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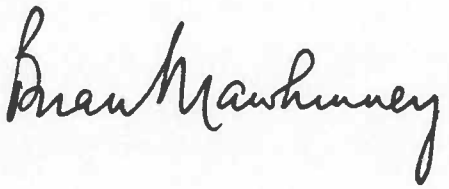
FOREWORD BY THE MINISTER FