medicines and to the protection of individuals taking part in clinical trials. We felt, however, that further consideration should be given to introducing legislation embodying the guidelines. A clinician who failed to comply with the guidelines might be subject to professional disciplinary action but not all researchers were subject to the jurisdiction of a professional body. The priority was the protection of trial subjects and it was the Commissions' view that the approach should be preventative rather than reactive.

HEARINGS

Human Medicines

17. The Commission held 2 hearings and considered one written representation in respect of applications for new product licences. In one case their advice was that a product licence should be granted and in 2 cases that a product licence should not be granted.

Human Medicines having Product Licences of Right

18. The Commission held 4 hearings and considered 5 written representations in respect of applications for reviewed product licences. In 5 cases they advised that a reviewed licence should be granted subject to certain conditions being met. In the remaining 4 cases their advice was that reviewed licences should not be granted.

Veterinary Products

19. The Commission held 4 hearings in respect of applications for reviewed product licences. In 2 cases the hearings were adjourned sine die to await further information from the Veterinary Medicines Directorate. In the other 2 cases the Commission advised that a reviewed licence should not be granted.

20. A Summary of representations dealt with by the Commission over the past five years is at Appendix III.

OTHER MATTERS

Medicines Control Agency
Veterinary Medicines Directorate

21. The Commission noted the formal establishment of the Medicines Control Agency (MCA) and the Veterinary Medicines Directorate (VMD) from April 1989. The new bodies subsume the functions of Department of Health's Medicines Division and the Veterinary Medicines Division of the Ministry of Agriculture, Fisheries and Food respectively. They were formed following the recommendations in the studies carried out in 1987 by Dr N B J Evans and Mr Peter Cunliffe CBE to which we referred in our report for 1988. The Commission noted the appointment of Dr Keith Jones as the Director of the MCA and the appointment of Dr J M Rutter as Director of the VMD.

Prescription Only Order

22. The Commission were consulted and were content with proposals for amending the Prescription Only Medicines Order. The proposals contained an important exemption from POM controls in regard to supply and administration for paramedical staff employed aboard offshore installations such as oil-rigs. The exemption acknowledged the special circumstances which might arise on such installations and permited trained rig-medics to supply and administer all prescription only medicines for the treatment of personnel aboard the off-shore installation.

General Sales List Order

23. The Commission were consulted and were content with proposals for amending the General Sales List Order.

General

24. The Commission recommended several people as being suitable for appointment to membership of the Committees established under Section 4 of the Medicines Act 1968.

25. The Commission recommended the following for publication:-

British Pharmacopoeia 1988:	amendment number 3 addendum 1990
British Pharmacopoeia (Veterinary) 1988:	amendment number 3
British Approved Names 1986:	supplement number 7 supplement number 8

European Pharmacopoeia Approved Synonyms.

REPORTS OF THE COMMITTEES

26. 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 and their sub-committees.

APPENDIX I

MEDICINES COMMMISSION
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 condider 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 IIA

MEMBERSHIP OF THE MEDICINES COMMISSION 1 JANUARY 1989

+ Professor Dame Rosalinde Hurley DBE LLB MD DUniv(Surrey) FRCPath (Chairman)
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Professor of Probability and Statistics, University College London

+ Professor A D Dayan MD BSc FRCP FRCPath FIBiol
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* H Cowan Wilson Esq BVMS FRCVS
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\+ Term of office expires 31 December 1989

* Term of office expires 31 December 1991

ϕ Retired 31 December 1989

MEMBERSHIP OF THE MEDICINES COMMISSION 1 JANUARY 1990

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APPENDIX III

REPRESENTATIONS CONSIDERED BY THE MEDICINES COMMISSION 1985-1989

	1985	1986	1987	1988	1989
Hearings	5	11	13	15	10
Written Representations	7	8	12	6	6

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COMMITTEE ON SAFETY OF MEDICINES

ANNUAL REPORT FOR 1989

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 1989 is at the end of this report. The period of appointment for all members expired on 31 December 1989. The Committee wishes to record its appreciation for the valuable work done by those members who left the Committee and Sub-Committees at the end of 1989. A new membership for the Committee and its Sub-Committees will be in place as from 1 January 1990.

The Committee would also like to record its thanks to Professor Peter Elworthy who left the Committee after 13 years of valuable service including 10 years as Chairman of the Sub-Committee on Chemistry, Pharmacy and Standards.

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 1989. A single two-day meeting, in July, was necessary to enable the Committee to complete its business.

CONSIDERATION OF APPLICATIONS

4. The table below provides a summary of applications for product licences (PLs) and clinical trial certificates (CTCs) considered by the Committee during 1989.

CSM - 1989 APPLICATIONS	PLs	CTCs
First Considerations by CSM		
Grant advised	93(74)	0(6)
Grant provisionally not advised	107(89)	0(2)

NOTE: 1988 figures are given in brackets.

CSM - ADVICE FOLLOWING HEARINGS AND WRITTEN REPRESENTATIONS 1989

25 Hearings held
9 Representations resolved with a hearing
27 Written Representations

Analysis	Hearings:	
New Active Substances	Yes	= 8
	Yes on condition	= 11
	No	= 4
Abridged	Yes	= 1
	Yes on condition	= 1
	No	= 0

Pre-hearings: used on 8 occasions

The issues were resolved on 6 occasions, and remained unresolved on 2.

	Written Representations:	
New Active Substances	Yes	= 4
	Yes on condition	= 9
	No	= 9
Abridged	Yes	= 3
	Yes on condition	= 0
	No	= 2

5. The total number of applications referred to the Committee in 1989 was 17% greater than in the preceding year. Of the product licence applications which were considered by the Committee in 1989 46.5% were considered to be satisfactory for the grant of a licence at the first consideration.

6. Product licence applications for new active substances accounted for 61% of all applications considered by the Committee in 1989.

7. The Committee noted a reduction in the average number of volumes of data submitted in support of an application from 170 volumes in 1988 to 58.9 volumes in 1989. This change is both interesting and welcome and it is believed that the reduction is a real one, although it has to be recognised that the large influx of applications received in March included many smaller dossiers, which may have distorted the figures.

8. 88 letters were written to companies in connection with unsatisfactory applications for PLs. These letters, informing companies that the Committee was provisionally intending to advise against the grant of a PL, detailed 1052 points of issue; an average of 9.8 points per application.

9. The applications considered by the CSM and included in the above table included 23 to the European Commission's Committee for Proprietary Medicinal Products (CPMP). The Committee also considered and commented on several CPMP draft guidelines.

10. The Committee considered on average 16 applications per meeting compared to 15.5 per meeting in 1988.

11. During the year there were several instances where Companies withdrew from planned hearings at short notice. The Committee is concerned at the impact this has on its carefully planned work schedule, and on the work of the Medicines Control Agency in general, and on the strict deadlines staff have to adhere to in putting reports to the Committee. It is not possible to fill vacated hearing slots at short notice.

12. Whenever possible, the Committee has been looking to seek clarification from companies on issues which it feels can be resolved without the need to issue section 21(1) letters. On occasion it has been prepared to defer items for one or two meetings to allow a company to provide reassurance on a particular point.

13. The Committee increasingly undertakes preliminary examination of applications for which oral hearings have been arranged. The aim of a 'pre-hearing' examination is to try to resolve outstanding issues wherever possible well in advance of the date fixed for the hearing. Used in appropriate cases, this procedure is proving a more efficient way of dealing with Committee business. In six of the eight pre-hearings held in 1989 the written data provided by applicants in preparation for oral hearing was sufficient to reassure the Committee and the hearings themselves were not necessary.

14. The Committee was consulted and gave advice to the Licensing Authority on a number of variations to product licences and clinical trial certificates.

15. 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. Four letters were sent in all two of which were complimentary. Other comments about the quality of applications are regularly conveyed to companies by the Committee's Secretariat.

CONSIDERATION OF OTHER MATTERS

16. In addition to applications and appeals the Committee also considered papers of medical and pharmaceutical interest. The total number of such papers considered in 1989 was 95, of which 32 dealt with adverse reactions associated with drugs (ADRs).

17. Bovine Spongiform Encephalopathy (BSE) - See Para 15 of the 1988 Report

Although the Southwood report which was issued in February 1989 advised that the risk of BSE being transferred to man through medicinal products was theoretical and remote, the Committee established a Working Party under the chairmanship of Professor J G Collee, of the University of Edinburgh Medical School, with the following terms of reference:

> To advise the Section 4 Committees on the implications of BSE to human medicinal products.

The Committee in conjunction with the Veterinary Products Committee endorsed guidelines, promulgated by the Department of Health and the Ministry of Agriculture, Fisheries and Food, to promote good manufacturing practices when bovine or other animal materials are used either as an ingredient or in the production process of human and veterinary medicines.

MARKETED PRODUCTS

18. Newly introduced products which hold a black triangle symbol are under intensive surveillance by the Committee. At the beginning of 1989 48 products were under intensive surveillance, over the year 20 drugs were removed from surveillance while 27 new products were added to surveillance. Listings of these drugs were sent to all doctors with the January and December issues of "Current Problems" to provide ready reference when reporting adverse reactions to the Committee.

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

Oral Contraceptives

In May, the Committee advised all doctors, dentists and pharmacists in "Current Problems 26" (see paragraph 20 below) about the possible effects of oral contraceptives on breast cancer, following the publication of the paper by the UK National Case-Control Study Group in the Lancet in May 1989. The Committee recommended that, taking into account both the benefits and potential risks of oral contraceptive use, there was no need for a change in oral contraceptive practice. The Committee continues to monitor ongoing studies and maintains close communication with all those concerned. Companies agreed to incorporate a statement on the findings of epidemiological studies investigating the risks of ovarian, endometrial, cervical and breast cancer associated with oral contraceptives, into product data sheets.

Human Insulin

There has been concern that the use of human insulin may be associated with impaired perception of hypoglycaemia and an increased frequency of sudden death in young diabetics, compared with animal insulins. As a consequence the Committee, in collaboration with the British Diabetic Association investigated reports of sudden deaths in diabetics and reviewed mortality statistics relating to diabetes and hypoglycaemia. These statistics show no increase in the number of deaths in young diabetics occurring over the period that human insulin has been introduced. In addition the cases of sudden death in young diabetics under investigation by the Committee do not

implicate human insulin as the cause. A number of studies are underway in this country, Europe and the USA to investigate perception of hypoglycaemia during treatment with animal and human insulins. In addition a variety of epidemiological surveys are examining mortality trends in diabetics.

Xamoterol (Corwin)

The safety of Xamoterol (Corwin) was reviewed by the Committee following clinical trial findings of higher mortality in patients with severe heart failure treated with Xamoterol compared with placebo. As a conquence of these findings the drug was contraindicated in patients with severe heart failure. A letter sent to all doctors in August 1989 by the company marketing Corwin, informed them of this and provided advice on diagnostic features indicative of severe heart failure. The data sheet provides similar advice.

L-tryptophan

In December, the Committee warned all doctors, dentists and pharmacists in "Current Problems 27" (see paragraph 20 below) about reports of a clinical syndrome of eosinophilia and myalgia which had been reported in the USA in association with over the counter dietary supplements containing L-tryptophan. It was suggested that an unidentified contaminant, as opposed to the L-tryptophan itself was the cause of the problem. The Department of Health advised the public to stop taking any non-prescription dietary supplements containing L-tryptophan as the sole or major ingredient. The Committee recommended that patients under treatment with L-tryptophan should continue their medication unless otherwise advised by their doctor, but requested reports of drug related eosinophilia. No reports of the syndrome have been received in relation to UK medicinal products.

Flecainide

The Committee conducted a review of the efficacy and safety of flecainide following the findings of the Cardiac Arrythmia Suppression Trial (CAST) which demonstrated increased mortality associated with flecainide in patients with asymptomatic ventricular arrythmias after myocardial infarction. As a consequence in December 1989, the Committee advised all doctors in "Current Problems 27" (see paragraph 20 below) about revised indications for flecainide.

COMMUNICATIONS WITH THE DOCTORS, DENTISTS AND PHARMACISTS

20. Four editions of "Current Problems", the Committee's drug safety information bulletin for doctors were issued as follows:

Current Problems 24 (January 1989) contained articles on

1. Parentrovite and allergic reactions.
2. Fenbufen, rash and pulmonary eosinophilia.
3. Nefopan hydrochloride (Acupan).
4. New drugs - the black triangle scheme.

A list of new drugs under intensive surveillance was included with this edition.

Current Problems 25 (March 1989) contained an article on mianserin and white blood cell disorders in the elderly. The original article was due to be issued in December 1988 but was the subject of an injunction brought by the manufacturers because of pending court proceedings. This was the first occasion that the publication of Current Problems has been prevented by legal action.

Current Problems 26 (May 1989) contained articles on

1. 25th anniversary of the yellow cards.
2. Oral contraceptives and carcinoma of the breast.
3. Propofol - convulsions, anaphylaxis and delayed recovery from anaesthesia.
4. Fluvoxamine and fluoxetine - interaction with MAOIs, lithium and tryptophan.
5. Serious interaction between tamoxifen and warfarin.

Current Problems 27 (December 1989) contained articles on

1. L-tryptophan and eosinophilia - myalgia syndrome in the USA.
2. Revised indications for flecainide (tambocor).
3. ACE inhibitors - use in pregnancy and the neonate.
4. Misoprostol (Cytotec) - reports of uterine bleeding and diarrhoea.
5. Oesophaglal injury with doxycycline.
6. Felbinac (Traxam) and bronchospasm.
7. New drugs under intensive surveillance by the CSM.
8. Names and addresses on yellow card reports.

A list of new drugs under intensive surveillance was included with this edition.

REPORTING OF SUSPECTED ADVERSE REACTIONS

21. The 25th anniversary of the Yellow Card reporting scheme was celebrated in 1989. A conference on the Clinical and Scientific basis of Drug Toxicity, held at the Royal College of Physicians in October to commemorate the anniversary, was a great success. The proceedings will be published.

22. Adverse reactions to medicinal products are reported to the Committee on a voluntary basis by doctors and dentists under the yellow card scheme. Reports are also received from pharmaceutical companies and other professional sources. The Committee very much appreciates the cooperation of those who submit reports.

23. 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

24. Yellow slips in the British National Formulary, the FP10 prescription pad and ABPI data sheet compendium are used for reports. Yellow slips were introduced into MIMS for the first time from August 1989. An analysis of all reports received in 1989 is set out in the table below.

Reports of Suspected Adverse Reactions Received in 1989

(Figures for 1988, where appropriate, are shown in brackets)

	Total	% of Total
Yellow Cards	7811 (8321)	40.59 (44)
BNF Slips	5116 (4084)	26.58 (21)
FP10 Slips	3896 (3396)	20.24 (18)
Data Sheet Compendium Slips	59 (120)	0.31 (-)
Industry Reports	1870 (2017)	9.72 (11)
Red Alert	35 (885)	0.18 (5)
Anaesthetists Yellow Cards	98 (37)	0.51 (-)
Cutaneous Reaction Reports	47 (7)	0.24 (-)
MIMS Slips (From August)	169 (-)	0.88 (-)

25. Red Alert Scheme

The Red Alert Scheme pilot study, run jointly by the Committee and the Drug Safety Research Unit, has provided some useful information, however it has not been considered worthwhile to continue this on a routine basis.

26. Viewdata

A number of improvements are in the process of being made to the information service. It is hoped that these will be completed, and the service re-launched in 1990.

27. Yellow Card for Anaesthetists

The pilot project to encourage reporting of drug reactions to anaesthetic agents, launched in September 1988 by the Committee, the Faculty of Anaesthetists, and the Association of Anaesthetists, continued throughout 1989. The project was based around a report form which was designed to make it easier for anaesthetists to provide information to the Committee about acute reactions to anaesthetics. The results of the project will be assessed in early 1990 and the findings published.

28. Hospital Pharmacists' Scheme

A pilot study, in which hospital pharmacists were involved in encouraging ADR reporting of suspected ADRs was completed in Wales and the Northern region during 1989. The use of a green card to be filled in by pharmacists and other health care professionals when an ADR was suspected, was found to be a useful adjunct to ADR reporting via the yellow card scheme.

29. Mersey Regional Monitoring Centre

A new Centre covering Mersey the region opened in October 1989. The Committee hopes that this will lead to increased adverse reaction reporting in the region and, where appropriate, more detailed follow-up of reports. The Centre's address has been added to all CSM adverse reaction reporting instructions on Yellow Cards.

30. ADROIT Adverse Reactions Computer System

The development of a new computer system to support the monitoring of adverse drug reactions (ADRs) was continued in 1989. Code-named ADROIT (Adverse Drug Reaction Online Information Tracking) it will increase the speed of handling ADR reports and greatly facilitate the analysis and assessment of these reports.

The design and implementation of the new system which will combine image storage on laser disk of ADR reports linked with a relational data base will be undertaken in 1990 and the system will go live in early 1991.

31. Litigation

During the year the Committee has been the subject of litigation concerning Opren, Factor VIII blood products, Valium and Mianserin.

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

Professor T G Booth OBE BPharm PhD F R Pharm S MCPP
Professor of Pharmacy Practice, University of Bradford

Professor A M Breckenridge MSc MD FRCP
Professor of Clinical Pharmacology, Liverpool University

Professor J G Collee MD FRCP FRCPath
Professor of Bacteriology, University of Edinburgh Medical School

Professor P H Elworthy BPharm PhD DSc MSc CChem MRSC F R Pharm S MCPP
Emeritus Professor of Pharmacy, University of Manchester
Visiting Professor of Pharmaceutics, King's College and the School of Pharmacy, University of London

Professor A T Florence DSc PhD FRSC FRSE F R Pharm S
Dean of the School of Pharmacy, University of London

Professor H S Jacobs BA MD FRCP
Professor of 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 BSc MD FRCP
Professor of Medicine, University of Birmingham

Professor D H Lawson MD FRCP (Edin) FRCP (Glas)
Consultant Physician, Glasgow Royal Infirmary and
Visiting Professor, Strathclyde University

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

Professor J O'D McGee MD PhD FRCPath MA (Oxon)
Professor and Head, Nuffield Department of Pathology and Bacteriology
University of Oxford, John Radcliffe Hospital

AH/8971L/11

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

Dr Elizabeth Mayne MD FRCP(G) FRCPath
Consultant Haematologist, Royal Victoria Hospital, Belfast

Professor S R Meadow MA DCh FRCP
Professor of Paediatrics and Child Health
St James' University Hospital, Leeds

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

Professor G Nuki MB BS FRCP(Ed) FRCP(London) MRCS LRCP
Professor of Rheumatology, Northern General Hospital, Edinburgh

Dr B L Pentecost MD FRCP
Consultant Physician, Birmingham

Professor M D Rawlins BSc MD FRCP (London) FRCP (Edin)
Professor of Clinical Pharmacology, Wolfson Institute of Clinical Pharmacology
University of Newcastle-upon-Tyne

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

APPENDIX II

COMMITTEE ON SAFETY OF MEDICINES

MEMBERSHIP OF SUB-COMMITTEES (CSM, CRM AND CDSM)

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

Professor M D Rawlins BSc MD FRCP (London) FRCP (Edin) (Chairman) *
Professor K B M M Alberti MA DPhil FRCP MRCPath
Dr Linda Beeley MA (Oxon) FRCP *
Professor A T Birmingham BSc MB BS
Professor A M Breckenridge MSc MD FRCP *
Dr C J Bulpitt MSc MD FRCP MRCS *
Dr R L Carter MA DM DSc FRCPath
Dr Joyce M Davidson BS FRCGP
Professor D S Davies BSc PhD CChem FRCS
Dr R Finch FRCP MRCPath
Professor C J Hull MB BS (Lon) MRCS (Eng) LRCP (Lon) FFA RCS (Eng) DA (Eng)
Dr D Jones B A MSc PhD
Dr B J Kirby MB ChB FRCP
Professor M J S Langman BSc MD FRCP *
Dr A V P Mackay BSc MA PhD MRCP
Professor J Malpas DPhil FRCP FRCR
Professor A E M McLean BM PhD FRCPath
Professor C G Swift PhD MRCP

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

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

Professor P H Elworthy B Pharm PhD DSc MSc CChem MRSC F R Pharm S MCPP
Dr M C Alwood B Pharm PhD MR Pharm S
Professor B W Barry PhD FR Pharm S CChem FRSC
Professor J R Brown BSc PhD MR Pharm S CChem FRSC MIBiol
Dr H Calam MA D Phil CChem FRSC
Dr R T Calvert BSc PhD MR Pharm S
Professor J E Carless B Pharm MSc PhD F R Pharm S
Dr A G Davidson BSc PhD M R Pharm S
Dr D J G Davies MSc PhD FRPharms
Professor F Fish B Pharm PhD F R Pharm S
Professor A T Florence DSc PhD FRSC F R Pharm S FRSE MCPP
Professor I W Kellaway B Pharm PhD M R Pharm S
Professor D W Mathieson BSc PhD CChem FRSC
Professor J M Newton B Pharm PhD F R Pharm S
Dr A E Theobald B Pharm PhD M R Pharm S
Dr D Watt MSc PhD F R Pharm S

SUB-COMMITTEE ON BIOLOGICALS

Professor J G Collee MD FRCP FRCPath (Chairman)
Professor J E Banatvala MA MD MRCP FRCPath
Professor W J Brammar BSc PhD
Dr S L Jeffcoate MB PhD FRCPath
Professor H Keen MD FRCP
Dr R S Lane MD MRCP MRCPath
Professor A J McMichael PhD CMAA MRCP
Professor J Melling MSc PhD FIBiol FPS
Professor E R Moxon MB BChir FRCP
Dr R J Perry BSc PhD MRSC CChem
Dr G Schild BSc PhD FIBiol
Dr D P Thomas DPhil MD FRCPath
Dr E G D Tuddenham MD FRCP FRCPath
Dr D A J Tyrrell CBE MD DSc FRCP FRCPath

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

Professor J G Collee MD FRCP FRCPath (Chairman)
Professor J E Banatvala MA MD MRCP FRCPath
Professor A M Breckenridge MSc MD FRCP
Dr N Cavanagh MD MRCP
Dr P E M Fine VMD PhD
Professor David Hull BSc FRCP DObst RCOG DCH
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 David L Miller MA FRCP FFCM DPH MD
Dr Elizabeth Miller MB BS BSc
Dr D Reid MD FRCP FFCM DPH
Dr Sheila Wallace FRCP DObst RCOG

VETERINARY PRODUCTS COMMITTEE
ANNUAL REPORT 1989

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:-

   a) "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 1968 is applicable.

   b) 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 1989
   (on 6 occasions over 2 days)

MEMBERSHIP

3. A list of members of the Committee is provided at Appendix 1. Dr Denyer, Miss Gibson and Dr Venitt joined the Committee in January 1989 and Dr De Matteis resigned later in the year due to other commitments. Professor Lacey and Professor Jarrett left the Committee at the end of December 1989 when their terms of office came to an end.

   The Chairman Professor Armour was awarded the CBE in June 1989 in the Birthday Honours List.

The Committee was grateful for advice it received from the Department of Health Committees on:-
Toxicity of Chemicals in Food, Consumer Products and the Environment: Carcinogenicity of Chemicals in Food, Consumer Products and the Environment: Mutagenicity of Chemicals in Food, Consumer Products and the Environment. The Committee also expressed its thanks for the work of the professional and administrative secretariat

APPLICATIONS FOR PRODUCT LICENCES AND ANIMAL TEST CERTIFICATES

4. During 1989 applications were received for 148 Product Licences and 65 Animal Test Certificates and Animal Test Certificate Exemptions. Of these, 5 were for new drug substances and 49 for reviewed Product Licences. Of the 75 applications considered in detail by the Committee 52 were recommended for refusal or revocation. Formal representations were considered in respect of 33 applications, 24 of which were oral representations, and favourable decisions were reached in 20 cases.

REPORTS OF SUSPECTED ADVERSE REACTIONS

5. Reports of suspected adverse reactions to licensed veterinary products or products undergoing trials in accordance with Animal Test Certificates were received through voluntary reporting by veterinary surgeons under the free post "yellow form" arrangements, and from pharmaceutical companies and the general public.

6. A total of 328 reports were received and investigated during 1989. Quarterly reports were submitted to the Committee and an annual summary was published in the Veterinary Record. Close liaison was maintained with the Health and Safety Executive and with the Department of Health in respect of any suspected adverse reactions reported in humans following the use of licensed veterinary products. The Committee noted that most reactions in humans followed misuse of a product or failure to observe the conditions of use or disposal specified on the label; it examined the wording of the labels concerned and considered that rewording would not help to avoid similar incidents in future.

7. Of particular interest were 79 reports, 29 involving anaphylactic type reactions of sheep reacting adversely following the simultaneous administration of clostridial and pasteurella vaccines. The Committee agreed that the vaccines involved were of satisfactory quality and that contamination was unlikely to be a contributory factor. It concluded that many of the affected sheep were subject for a variety of reasons (including disease, concurrent courses of medication and nutritional imbalance) to abnormal levels of stress at the time of vaccination and that this contributed to the reaction. The Committee recommended that the product literature of such vaccines be modified so as to clarify the circumstances when vaccination might be inadvisable.

BOVINE SOMATOTROPINS AND PRODUCTS DERIVED FROM BIOTECHNOLOGY

8. The Committee considered data in respect of applications concerning recombinant bovine somatotropin products on several occasions. At the request of Ministers, the Committee also considered whether milk from cow receiving rBST in efficacy trials covered by Animal Test Certificates should continue to enter the food chain. The Committee re-affirmed its previous advice that milk obtained from such animals was safe.

9. The Committee was informed that since products containing rBST were subject to the requirements of the Biotechnology Directive (87/22) no Product Licences should be issued without an opinion from the Committee on Veterinary Medicinal Products. The Commission had proposed a moratorium on marketing authorisations in any Member State until December 1990.

VETERINARY MEDICINES DIRECTORATE

10. The Committee noted that the separate sections of the Ministry of Agriculture Fisheries and Food concerned with technical support for the Committee, assessment and licensing of product applications and with inspection of premises manufacturing veterinary immunological products were merged into a single Veterinary Medicines Directorate on the 3rd April 1989 and that Dr J M Rutter was appointed Director.

CONFIDENTIALITY OF PROCEEDINGS

11. Members of the Committee were reminded of the current legal position of confidentiality. Changes to the Official Secrets Act would make confidentiality under this Act no longer applicable to matters coming before the Committee but the law of confidentiality and the restrictions on disclosure in Section 118 of the Medicines Act would continue to apply.

COMMITTEE OF MUTAGENICITY GUIDELINES ON THE TESTING OF CHEMICALS FOR MUTAGENICITY

12. The Committee commented on the revised Department of Health's Committee of Mutagenicity guidelines on the testing of chemicals for mutagenicity. It accepted the importance of the document which indicated inter alia that it was prudent to assume that any chemical capable of causing mutations in vivo in mammals was a potential carcinogen.

LEVAMISOLE

13. The Committee endorsed the view [of the Committee on Toxicity of Chemicals in Food, Consumer Products and the Enviornment] that some human beings particularly those with rheumatoid disease, were more sensitive to levamisole than others. Consequently the Committee agreed an M.R.L. (maximum residue level) of 0.01 parts per million in meat, milk and eggs. The Committee considered that all applicants for new or reviewed licences for products containing levamisole should be asked to submit mutagenicity data in accordance with the Committee on Mutagenicity of Chemicals in Food, Consumber Products and the Environment guidelines.

FURAZOLIDONE

14. The Committee, as part of its review of products containing nitrofurans advised that furazolidone was considered to be a genotoxic carcinogen. Products might only be acceptable for use as veterinary medicines if adequate toxicity data including C14 studies were provided to take account of furazolidone metabolites. It was also considered that adequate account must be taken of operator safety, and in the case of premixes, hazards associated with dust must be fully evaluated. A maximum residue level of 1-2 parts per billion was considered acceptable; the Committee considered that the withdrawal period for each product containing furazolidone should be greater than the time taken for residues to reach this level.

BOVINE SPONGIFORM ENCEPHALOPATHY

15. The Committee jointly agreed with the Committee for Safety of Medicines (CSM) a set of guidelines to be provided to holders of Product Licences containing material derived from cattle.

GUIDELINES

16. The Committee approved the following guidelines:

a) Guidelines for Immunological Products for Export Only

b) Guidelines for the Production and Control of Bovine Virus Vaccines.

c) Guidelines for the Production and Control of Avian Virus Vaccines.

17. The Committee also approved a Guideline in connection with the forthcoming Review of Drugs Acting on the Central Nervous System, and a Guideline for the Review of Medical Disinfectants for veterinary use.

APRAMYCIN

18. A maximum residue level of 0.1 ppm had originally been set by the committee in respect of products containing this antibiotic. After further examination of toxicology data the Committee agreed this was unnecessarily stringent and adopted a revised MRL of 1.0 ppm.

BABESIOSIS

19. The voluntary withdrawal for manufacturing reasons of the only two products licensed for use in the treatment of babesiosis in animals, was brought to the Committee's attention when it considered an application for a product containing a well established active ingredient where the toxicological data were old and had not been performed to modern standards. A final view on this application had not been reached by the end of 1989.

GUMBORO DISEASE VACCINE

20. The Committee's attention was drawn to the current serious disease situation in 1989 in which outbreaks of Gumboro Disease in poultry (Infectious Bursal Disease) did not appear to be controlled effectively with existing licensed vaccines, and mortality rates were high. The Committee considered applications for Animal Test Certificates for two vaccines both currently marketed within the Community. Since use of the vaccines posed no hazard to human health nor to the environment, the Committee recommended the issue of Animal Test Certificates subject to stringent supervision of use and immediate reporting of any suspected adverse reaction.

TURKEY RHINOTRACHEITIS VACCINE

21. The Committee recommended the issue of a Product Licence for a vaccine for use in the prevention of turkey rhinotracheitis a disease which had been responsible for significant mortality in turkeys and for which no other licensed alternative vaccine was available.

PARLIAMENTARY QUESTIONS

22. During the year, the Committee was regularly informed of Parliamentary Questions concerned with veterinary medicines, and replies provided by the Minister.

PRESS BRIEFING

23. From April 1989, the Committee agreed at the end of each meeting, a synopsis of its discussions and conclusions for use in response to enquiries from the press.

REVISED PROCEDURES

24 The Committee endorsed a revision of the notes for applicants appearing before or making written representations to the Committee.

LIAISON WITH THE ADVISORY COMMITTEE ON PESTICIDES

25. The Committee agreed that closer liaison was desirable with the Advisory Committee on Pesticides, and that it should work towards this objective in future.

EUROPEAN COMMISSION PROPOSALS

26. The Committee took note of proposals which the European Commission made to the Council in January 1989 in order to adapt Community licensing arrangements for animal medicines to the Single European Market. These related in particular to vaccines, maximum residue levels, the multi-state licensing procedures and distribution controls.

AMENDMENTS TO COMMUNITY LICENSING ARRANGEMENTS

27. The Committee also took note of a European Commission memorandum about further amendments to the Community licensing arrangements. The main features which they suggested proposing were that all products manufactured biotechnologically, or containing new pharmaceutical substances, should be assessed centrally within the European Community; companies applying to market other products should have a choice of national or Community licensing avenues. Whichever avenue was appropriate, assessment should be based strictly on objective consideration of safety, quality and efficacy, with access to independent scientific opinion.

PRODUCTS CONSIDERED UNDER DIRECTIVE 70/524 PROCEDURES

28. The Committee noted an Annex I entry for nifursol for use in turkeys as a coccidiostat. This was a new formulation compared with the previous entry in Annex II. The Committee noted that the Annex II entry for nitrovin expired at the end of June 1989. This additive is therefore no longer permitted.

The Committee noted that periods of authorisation in Annex II had been extended until November 1990 in respect of virginiamycin (cattle for fattening) avoparcin (lambs) salinomycin (pigs and piglets) avilomycin (pigs and piglets) meticlorpindol/methylbenzoquate (rabbits) lasalocid sodium (turkeys) and maduromycin (chickens for fattening).

CARBADOX

29. During consideration of a Product Licence application, the Committee re-iterated its concern that carbadox, a known mutagen and carcinogen continued to be permitted as the active ingredient of products subject to mandatory marketing authorisation under EC Directive 70/524. The Committee asked that this concern should be brought to the attention of U.K. Ministers and European Commission officials.

VETERINARY PRODUCTS COMMITTEE 1989

Chairman

Professor J Armour CBE* PhD, Dr hc (Utrecht), MRCVS	Titular Professor in Veterinary Parasitology, University of Glasgow

Membership

Professor P M Biggs* CBE, DSc, DVM (hc), FRCPath, CBiol FI Biol, FRCVS, FRS	Visiting Professor Royal Veterinary College, Microbiology, Professor at large, Cornell University, USA
Professor P G Blain* B MedSci, MB BS,PHD MRCP, CBiol, FIBiol	Professor of Environmental Medicine University of Newcastle-upon-Tyne
Professor J W Bridges** BSc, PhD, MRC Path, C Chem FRCS CBiol FIBiol, M.Inst Enc Sci	Professor of Toxicology and Director of the Robens Institute, University of Surrey
Professor J R Brown** Bsc MSC, PHd FR Pharm C.Chem, FRSC, CBiol, FIBiol	Professor of Pharmaceutical Chemistry Dean of Faculty of Science Sunderland Polytechnic
Mr D S Collins** MVB, CBiol, MIBiol, DVPH (MH), MRCVS	City Veterinarian, Belfast
Mr P J Crossman** B Vet Med, MSc, MRCVS	Practising Veterinary Surgeon Chichester, West Sussex
Dr.S Denyer** Pharm, PhD, MPS MRPharm	Department of Pharmaceutical Sciences, University of Nottingham
Miss K Gibson* BVMS, MRCVS	Practising Veterinary Surgeon Southend-on-Sea
Professor J O Jarrett# BVMS, PhD, MRCVS	Titular Professor of Veterinary Pathology, University of Glasgow
Professor D E Jacobs**	Professor of Veterinary Parasitology, Royal Veterinary College Department of Veterinary Pathology University of London
Pofessor R W Lacey# MD, PhD, MC, BChir, BA, MRCPath, DCH	Professor of Clinical Microbiology University of Leeds

Professor G E Lamming OBE* DSc, PhD, MS, BSc(Agric), Hon Assoc RCVS,FIBiol,NDA	Department of Physiology and Environmental Science, University of Nottingham
Professor P Lees** B Pharm, PhD, Hon Assoc MRCVS CBiol, FIBiol	Department of Veterinary Basic Sciences, Royal Veterinary College, University of London
Dr de Matteis PhD, State DMS (Bari),Dip Intern Med (Bari)	Medical Research Council, Toxicology Unit, Carshalton
Professor I K M Smith* MSc, PhD, MRCVS	Professor of Microbiolgy The Department of Veterinary Pathology, Royal Veterinary College, University of London
Dr S Venitt** BSc, PhD	Team Leader, Institute of Cancer Research Royal Cancer Hospital Sutton, Surrey

* Term of office expires 31.12.91.
** Term of office expires 31.12.93.
\# Term of office expired 31.12.89.

BRITISH PHARMACOPOEIA COMMISSION

ANNUAL REPORT FOR 1989

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-dated. It is also responsible for maintaining liaison with 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 for the publication of British Approved Names under Section 100 of the Medicines Act. The membership of the Commission during 1989 is given in Appendix I.

2. The Addendum 1989 to the British Pharmacopoeia 1988 was published in February. The seventh and eighth supplements to British Approved Names 1986 have also been published.

3. The British Pharmacopoeia Commission, which met six times during 1989, has appointed twelve Committees and seven Consultative Groups to assist it in its work. There were eighteen 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 wishes to thank these members for their enthusiastic support.

4. The activity of the Committees during 1989 was curtailed in comparison with that of recent years, due to delays of over a year in filling three posts in the Secretariat. There were shorter, but still significant, delays in filling vacancies in the staff of the Commission's Laboratory. The Commission expresses its gratitude to all the staff for their loyalty and hard work in this difficult year.

5. The Commission noted with pleasure the following awards made to its members and a committee member. Professor F Fish and Mr T D Turner were appointed Officer Members of the Order of the British Empire. Professor A F Fell was presented with the Royal Society of Chemistry 1988 award for chromatography and separation chemistry.

6. The Commission noted with sorrow the deaths of Sir Ashley Miles (former member of the Commission), Mr J O Dawson (former member of the consultative group on surgical sutures), Dr E F Hersant (former member of the erstwhile chemical, tablets and capsules committees) and Mr A J Middleton (former member of the erstwhile alkaloids and related substances committee).

7. At the end of the year the Chairman, Professor J B Stenlake and a member, Mr A Holbrook, retired from the Commission. Professor Stenlake had served on the Commission for over 25 years and had been Chairman since 1980: the Commission is deeply grateful for the dedicated and skilled leadership he provided during his term of office. During over 15 years with the Commission, Mr Holbrook had served as Chairman or Vice-chairman of five of the Commission's technical committees and had also contributed actively to the work of the European Pharmacopoeia. The Commission was pleased to learn that Professor Stenlake would be succeeded as Chairman by Professor D Ganderton, a member of the Commission since 1980.

POLICY MATTERS

8. The Commission has continued to reduce reliance on *in vivo* test methods wherever this is compatible with its primary objective of providing satisfactory pharmacopoeial standards. In the Addendum 1989, liquid chromatographic assays replaced biological assays for Gonadorelin and for the oxytocin component of Ergometrine and Oxytocin Injection. In addition, the European Pharmacopoeia *in vitro* test for bacterial endotoxins was introduced. It is expected that this test will find progressive application in appropriate monographs of both the British and European Pharmacopoeias in place of the *in vivo* test for pyrogens. With respect to monographs for medicinal substances of the British Pharmacopoeia, the Commission has embarked on a programme of seeking the necessary information to allow such replacement.

9. The Commission holds the view that the number of tests for Identification in many monographs of the British Pharmacopoeia and the British Pharmacopoeia (Veterinary) is greater than necessary. For many medicinal substances, comparison of the infra-red absorption spectrum with the printed reference spectrum is sufficient to verify that the identity of the material being examined is in accordance with the label on the container. The Commission has asked its advisory committees to review monographs over the next two or three years and to restrict the number of identity tests to the minimum consistent with the need to maintain the overall standard of monographs. The results are unlikely to become obvious before the next full editions of the British Pharmacopoeia and the British Pharmacopoeia (Veterinary).

BRITISH PHARMACOPOEIA 1988

10. The Addendum 1989 to the British Pharmacopoeia 1988 was published in February and came into effect on 1 July 1989. Amendments No 3 were issued, also with effect from 1 July 1989. The Addendum costs £15.00 and is available from Government Bookshops or from the Pharmaceutical Press (ISBN 0 11 321162 7). Amendments No 3 are supplied free of charge to registered purchasers of the British Pharmacopoeia or may be purchased separately as above (ISBN 0 11 321230 5, price £1.95).

11. The Addendum includes eight monographs that are new to the British Pharmacopoeia and a considerable number of amended texts. As foreshadowed in the introduction to the British Pharmacopoeia 1988 procedures for carrying out the test for uniformity of content of active ingredient have been added to a number of monographs for capsules and tablets.

BRITISH PHARMACOPOEIA (VETERINARY) 1985

12. Amendments No 3 to the British Pharmacopoeia (Veterinary) 1985 were published with an effective date of 1 July 1989. The Amendments may be purchased from HMSO and other bookshops (ISBN 011 321231 3, price £2.40).

EUROPEAN PHARMACOPOEIA

13. The European Pharmacopoeia Commission met on three occasions during 1989. In addition, forty-three meetings of its Groups of Experts were held.

14. 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. Professor J B Stenlake retired from the delegation on 31 December 198. and is succeeded by Professor D Ganderton. Miss M L Rabouhans was appointed an alternate member of the delegation. The British Pharmacopoeia Commission records its appreciation and gratitude to the delegation and to the Group

members who unstintingly continue to devote their time, care and expertise to this important task, in particular to Professor Stenlake whose leadership during his tenure of membership of the delegation has proved invaluable.

15. Portugal signed the European Pharmacopoeia Convention with effect from 22 July, exactly 25 years after the signature of the Convention by the eight founder states.

16. The European Pharmacopoeia Commission celebrated the 25th anniversary of the Convention on the Elaboration of a European Pharmacopoeia with a scientific congress held at the Palace of Europe in Strasbourg from 26 to 28 June 1989. The then Minister of State for Health, Mr David Mellor QC MP, was a principal speaker at the opening session. Two members of the United Kingdom delegation, Dr Calam and Dr Rogers, were members of the scientific organising committee and staff from the British Pharmacopoeia Laboratory contributed to a poster presentation. The congress was attended by over 400 participants from the 19 signatory states to the Convention, including several members of the British Pharmacopoeia Commission and its staff, as well as from east European countries, the United States of America and Japan.

17. Dr A Artiges of the French delegation was elected Chairman of the European Pharmacopoeia Commission and took up office at the 75th Session in November. Dr A R Rogers of the UK delegation and Professor I Sjöholm of the Swedish delegation were elected First and Second Vice-chairmen respectively.

18. In November, following two years of negotiation, a protocol to the European Pharmacopoeia Convention, providing for the European Community to adhere to the Convention, was opened for signature by member states.

19. 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 on the recommendation of the Medicines Commission.

20. The date of implementation of the monographs and other texts in the thirteenth fascicule of the second edition of the European Pharmacopoeia is 1 January 1990.

LIST OF NAMES

21. 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.

22. During 1989 Supplements Nos 7 and 8 to 'British Approved Names 1986' were prepared and published on the recommendation of the Medicines Commission; 71 names were thereby added to the list. There are now also 22 single-word names ('Co-' names) for combination products.

23. The British Pharmacopoeia Commission continued to participate in the work of the World Health Organization (WHO) 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 (USAN) Council. In April, the secretary to the Commission's Nomenclature Committee attended consultations on International Nonproprietary Names (INNs), held in Geneva, that led to the publication

during the year of two further lists (Nos 61 and 62) of proposed International Nonproprietary Names.

24. The Commission continued to consider ways in which support could be given to the WHO in its quest to achieve protection of INNs from infringement by trade marks. The WHO considers that trade marks that infringe INNs pose potential safety hazards and impede the orderly selection of nonproprietary names for new medicinal substances.

25. The Commission stresses that certain Recommended INNs are unsuitable for labelling purposes in the United Kingdom either because of their conflict with trade marks registered only in the UK or because of well established British precedents. The Commission is working to ensure that there is no hindrance to the continued use of 'aspirin', 'adrenaline' and over 100 other names that are not INNs.

COMMISSION LABORATORY

26. The point has been reached where it is possible to assess progress of the programme of work initiated in April 1987. It is apparent that the production of new monographs is slower than had originally been projected. Several factors have contributed to this situation, including slow responses by some manufacturers in providing specifications and the unexpectedly long time required to develop single monographs for combination products available from several manufacturers. Additionally, the increased rate of introduction of drug substance monographs in the European Pharmacopoeia has led to an increasing amount of revision of the dosage form monographs and the continued emphasis on the critical assessment of methods, which ensures the robustness of published methods, is necessarily time consuming. Further progress was made on the inclusion of a test for dissolution in selected monographs for capsules and tablets.

27. Support has been provided to UK members of European Pharmacopoeia Groups of Experts. In particular it has been possible to take part in some collaborative exercises in which proposed assays or tests for Ph Eur monographs have been critically examined.

28. The introduction of the Control of Substances Hazardous to Health (COSHH) regulations has placed an additional responsibility on senior staff. The assessment necessary to provide information to laboratory staff and to customers of reference substances has been lengthy and still continues.

29. The demand for reference substances continues to rise and this, in conjunction with a price increase from £25 to £30, has resulted in projected sales totalling £170,000 for the year 1989-1990. This may be compared with about £120,000 for 1988-89 and £92,000 for 1987-88. The proportion of these sales to overseas destinations remains at about two thirds. Computerisation of the sales procedures is allowing a more efficient service to be provided.

30. An additional 14 reference materials were established. This was offset to some extent by the introduction of Ph Eur reference substances where a change of monograph responsibility has taken place. Overall, there was little change to the total number of reference substances maintained by the Laboratory. However, the greater demand does result in an increased amount of replacement substances and subsequent authentication.

LIAISON WITH OTHER ORGANISATIONS

31. The British Pharmacopoeia Commission is again pleased to pay tribute to the valuable support for its work that continues to be provided by members of the staff of the National Institute for Biological Standards and Control, extending over a wide range of topics embracing antibiotics, hormones, immunological and other products. Similar valuable support has again been received from staff of the Veterinary Medicines Directorate, Weybridge, in respect of veterinary medicines.

32. Fruitful contact is also maintained on a wide range of topics with overseas authorities, in particular with the United States Pharmacopeia Convention, the Therapeutic Goods Administration Laboratories, Canberra, Australia and a number of official laboratories in countries party to the European Pharmacopoeia Convention.

33. 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 of the British Pharmacopoeia Commission's Secretariat participated in WHO consultations.

APPENDIX I

MEMBERSHIP OF THE BRITISH PHARMACOPOEIA COMMISSION

† J B Stenlake CBE DSc HonDSc(Strathclyde) PhD FRPharmS CChem FRSC FRSE (Chairma
Honorary Professor of Pharmacy in the University of Strathclyde

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 Quality and Compliance 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

* D Ganderton BPharm PhD FRPharmS
Professor of Pharmaceutics in the 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

† A Holbrook MChemA CChem FRSC
A Scientific Adviser in the Pharmaceutical Industry

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

* 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

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

† Term of office ended 31 December 1989
* 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), J B Stenlake (Vice-Chairman), A L Barber, A G Davidson, J A Goldsmith, N Randall, C Ratcliffe, G D Rees, J E Shinner, J R Slater, P R Wood
B : Medicinal Chemicals	A F Fell (Chairman), A Holbrook (Vice-Chairman), F Bailey, J K Bailey, F Breslin, P H Cobb, H B Davis, G Drewery, B M Everett, E J Kempster, M Martin-Smith, B Midcalf, R N Thornhill (Corresponding member B Warren)
C : General Chemicals	G F Phillips (Chairman), A Holbrook (Vice-Chairman), G Bratt, P N Brittain, A Burbage, A G Davidson, B M Everett, R E King, A McCraight, J M Midgley, S U Ruff, J M Sprake, C H Thorpe
D : Medicinal Chemicals	A Holbrook (Chairman), J F Chissell (Vice-Chairman), G P R Carr, L A Gifford, J A Goldsmith, D W Houghton, J P Jefferies, W McMeekin, 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 W Adams, E Addison, A E Bird, A K Coulter, P J Duff, D Moriau, A H Thomas, I R Williams (Corresponding member R K Howard)
F : Pharmacy	D Ganderton (Chairman), B A Wills (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 J Brown, D Griffin, K Helliwell, B P Jackson, P Linley, J D Phillipson, A R Rixon, A J Woodgate (Corresponding member J R Slater)
H : Biological Materials	D H Calam (Chairman), D R Bangham (Vice-Chairman), D M Benoliel, 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, A F Machin, G Moss, H McNulty, M A Simmonds, A Wade (Corresponding members G R Tudhope, A Wehrli)
N : Veterinary Medicine and Doses	A O Betts (Chairman), W G Allen (Vice-Chairman), R J Bywater, D E Jones, A R M Kidd, A Knifton, D G McBeath, D A Rutty

CORRESPONDING CONSULTATIVE GROUPS

K : Blood Products	K J Ayling (Chairman), T W Barrowcliffe, R S Lane, R J Perry, D S Smith, 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, D W Mathieson, W I Stephen, J S Wragg
U : Reagents	A Holbrook (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), J O Dawson†, 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

† deceased May 1989

APPENDIX III

EUROPEAN PHARMACOPOEIA COMMISSION

UNITED KINGDOM DELEGATION		J B Stenlake (Head of Delegation) D H Calam A R Rogers
	Alternates:	D Ganderton 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	G P R Carr
Group 3	Nomenclature and Drafting	A R Rogers
Group 4	Physical and Physico-chemical Methods	G P R Carr
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	T D Turner
Group 9	Inorganic Chemistry	S U Ruff
Group 10A	Organic Chemistry (Synthetic Products)	A C Caws
Group 10B	Organic Chemistry (Synthetic Products)	A R Rogers (Chairman) A Holbrook
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
	Sub-group on Fatty Oils	J D Phillipson
Group 14	Radioactive Compounds	D E Lovett
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 1989

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 six meetings in 1989. During the year the CRl held 16 oral hearings and considered 23 written representations against their provisional advice. The Committee also considered a further 51 applications referred to them. Details are given at Appendix II.

5. After extensive discussions and consultation, the Committee recommended that the Licensing Authority adopt a standard method of assessing the bioequivalence of different phenytoin products. The method recommended involved a comparison of pharmacokinetic parameters after single doses of the test formulation and a standard/reference solution of phenytoin.

6. Following adoption of this practice, the review of all outstanding phenytoin formulations was completed during the year.

7. A review of the bioequivalence of digoxin products was also completed during the year.

8. The Committee noted with concern the potential for poor and variable absorption of aminophylline from fat-based suppositories. As a result, these products are no longer licensed in the UK.

9. The Committee expressed concern over the availability of herbal infusions (teas) containing comfrey. This followed their earlier advice that the risks posed by products containing comfrey, although small, were unacceptable.

10. The Committee, and the Committee on the Safety of Medicines, considered the risks of prolonged use of laxatives containing liquid paraffin. A change of legal category and restrictions to use were recommended.

11. Despite staff shortages throughout most of 1989, a steady rate of clearance of applications was maintained. Statistics of the review progress are given at Appendix III. The number of applications remaining to be processed under the review programme is 1687.

12. The Committee noted with approval the strengthening of professional staff resources towards the end of the year. It is hoped that staffing will remain at a level sufficient to ensure that the review is completed in 1990.

13. The Committee expressed their appreciation of the valuable contributions made to its work by Professor Lader and Dr Munro-Faure who left the CRM at the end of 1989.

MEMBERSHIP OF THE COMMITTEE ON THE REVIEW OF MEDICINES

Professor D H Lawson MD FRCP (Chairman)
Consultant Physician, Royal Infirmary, Glasgow. Visiting Professor, Universit 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 FFCM 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, Hammersmit 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 Pediatrics 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. Consulta Physician, Royal Devon and Exeter Hospital.

* Professor M H Lader DSc PhD MD FRC Psych
Professor of Clinical Psychopharmacology, University of London.

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.

MEMBERSHIP OF THE COMMITTEE ON THE REVIEW OF MEDICINES

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

* Dr A Douglas Munro-Faure MA BM FRCP (Lond) FRCP (C)
Retired Director of Clinical and Applied Research, Wellcome PLC, London.

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.

NOTE

Term of office for all members expired on 31 December 1989.
All except those marked * were reappointed from 1 January 1990.

Members appointed for specific meetings-

March	Professor M D Rawlins BSc MD FRCP (London) FRCP (Edin) Professor of Clinical Pharmacology Wolfson Institute.
March	Dr D J Davies MSc PhD FRPharmS Reader in Pharmaceutics University of Bath.
July and November	Dr R Thorpe BSc PhD Head of the Division of Immunobiology National Institute for Biological Standards and Control.

1. COMMITTEE PROCEEDINGS 1989

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

a.	applications	51
b.	written representations (following notification under Section 21(1)*)	23
c.	hearings (following notification under Section 21(1)*)	16
	Total	90

1.2 Advice given to Licensing Authority following reference

a.	licence should be granted without amendment to application	11
b.	licence should be granted with amendment to the application (as accepted by the applicant)	24
c.	CRM unable to recommend that a reviewed product licence should be granted	55
	Total	90

2. COMMITTEE PROCEEDINGS 1985-1989

Referred to CRM for advice:	1985	1986	1987	1988	1989
Applications	118	93	52	45	51
Written Representations	26	34	22	19	23
Hearings	13	8	12	8	16
Advice:					
Licence should be granted	10	2	1	nil	11
Licence should be granted with amendment	40	47	29	40	24
Licence should not be granted	105	85	56	32	55

* 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 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 of the grounds for any unfavourable advice.

APPENDIX III

PROCESSING OF APPLICATIONS FOR REVIEWED PRODUCT LICENCES

1. Applications Received

i.	in house, awaiting action at 1 January 1989	2060 +
ii.	under Section 24(1A)*	65 #
iii.	under 1987-1988 review programme	472 #
iv.	total available for review in 1989	2597

2. Applications Processed

i.	reviewed licences granted in 1989	719
ii.	applications withdrawn	132
iii.	licences revoked	2
iv.	applications refused	57
v.	licences of right renewed by the Licensing Authority and applications therefore cancelled	NIL
vi.	total applications processed	910

3. Applications in-house awaiting assessment, advice or licensing action at 31 December 1989 — 1687

4. Review Applications Processed from 1985 to 1989

	1985	1986	1987	1988	1989
Licences granted	425	435	639	565	719
Total number applications processed	567	704	831	735	910

NOTES:

This figure is different from that quoted in the 1988 report due to the correction of a statistical error.

Section 24(1A), which was inserted into the Medicines Act by SI 1977/1050, provides power to the Licensing Authority to terminate a licence where it considers that it would no longer be possible to grant that licence without contravening a Community obligation. It is often for companies to decide whether to apply for a reviewed product licence. Practice is to allow 6 months between the issue of a S24(1A) notice and expiry of a licence. The figures at 1(ii) and (iii) include applications for which notices were issued in 1988 and 1989.

Late applications received in 1989.

COMMITTEE ON DENTAL AND SURGICAL MATERIALS

ANNUAL REPORT FOR 1989

INTRODUCTION

1. The Committee on Dental and Surgical Materials was established in 1975 under Section 4 of the Medicines Act 1968. Its terms of reference are :

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

(i) substances or articles for dental or surgical use including instruments apparatuses or appliances to which any provision of the Medicines Act 1968 applies, and medicinal products or other substances or articles 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;

(ii) substances and fluids for use with contact lenses or blanks.

b. to promote the collection and investigation of information on 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. The number of cases referred to the Committee for advice is given in Appendix II.

4. The Committee considered a variety of topics and gave advice on them to the Licensing Authority. CDSM workload has grown over the past year, with a noticeable increase in the number of new chemical entities, including new treatments for glaucoma, raised intraocular pressure following laser surgery, and allergic eye disease.

5. The Committee considered applications for product licences for a novel solid dosage form for delivery of ophthalmic antibiotics and other medications, and a new approach to contact lens disinfection. Several applications to the Committee on Proprietary Medicinal Products of the European Community (CPMP) were considered, including a new ocular anti-inflammatory agent.

6. Following their consideration of yellow card reports of wound dehiscence in association with a synthetic absorbable suture, the Committee set up a working party to examine these in more detail. The Chairman wrote to surgeons alerting them to the apparent problem, and asking to be notified of any further adverse events.

7. The Committee considered yellow card reports of ocular intolerance in relation to ophthalmic products.

8. The Committee notified the Licensing Authority of its general concern about the levels of an antimicrobial agent in the blood of normal volunteers arising from its use in cosmetic as well as medicinal products.

9. The Committee considered a proposal that the legal status of a corticosteroid dental paste should be changed from Prescription Only Medicine (POM) to Pharmacy (P). On grounds of safety, the CDSM advised the Licensing Authority against the change.

10. The Committee considered the draft of a European Directive on Active Implantable Medical Devices. They had in the past expressed concern over the safety of certain medical devices. The Chairman also wrote to the Chief Medical Officer to convey concerns over future regulation of medical devices, in particular those products currently licensed under the Medicines Act and its Amendment Orders.

11. The Committee also gave advice on draft European Guidelines on Good Clinical Practice.

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 College
London
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

Mr J Cunningham FDS RCS Ed
Senior Lecturer
Department of Operative Dental Surgery
Liverpool University

Mr S Davidson MB ChB FRCS DO
Director of Studies in Ophthalmology
University of Liverpool
Consultant Ophthalmic Surgeon
St Paul's Eye Hospital

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

Professor P H Elworthy B Pharm PhD DSc MSc C Chem MRSC FRPharmS MCPP
Emeritus Professor
Department of Pharmacy
University of Manchester

Mr J Guillebaud MA FRCSE FRCOG
Senior Lecturer in the Academic Unit of Obstetrics of Gynaecology
University College and Middlesex School of Medicine
Medical Director
Margaret Pyke Centre for Study and Training in Family Planning
London

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

APPENDIX I
(continued)

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

Professor D Poswillo CBE DDS DSc MDhc FDS FRACDS Hon FFD RCSI FIBioL FRC Path
Professor of Oral and Maxillofacial Surgery
United medical and Dental Schools
Guy's and St Thomas's Hospital
University of London

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 D W Vere MD FRCP
Professor of Therapeutics
Department of Pharmacology and Therapeutics
London Hospital Medical College
University of London

Dr J R B Williams MD FRC Path
Honorary Consultant Haematologist
Lister Hospital
Stevenage

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

APPENDIX I
(continued)

NOTE

1. Term of office for all members expires 31 December 1989.

Members appointed for specific meeting:-

January - Mr J K G Dart FRCS Clinical Lecturer and Honorary Consultant, Moorfields Eye Hospital

Professor A M Mclean BM PhD FRC Path, Professor of Toxicology, Department of Clinical Pharmacology, University College Hospital Medical School

Professor D W Mathieson PhD BSc C Chem FRSC

Dr B Tighe BSc PhD FRS Chem, Reader in Polymer Science, Aston University

July - Professor N B Graham BSc PhD C Chem FRSC FPRI FRSC, Professor of Chemical Technology, University of Strathclyde

September - Mr Peter Wright MBBS FRCS MRCS LRCP, Consultant Ophthalmologist, Moorfields Eye Hospital

November - Dr A D Russell BPharmS PhD FRPharmS FRC Path, Reader in Pharmaceutical Microbiology, University of Wales, Institute of Science and Technology

Dr Eric Chantler BSc PhD, Senior Lecturer in Biochemistry, Department of Obstetrics and Gynaecology, University of Manchester

Dr Ian White MBBS MRCP MRCS LRCP DIH, Consultant Dermatologist, St John's Hospital

APPENDIX II

COMMITTEE ACTIVITIES	PRODUCT LICENCES +	CLINICAL TRIAL CERTIFICATES
A. APPLICATION FOR LICENCES AND CERTIFICATES		
Number of applications referred to Committee during the year	62	
B. ADVICE ON APPLICATIONS		
Grant advised without hearings or representations:		
in accordance with applications	1	
other than in accordance with application	6	
Grant advised following hearing or representations (Section 21(1) action) *	8	
Refusal advised	23	
Application withdrawn:		
following Section 21(1) action *	2	
following Section 44 action **	NIL	
C. APPLICATIONS OUTSTANDING		
Applications subject to Section 21(1) action * not yet complete	22	
Applications subject to Section 44 action ** not yet complete	NIL	
D. ADVICE ON EXISTING LICENCES AND CERTIFICATES		
Variations determined:		
Grant advised	1	
Refusal advised	NIL	
Revocation considered	2	

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 Licensing Authority. For this purpose the Committee is required to notify the applicant of the grounds for any unfavourable advice.

APPENDIX II
(continued)

** Applications considered by the Committee and referred under Section 44 of the Medicines Act 1968 which enable the Licensing Authority to seek additional information from applicants in order to determine applications.

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 mentioned 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 medication 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.

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.

b. Section 4 Committees The Committee on Safety of Medicines, the Committee on the Review of Medicines 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.

* Excluding the British Pharmacopoeia Commission and its Committees

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.

8. Non-Personal Interests

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 a 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 or, except as set out below, non-personal interests in the pharmaceutical industry. The one exception is where a member of staff in a unit for which the Chairman is responsible is engaged on research, giving advice or other commissioned work for the pharmaceutical industry, but the Chairman has no personal involvement in any way with the work done or advice given. The position of Sub-Committee Chairmen is the same as for all other members, since Sub-Committees report to the main Committees 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 an 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	DIRECTOR AND FEE	NONE		
MR M J S BUTLER	NONE		NONE		
DR M G CARTER	ICI PLC	SALARY AND SHARE HOLDER			
PROFESSOR W I CRANSTON	NONE		SERVIER LTD ELI LILLY DUNCAN FLOCKHARD LILLY BAYER EFAMOL ICI KABI VITRUM AYERST LABS LTD SQUIBB PHARMACIA BEECHAM PHARMACEUTICALS FISONS PLC GLAXO RESEARCH LTD ROUSSEL UCLAF (PARIS)	RESEARCH FUNDING	YES

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 W I CRANSTON (CONTINUED)			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 F D'ARCY	WELLCOME PLC	SHARE HOLDER	NONE		
PROFESSOR A P DAWID	GLAXO GROUP RESEARCH LIMITED	CONSULTANCY/GRANT	NEUROENDOCRINOLOGY AND OPTHALMOLOGY RESEARCH TRUST	TRUSTEE	YES
	FASTMALT LIMITED	DIRECTOR/SHAREHOLDER	IPSEN BEAUFOUR	SUPPORT FOR ABOVE TRUST	

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 A D DAYAN	SMITH KLINE BEECHAM BOOTS GLAXO	SHAREHOLDER	ASTRA	SUPPORT FOR PHD STUDENT	YES
			GLAXO	SUPPORT FOR PHD STUDENT	YES
			GLAXO	RESEARCH GRANT	YES
	BEECHAM BIOGEN CELLTECH WELLCOME FOUNDATION	CONSULTANCY			
	ORTHO CILAG WYETH AYERST	ADVICE ON ONE COMPOUND			
PROFESSOR M F DRUMMOND	THE WELLCOME FOUNDATION LTD	CONSULTANCY	THE WELLCOME FOUNDATION LTD	RESEARCH GRANT	YES
	MERCK SHARP AND DOHME INTERNATIONAL	CONSULTANCY	SEARLE AND CO	RESEARCH GRANT	NO
	UPJOHN LTD	CONSULTANCY	LIPHA	RESEARCH GRANT	YES
	SANDOZ	CONSULTANCY	RHONE POULENC	RESEARCH GRANT	NO
	SMITH KLINE BEECHAM	CONSULTANCY	MERCK SHARP AND DOHME INTERNATIONAL	RESEARCH GRANT	YES
	GLAXO	CONSULTANCY			
DR J C GOULD	BEECHAM PHARMACEUTICALS	CONSULTANCY	NONE		
MISS J C V GREENLEAF	NONE		NONE		

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 B D HOSKIN	COOPERS ANIMAL HEALTH LTD	SALARIED UNTIL 31.8.89	NONE		
	PITMAN MOORE EUROPE	CONSULTANCY FROM 1.11.89			
	WELLCOME PLC	SHARE HOLDER			
	ICI PLC	SHARE HOLDER			
	OXFORD VIROLOGY LTD	CONSULTANCY (NOW COMPLETED)			
MR C N HUDSON	NONE		NONE		
PROFESSOR J M JONES	WELLCOME PLC	DIRECTOR	NONE		
PROFESSOR I KENNEDY	NONE		NONE		
DR M J LINNETT	ICI	SHARE HOLDER	NONE		
PROFESSOR D G MCDEVITT	DRUG DEVELOPMENT SCOTLAND LTD	DIRECTOR (EX-OFFICIO)	ASTRA	RESEARCH GRANT	NO
	ICI	ADVISORY GROUP	BAYER	RESEARCH GRANTS	YES
	WARNER-LAMBERT	MEDICAL REFEREE	BEECHAM	RESEARCH GRANT	YES
			BOOTS	RESEARCH GRANT	YES
			GLAXO	SUPPORT FOR RESEARCH FELLOW	YES
			ICI	RESEARCH GRANTS	YES
			LEDERLE	RESEARCH GRANT	YES
			JANSSEN	RESEARCH GRANT	YES
			PARKE-DAVIS	RESEARCH GRANTS	YES
			G D SEARLE	RESEARCH GRANTS	YES
			SMITH KLINE AND FRENCH	SUPPORT FOR RESEARCH FELLOW	YES
			SQUIBB	RESEARCH GRANTS	YES

MEDICI COMMISSION

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 P C PIETRONI	NONE		NONE		
PROFESSOR J RHODES	SMITH, KLINE AND FRENCH	CONSULTANCY	SMITH KLINE AND FRENCH	FINANCE FOR RESEARCH STAFF)	
	TILLOTTS LABORATORIES	CONSULTANCY	TILLOTTS LABORATORIES	FINANCE FOR RESEARCH STAFF)	YES
	ICI	SHARE HOLDER	MERCK SHARP AND DOHME	FINANCE FOR CLINICAL TRIAL)	
	SMITH AND NEPHEW	SHARE HOLDER	GLAXO LABORATORIES	GRANT FOR EQUIPMENT)	
			LEDERLE	FINANCE FOR CLINICAL RESEARCH	
PROFESSOR J B STENLAKE	AMERSHAM INTERNATIONAL) BOOTS) ICI)SHARE HOLDER SMITH AND NEPHEW)		NONE		
	WELLCOME FOUNDATION LTD	SHARE HOLDER ROYALTY INCOME FROM TRACRIUM (ATRACURIUM) RESEARCH CONTRACT			
MR G C TUCK	MILES LIMITED	COMPANY SECRETARY AND LEGAL DIRECTOR (SALARIED)	NONE		
PROFESSOR D W VERE	RHONE POULENC (UK) LTD	CONSULTANCY (WITHOUT PERSONAL FINANCIAL INTEREST)	SANDOZ, BASLE	RESEARCH GRANT	NO
DR D R WILLIAMS	NONE		NONE		
MR H C WILSON	NONE		NONE		

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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		UPSA KNOL DELTA BIOTECHNOLOGY LTD MAY AND BAKER JANSSEN PHARMACEUTICALS PHARMAX LTD GLAXO LABORATORIES SANOFI MILUPA LTD ADVISORY SERVICES (CLINICAL & GENERAL) LTD HOECHST UK LTD ACRAF UK LTD SMITH KLINE AND FRENCH E R SQUIBB AND SONS LTD GLAXO GROUP RESEARCH LTD SEVEN SEAS LTD ZYMA UK LTD MERRELL DOW ICI PHARMACEUTICALS PFIZER LTD	DEPARTMENTAL RESEARCH GRANTS	YES

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 S S BLEEHEN	STEIFEL LABS (UK)	SKIN FORUM ADVISORY BOARD (FEE)	UNILEVER RESEARCH	RESEARCH GRANT	YES
	SANDOZ	RESEARCH GRANT	ROCHE	GRANT TO DEPARTMENT	NO
PROFESSOR T G BOOTH	WELLCOME PLC	SHARE HOLDER	BOOTS PLC	STAFF FUNDING	YES
	SCHOLL UK LTD SMITH & NEPHEW LTD NICHOLAS LABORATORIES LTD CONVATEC LTD CELL-TECH LTD	) CONSULTANCY AND FEE PAID WORK	AAH PHARMACEUTICALS LTD GLAXO PHARMACEUTICALS LTD JANSSEN PHARMACEUTICALS LTD LILLY INDUSTRIES LTD	GRANT SUPPORT FOR CHAIR FELLOWSHIP SUPPORT RESEARCH SUPPORT	YES YES YES YES
PROFESSOR A M BRECKENRIDGE	SMITH KLINE AND BEECHAM	CONSULTANCY	BOEHRINGER MANNHEIM BRISTOL MYERS CO LTD DUNCAN FLOCKHART & CO LTD GLAXO PHARMACEUTICALS ICI KIRBY WARRICK ORGANON LABORATORIES LTD ORTHO PHARMACEUTICALS PARKE DAVIS RESEARCH LABORATORIES PFIZER LTD SANDOZ PHARMACEUTICALS	DEPARTMENTAL RESEARCH GRANTS	YES

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 M BRECKENRIDGE (CONTINUED)			SCHERING HEALTH CARE LTD G D SEARLE SMITH KLINE & FRENCH LABORATORIES STUART PHARMACEUTICALS	DEPARTMENTAL RESEARCH GRANTS	YES
PROFESSOR J G COLLEE	NONE		THE WELLCOME TRUST ETHICON LIMITED BAYER (UK) LTD WELLCOME DIAGNOSTICS SMITH & NEPHEW LTD THE WELLCOME FOUNDATION LTD COGENT UNIPATH LTD GLAXO LABORATORIES BEECHAM PHARMACEUTICALS	FUNDING FOR RESEARCH PROJECTS AND SURVEYS	YES
PROFESSOR P H ELWORTHY	NORWICH EATON	CONSULTANCY	NONE		
PROFESSOR A T FLORENCE	NAPP RESEARCH CONTROLLED THERAPEUTICS	CONSULTANCY	BAYER AG BEECHAM BOOTS PLC DAIICHI SEYAKU (JAPA	RESEARCH GRANTS TRAVEL GRANTS, GIFTS OF RESEARCH MATERIAL AND EQUIPMENT, STUDENT GRANTS AND LECTURE FEES	YES
	SYNTEX RESEARCH CENTRE EDINBURGH MEDIRACE PLC	CONSULTANCY AND MEMBER OF SCIENTIFIC ADVISORY BOARD			

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 T FLORENCE (CONTINUED)			FMC CORPORATION (PHILADELPHIA), GLAXO GROUP RESEARCH, GLAXO, (VERONA), HOECHST (UK), SANDOZ PRODUCTS, SKF, WYETH RESEARCH (UK), LILLY INDUSTRIES, BAXTER HEALTH CARE, BOEHRINGER, CIS PHARMACEUTICALS, CIBA-GEIBY, ICI, JANSSEN, MSD, RHONE-POULENC, ROCHE, UPJOHN, R P SCHERER, WELCOME, SYNTEX	RESEARCH GRANTS, TRAVEL GRANTS, GIFTS OF RESEARCH MATERIAL AND EQUIPMENT, STUDENT GRANTS AND LECTURE FEES	YES

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 H S JACOBS	SERONO NOVO-NORDISK	CONSULTANCY	SYNTEX SANDOZ NOVO-NORDISK (DENMARK) SANDOZ (UK)	LABORATORY EXPENSES FOR TRIALS AND RESEARCH FELLOW	YES
DR W A JERRETT	NONE		NONE		
PROFESSOR M J S LANGMAN	BAYER WELLCOME	CONSULTANCY	GLAXO SMITH KLINE BEECHAM ASTRA LEDERLE FISONS PHARMA ITALIA SCHERING MERCH SHARPE AND DOHME ICI	DEPARTMENTAL SUPPORT	YES

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 D H LAWSON	NONE		NONE		
MR F E LOEFFLER	NONE		SERONO	TREASURE: BRITISH FERTILITY SOCIETY: FINANCIAL SUPPORT	YES
DR E MAYNE	BOOTS PLC) GLAXO)	SHARE HOLDER	NONE		
PROFESSOR J O'D McGEE	AMERSHAM INTERNATIONAL PLC (UK)) HOFFMAN - LA ROCHE INC (USA))	CONSULTANCY	SMITH KLINE AND FRENCH	RESEARCH GRANT	YES
			UPJOHN	FINANCIAL ASSISTANCE (STUDENTS)	YES
			DAKO LTD (DENMARK)	STUDENT GRANT AND DEPARTMENTAL CONSULTANCY	YES
PROFESSOR A E M McLEAN	WILLFARM (BELGIUM)) ROUSSEL LTD) SMITH & NEPHEW) RESEARCH LTD) RIKER 3M HEALTHCARE)	CONSULTANCY	STERLING WINTHROP	RESEARCH GRANT	YES
	BRITISH TECHNOLOGY GROUP	PATENT ROYALTIES			

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 E M McLEAN (CONTINUED)	DELTA BIOTECHNOLOGY) (NOTTINGHAM)	CONSULTANCY			
PROFESSOR S R MEADOW	BOOTS) BEECHAM)	SHARE HOLDER	FERRING	FEE TO DEPARTMENT	YES
DR S MONTGOMERY	LILLY INDUSTRIES) ORGANON INTERNATIONAL) BEECHAM) MERCK) SANOFI)	LECTURES/ADVICE	ICI) NOVO) GLAXO)	CONTRIBUTION TO SUPPORT RESEARCH AND STAFF COSTS	YES
PROFESSOR G NUKI	MERCK SHARP & DOHME SMITH KLINE & FRENCH	SENIOR MEMBER - MEDICAL ADVISORY COUNCIL MEMBER RHEUMATOLOGY ADVISORY BOARD	CIBA-GEIGY SANDOZ BIOGEN CORPORATION CYSTRON BIOTECHNOLOGY AMERSHAM INTERNATIONAL ROUSELL MEDGINEX	RESEARCH GRANT RESEARCH GRANT RESEARCH GRANT RESEARCH GRANT RESEARCH GRANT RESEARCH GRANT RESEARCH GRANT	NO NO YES NO NO NO NO

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 G NUKI (CONTINUED)			A H ROBINS	RESEARCH FELLOWSHIP	YES
			WYETH LABS	RESEARCH FELLOWSHIP	YES
			GLAXO	PHD STUDENTSHIP	YES
DR B L PENTECOST	NONE		NONE		
PROFESSOR M D RAWLINS	NONE		JANSSEN SANDOZ ELI LILLY STERLING WINTHROP MSD ASTRA BAYER STERLING RESEARCH BOOTS E MERCK ALMIRAL BYK GULDER	DEPARTMENTAL RESEARCH GRANTS AND CONSULTANCIES	YES
PROFESSOR M P VESSEY	NONE		SMITH, KLINE & BEECHAM CIBA-GEIGY MERCK SHARPE AND DOHME ICI	GRANTS	YES

SUB COMMITTEE ON SAFETY EFFICACY AND ADVERSE REACTIONS

MEMBERS HAVE DECLARED CURRENT PERSONAL AND NONPERSONAL INTERESTS AS FOLLOWS:

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		Whether Current
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
Professor K G M M Alberti	None		Novo Industrias (Denmark)	Research Grant	Yes
			Novo Industries (UK)	" "	Yes
			Hoechst UK	" "	Yes
			Glaxo	" "	Yes
			Bayer UK	" "	Yes
			Farmitalia Carlo Erba	" "	Yes
			Parke Davis	" "	Yes
			Novo Denmark	Donation	Yes
			Farmitalia Carlo Erba	Donation	Yes
			Miles (USA)	Donation	Yes
			Boehringer Mannheim	Donation	Yes
			Merck Sharp & Dohme	Research Grant	Yes
			Nordisk Insulins	" "	Yes
			Ames UK	" "	Yes
			Roche	" "	Yes
			Servier Laboratories	" "	Yes
Dr L Beeley	None		None		Yes
Professor A T Birmingham	Wellcome Research Labs) Consultancy: Protocol Welcome Foundation) Review Committee.		Alza) Abbott) Beechams) Boehringer) Boots) Celltech) Glaxo)	Various support of Staff, Equipment & Consumable costs	Yes

SUB COMMITTEE ON SAFETY EFFICACY AND ADVERSE REACTIONS

MEMBERS HAVE DECLARED CURRENT PERSONAL AND NONPERSONAL 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 T Birmingham (contd)			ICI Johnson & Johnson Janssen Merck, Sharpe and Dohme Merrell-Dow Proctor & Gamble Reckitt & Colman Roussel Smith Kline Squibb Syntex Upjohn	) for Research Studentships, Grants and Contracts	
Professor A M Breckenridge	(See entry under Committee on Safety of Medicines)				

JB/1837m/3

SUB COMMITTEE ON SAFETY EFFICACY AND ADVERSE REACTIONS

MEMBERS HAVE DECLARED CURRENT PERSONAL AND NONPERSONAL INTERESTS AS FOLLOWS:

	PERSONAL INTERESTS		NON PERSONAL INTERESTS		Whether Current
MEMBER	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
Dr C J Bulpitt	Wellcome Foundation Ltd	Consultancy Fee: for acting on the Welcome Protocol Review Committee	E R Squibb & Sons Ltd Merck Sharp & Dohme Ltd (Chibret Int) F Hoffman LA Roche	Departmental Grants	Yes
	I S F (Italian S K & F Company)	Consultancy	Zambon Group Pfizer Ltd UK Servier Laboratories Ltd Kirby-Warrick Pharmaceuticals Smith Kline & French Laboratories Ltd	Clinical Trials	
Dr R L Carter	ICI	Shareholder	None		
Dr J M Davidson	Allen & Hanbury	Fee for Clinical Trial	None		
Professor D S Davies	ICI ML Laboratories	Shareholder Non Executive Director	Astra/Draco Squibb	Fellowship	Yes
	Clinical & Biochemical Pharmacology Consultancy Ltd	Director	Fisons Merk Sharp & Dohme Servier SKF Beecham Procter & Gamble Astra/Draco Squibb Abbott Bayer (I	Commissioned Research	Yes

SUB COMMITTEE ON SAFETY EFFICACY AND ADVERSE REACTIONS

MEMBERS HAVE DECLARED CURRENT PERSONAL AND NONPERSONAL INTERESTS AS FOLLOWS:

	PERSONAL INTERESTS		NON PERSONAL INTERESTS		Whether Current
MEMBER	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
Professor D S Davies (cont)			Hoechst Merrell Dow Schering Bristol Myers Ciba Welcome ICI Boehringer Ingelheim Lorex ML Labs	))))Commissioned)Research)(contd)))))	
			Glaxo	Fellowship/ Commissioned Research	Yes
Dr R G Finch	Bristol Myers Norwich-Eaton Rhone-Poulenc Pfizer Roussel	))))) Consultancy	Roussel Searle ICI Merrell Dow	)))Reseach Grant)	Yes
	Bayer	Honorarium: Quinolone Board Member			
Professor C J Hull	Janssen Pharmaceuticals	Consultancy	Janssen Pharmaceuticals ICI	)Sponsored)Clinical trial	Yes

JB/1837m/5

SUB COMMITTEE ON SAFETY EFFICACY AND ADVERSE REACTIONS

MEMBERS HAVE DECLARED CURRENT PERSONAL AND NONPERSONAL INTERESTS AS FOLLOWS:

	PERSONAL INTERESTS		NON PERSONAL INTERESTS		Whether Current
MEMBER	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
Dr D R Jones	None		None		
Dr B J Kirby	None		Sterling-Winthrop	Research Support	Yes
Professor M J S Langman	(See entry under Committee on Safety of Medicines)				
Professor J S Malpas	None		None		
Dr A V P Mackay	Glaxo Group Research Ltd	Consultancy	Efamol Ltd	Research Grant	Yes
Professor A E M McLean	(See entry under Committee on Safety of Medicines				
Professor M D Rawlins (Chairman)	(See entry under Committee on Safety of Medicines				
Professor C G Swift	None		Astra Rhone Poulenc Boots Sanofi ICI Laboratories for Applied ogy	))) Departmental) Research Grants)))	Yes

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
DR M C ALLWOOD	TILLOTS LABS LTD KABI-VITRUM LTD	ROYALTY AGREEMENT CONSULTANCY	TILLOTTS LABS LTD) OXFORD NUTRITION LTD)	RESEARCH CONTRACT	YES
PROFESSOR B W BARRY	APS RESEARCH LTD	CONSULTANCY	GLAXO	FELLOWSHIP AND CHAIR	YES
	BEECHAM PHARMACEUTICALS) SQUIBB)	CONSULTANCY	BOOTS	PART TIME STAFF	YES
PROFESSOR J R BROWN	MERCK SCHERING-PLOUGH	) CONSULTANCY)))	NONE		
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		

GO/1392m/2

Sub-Committee on Chemistry, Pharmacy and Standards

Members have declared Current Personal and non-Personal Interests as follows:

MEMBER	CURRENT PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
DR D J G DAVIES	SMITH AND NEPHEW PHARMACEUTICALS	1. ROYALTY PAYMENT ON PRYME CARE PRODUCT 2. FEES FOR OCCASIONAL DEVELOPMENT WORK	CONTACTASOL SMITH AND NEPHEW PHARMACEUTICALS COOPER VISION UNIPATH HYDRON EUROPE (ALLERGAN INC)		YES
	CO-ORDINATED DRUG DEVELOPMENT LIMITED	DIRECTOR AND SHAREHOLDER			
	CONTROLLED THERAPEUTICS INC	1. ROYALTY PAYMENTS	PITMAN MOORE INC ALLERGAN INC CONTROLLED THERAPEUTICS INC BAUSCH & LOMB INC HYDROPHARMA VISTA OPTICS DELTEX INSTRUMENTS		YES
	ALLERGAN INC	1. HOLD LICENCE OPTION ON ONE POTENTIAL CONTACT LENS PRODUCT 2. FEES FOR OCCASIONAL DEVELOPMENT WORK	FISONS PHARMACEUTICALS PLC NICHOLAS LABS GLAXO GROUP RESEARCH CELLTECH ROUSELL - UCLAF (FRANCE P A CONSULTANTS	RESEARCH PROJECTS AND STUDIES	YES
	VISTA OPTICS LTD	HOLD LICENCE OPTION ON POTENTIAL CONTACT LENS PRODUCTS			
	BAUSCH AND LOMB GLAXO GROUP RESEARCH NICHOLAS LABS LTD UNIPATH LTD PITMAN MOORE INC HYDROPHARMA	MARKETING AGREEMENT OCCASIONAL FEES	A H ROBBINS RIKER PHARMACEUTICALS		

Sub-Committee on Chemistry, Pharmacy and Standards

Members have declared Current Personal and non-Personal Interests as follows:

MEMBER	CURRENT PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
PROFESSOR P H ELWORTHY (CHAIRMAN)	NORWICH EATON	CONSULTANCY	NONE		
PROFESSOR F FISH	NONE		GLAXO WELLCOME	) COLLABORATIVE) RESEARCH	YES
PROFESSOR A T FLORENCE	(SEE ENTRY UNDER COMMITTEE ON SAFETY OF MEDICINES)				
PROFESSOR I W KELLAWAY	E R SQUIBB BEECHAM CELLTECH DOW-CORNING (FRANCE) ACO LAKMEDEL (SWEDEN)	))) CONSULTANCY))	E R SQUIBB RECKITT & COLMAN SMITH & NEPHEW BOOTS FISONS UPJOHN INTERSURGICAL R P SCHERER INNOVATA BIOMED	RESEARCH GRANT RESEARCH GRANT RESEARCH GRANT RESEARCH GRANT RESEARCH GRANT RESEARCH GRANT CONTRACT STUDY CONTRACT STUDY CONTRACT STUDY	YES YES YES YES YES NO YES NO YES
PROFESSOR D W MATHIESON	NONE		NONE		
PROFESSOR J M NEWTON	MAY AND BAKER	CONSULTANCY	ICI PHARMACEUTICALS BOOTS COMPANY WELLCOME FOUNDATION GLAXO GROUP BEECHAM LABORATORIES MAY & BAKER	))) RESEARCH GRANTS)))	YES
DR A E THEOBALD	NONE		NONE		
DR D WATT	NONE		NONE		

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SUB-COMMITTEE ON BIOLOGICALS

Members have declared current Personal and Non-personal Interests as follows:

MEMBER BIOLS	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
PROFESSOR J E BANATVALA	NONE		SMITH, KLINE AND FRENCH	RESEARCH GRANT	YES
PROFESSOR W J BRAMMAR	ICI	CONSULTANCY	AMERSHAM	CONSULTANCY	YES
	WELLCOME FOUNDATION	CONSULTANCY			
PROFESSOR J G COLLEE (CHAIRMAN)	(SEE ENTRY UNDER COMMITTEE ON SAFETY OF OF MEDICINES)				
DR S L JEFFCOATE	NONE		NONE		
PROFESSOR H KEEN	ICI	MEMBER OF ADVISORY GROUP ON STATIL and CONSULTANCY FEE	SQUIBB) SERVIER) DUNCAN FLOCKHART)	RESEARCH SUPPORT	YES
	THOMAE	CONSULTANCY FEE			
DR R S LANE	NONE		NONE		
PROFESSOR A J McMICHAEL	BRITISH BIOTECHNOLOGY OXFORD, UK	CONSULTANCY	NONE		
	IMMUNOLOGIC BOSTON, USA	CONSULTANCY			

SUB-COMMITTEE ON BIOLOGICALS

Members have declared current Personal and Non-personal Interests as follows:

MEMBER BIOLS	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
PROFESSOR J MELLING	NONE		AGEN BIOMEDICAL	PATENT	YES
			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 MANNHEIM	PATENT	
			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	

SUB-COMMITTEE ON BIOLOGICALS

Members have declared current Personal and Non-personal Interests as follows:

MEMBER BIOLS	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
PROFESSOR J MELLING (contd)			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)	
			HOECHST AG	PATENT)	
			HOFFMAN LA ROCHE	PATENT/SUPPLY)	YES
			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)	
			OXFORD GLYCOSYSTEMS	CONTRACT)	
			OXFORD VIROLOGY	CONTRACT)	
			OXOID	CONTRACT)	
			PEPTIDE TECHNOLOGY	PATENT)	
			PFIZER	CONTRACT)	
			PHARMACIA AG	PATENT)	

SUB-COMMITTEE ON BIOLOGICALS

lembers have declared current Personal and Non-personal Interests as follows:

	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
IEMBER BIOLS	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
ROFESSOR J MELLING (contd)			PITMAN MOORE	CONTRACT/SAFE DEPOSIT/ SUPPLY	
			PHARMA BIOTECHNOLOGIE	PATENT	
			PORTON PRODUCTS	ALL SERVICES AND 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	
			SHIELD DIAGNOSTICS	CONTRACT/PATENT	
			SMITH KLINE FRENCH	SUPPLY	
			SMITH KLINE BECKMAN	ALL SERVICES	
			SMITH KLINE RIT	CONTRACT	
			SQUIBB SURGICARE	SUPPLY	
			STABILIGEN	PATENT	YES
			UPJON	TRAINING/SUPPLY	
			WELLCOME	ALL SERVICES AND SALES	
			VUMAN LTD	SAFE DEPOSIT	
			XENOVA	ALL SERVICES	

SUB-COMMITTEE ON BIOLOGICALS

Members have declared current Personal and Non-personal Interests as follows:

MEMBER BIOLS	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
PROFESSOR J MELLING (contd)					

DEFINITIONS

1.	Patent	Loging 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	Loging 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.

Members have declared current Personal and Non-personal Interests as follows:

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS		
MEMBER BIOLS	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	WHETHER NATURE OF INTEREST	CURRENT
R R J PERRY	SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE	OPERATIONAL DIRECTOR	CELL TECH LTD	RESEARCH GRANT	YES
R G C SCHILD	NONE		NONE		
R D THOMAS	WELLCOME FOUNDATION LTD	SHAREHOLDER	MEDIOLANUM FARMACEUTICI MILAN, ITALY	RESEARCH GRANT	YES
R E G D TUDDENHAM	DELTA BIOTECHNOLOGY LTD	CONSULTANCY	CIBA-GEIGY	SPONSORED PHD STUDENTSHIP	YES
D A J TYRRELL	PROCTER & GAMBLE	CONSULTANCY	NOVA PHARMACEUTICALS) VIRATEK)	CLINICAL TRIALS-FEES)	YES

SUB-COMMITTEE ON ADVERSE REACTIONS TO VACCINES AND IMMUNOLOGICAL PRODUCTS

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 E BANATVALA	NONE		SMITH KLINE & FRENCH	RESEARCH GRANT	YES
DR C BOWIE	NONE		SMITH KLINE & FRENCH	RESEARCH GRANT	YES
PROFESSOR A M BRECKENRIDGE	(SEE ENTRY UNDER COMMITTEE ON SAFETY OF MEDICINES)				
DR N CAVANAGH	NONE		NONE		
PROFESSOR J G COLLEE (Chairman)	(SEE ENTRY UNDER COMMITTEE ON SAFETY OF MEDICINES)				
DR P E M FINE	PASTEUR VACCINES	SCIENTIFIC ADVISORY COMMITTEE	NONE		
PROFESSOR D HULL	NONE		NONE		
DR B W McGUINNESS	NONE		STUART LABS	RESEARCH GRANT	YES
PROFESSOR S R MEADOW	BEECHAMS) BOOTS)	SHARE HOLDER	FERRING	RESEARCH GRANT	YES
PROFESSOR D L MILLER	NONE		NONE		
DR E MILLER	NONE		NONE		
DR D REID	NONE		NONE		

VETERINARY PRODUCTS COMMITTEE - 1989

Members have declared current Personal and Non-Personal Interest 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 Sharp and Dohme	Consultancy and Fees	None		
Professor P M Biggs	Hoechst UK Ltd	Consultancy	None		
Professor Blain	ICI Plc	consultancy	MSD	Clinical Trial	No
	Sterling Winthrop	Member of Ethical Committee	ICI Plc	Research Grant	Yes
Professor Bridges	None		None		
Professor J R Brown	Merck Schering-Plough	Consultancy	None		
Mr D S Collins	None		None		
Mr P J Crossman	Beechams Pharmaceuticals	Fees for clincial trials	None		
Dr S P Denyer	Amersham International	Consultancy	None		
	Beecham Pharmaceuticals	Contract Research and consultancy			
	Glaxo Pharmaceuticals	Contract Research			
Miss K Gibson	None				

	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
MEMBER	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor D E Jacobs	Sorex Ltd	Consultancy	Bayer) Coopers Pitman-Moore) Cyanamid)	Yes	
			Merck Sharp and Dohme) Smithkline-Beecham) Temana)		
Professor J O Jarrett	None		None		
Professor R W Lacey	None		None		
Professor G E Lamming	None		Abbott Laboratories) Ciba-Geigy)	Support for research	Yes
			Hoechst)		
			Monsanto) Reckitt and Colman) Sterling Withrop)		
			Upjohn) Sandox) SKF)	Material for research projects	Yes
			Duphar) Dupont UK)		
			Johnson and Johnson -	Support for research student	Yes

ME	NAME OF COMPANY	ATURE OF INTEREST	NAME OF COMPAN	NATURE OF INTEREST	WHETHEF CURREN
Professor P Lees	Norbrook Laboratories Ltd	Consultancy	Rycovet	Support for research project	No
			Intervet	Support for research project	No
			Intervet	Support for research project	Yes
Professor A H Linton	Norbrook Laboratories Ltd	Consultancy	None		
Dr F de Matteis	ICI Plc	Research Grant	None		
Professor I Smith	None		Duphar		Yes
Dr S Vennitt	None		None		

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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			
	BOOTS	TRAVEL EXPENSES FOR LECTURES (AUG/SEPT 1989)	NONE		
PROFESSOR C J BULPITT	WELLCOME FOUNDATION LTD	WELLCOME PROTOCOL REVIEW COMMITTEE CONSULTANCY FEE	E R SQUIBB & SONS LTD) MERCK SHARP & DOHME LTD) (CHIBRET INT)) F HOFFMAN LA ROCHE)	DEPARTMENTAL GRANTS	YES
PROFESSOR J E CARLESS	NONE		NONE		
MR W M DARLING	NONE		NONE		
PROFESSOR F FISH	NONE		GLAXO GROUP RESEARCH) WELLCOME FOUNDATION)	COLLABORATIVE RESEARCH	YES
PROFESSOR F HARRIS	NONE		BAYER UK LTD) GIST BROCADES DELFT) UNILEVER RESEARCH LTD) PHARMACIA LTD) FISONS PHARMACEUTICALS LTD) NYCOMED (UK)) MEADOX UK) ABBOTT LABS) ICI) WYETH LABS DRUGINAL) BEECHAMS) SMITH, KLINE & FRENCH LABS LTD) SERVIER) BEECHAM WULFING) GLAXO LABORATORIES LTD) JANSEN PHARMACEUTI S LTD)	DEPARTMENTAL GRANTS	YES

Member e declared current Personal and no sonal Interests as follows:

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
			ALLEN & HANBURY'S) MERCK SHARP & DOHME) BOOTS PHARMACEUTICALS) LEO LABS LTD) PFIZER) ROVER PHARMACEUTICALS) BOEHRINGER-INGELHERAL LTD) CIBA GEIGY) SYNTEX)	DEPARTMENTAL GRANTS	YES
PROFESSOR J G R HOWIE	NONE		RHONE-POULENC	CLINICAL TRIAL	YES
			STUART PHARMACEUTICALS	BUILDING EXTENSION	YES
DR B KIRBY	NONE		STERLING WINTHROP	RESEARCH GRANT	YES
PROFESSOR M H LADER	BRISTOL-MYERS) LERS-SYNTHELABO) CONSULTANCY THE BOOTS COMPANY)		CIBA GEIGY) LERS SYNTHELABO) BRISTOL-MYERS)	SUPPORT FOR RESEARCH TEAM	YES
	LILLY INDUSTRIES LTD) CLINICAL TRIAL A H ROBINS COMPANY) CO ORDINATOR SANDOZ PHARMACEUTICALS)				
PROFESSOR D H LAWSON (Chairman)	NONE		NONE		
PROFESSOR R M MACKIE	NONE		BEECHAM	RESEARCH FELLOWSHIP	YES
DR A McKNIGHT	SCHERING HEALTH CARE LTD	RESEARCH FUNDING	NONE		

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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
PROFESSOR J M MIDGLEY	CONVATEC WOUND HEALING RESEARCH INSTITUTE	CONSULTANCY GRANUFLEX DRESSING	WELLCOME FOUNDATION LTD	ENDOWED LECTURESHIP	YES
			ALCON LTD) ALLERGAN LTD) SMITH AND NEPHEW) (P'CEUT) LTD) CONVATEC BRL) FISON LTD) ROCHE PRODUCTS LTD) UPJOHN LTD) SERAMI PLC) STD PHARMACEUTICALS LTD) GEISTLICH - PHARMA) RHONE POULENC)	RESEARCH	YES
DR A D MUNRO-FAURE	WELLCOME	SHARE HOLDER CONSULTANCY AND PENSIONS	NONE		
DR A T PROUDFOOT	NONE		NONE		
DR L E RAMSAY	NONE		I.C.I.	RESEARCH	YES

COMMITTEE ON DENTAL AND SURGICAL MATERIALS

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 INTERSEST	WHETHER CURRENT
Professor C L Berry (Chairman)	None		None		
Professor W Bonfield	Smith and Nephew Research	Consultancy	Smith and Nephew Research	Research Contract	Yes
			Johnson and Johnson Orthopaedics	Research Contract	Yes
			ICI	Research Contract	Yes
			Biomet Ltd	Research Contract	Yes
Mr R J Buckley	Fisons PLC	International Congress of Ophthalmology, Singapore (Travel Grant)	Fisons PLC	Research Support	Yes
			Award Technology Associates	Research Support	Yes
Professor H D Edmondson	Astra Pharmaceuticals Ltd	Expert Opinion at Annual Conference (Partial Group Sponsorship)	Astra Pharmaceuticals	Expert Opinion	Yes
			Straumann	Expert Opinion	Yes
			Corvent	Expert Opinion	Yes
			SKF Ltd	Expert Opinion	Yes
			Thames Laboratories	Clinical Trials	Yes
			Glaxo	Clinical Trials	Yes

COMMITTEE ON DENTAL AND SURGICAL MATERIALS

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 INTERSEST	WHETHER CURRENT
Mr J A Elias	None		None		
Professor M Elstein	Schering Healthcare, Schering AG.	Editorship and Lecture Fees	Schering Healthcare,) Schering AG)		Yes
	Ortho Cilag.	Advisory Panel Fees	Organon International)		Yes
	Wyeth Laboratories.	Fees	London International)		Yes
			Femcare)		Yes
			Leiras)	Research Studies	Yes
			Conrad USA/AID)	and Clinical Trials	Yes
			Ortho-Cilag)		Yes
			Wyeth - Ayerst)		Yes
			Cambridge Research) Institute)		Yes
			Medgenix)		Yes
Mr J Howe	None		None		
Professor G C Jenkins	None		None		
Professor R B Johns	Nobelpharma AB (Sweeden)	Clinical Research	Boots PLC	Research Study	Yes
Professor I D A Johnston	Baxter Healthcare Ltd	Consultancy	Kabi Vitrum (Sweeden)	Research Support	Yes
			Roussel Ltd	Research Support	Yes
Dr J R Larke	Pilkington Vision Care Ltd	Consultancy	None		

COMMITTEE ON DENTAL AND SURGICAL MATERIALS

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 INTERSEST	WHETHER CURRENT
Mr B J Meakin	Allergan-Hydron	Consultancy	None		
	P A Technology	Consultancy			
	Abatron	Consultancy			
	Bausch and Lomb	Consultancy			
	Glaxo Group Research	Research. Unpaid Contracts to University			
	Market Access International	Research Unpaid Contracts to University			
	Polymer Technology Corp.	Research Unpaid Contracts to University			
	Smith and Nephew	Fees			
	Controlled Therpeutics Corp.	Patent Holder for University of Bath			
	Co-ordinated Drug Development Ltd	Director and shareholder			
Mr B Midcalf	None		None		
Professor C Scully	None		Vitabiotics	Research	Yes
			Wyeth Laboratories	Research	Yes
Miss A B Sutherland	None		None		
Professor D E M Taylor	Geistich Sons Ltd	Consultancy Grant	Sutures (UK) Ltd	Research	Yes
	Meadox (UK) Ltd	Consultancy (Unpaid) Grant			

COMMITTEE ON DENTAL AND SURGICAL MATERIALS

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 INTERSEST	WHETHER CURRENT
Mr T D Turner	Ultra Laboratories	Consultancy One Product Only	Courtaulds	Research Grant	Yes
	Johnson and Johnson	Consultancy			
Professor B Whiting	Warner Lambert	Consultancy	Riker	Research Grant	Yes
	Boehringer Ingelheim	Expert Opinion (Pharmacokinetics)	Syntex	Research Grant	Yes
			Wyeth	Research Grant	Yes
Professor E G Woodward	None		Pilkington Vision Care Ltd	Student Funding	Yes
			Allergan Pharmaceutics	Contract	Yes

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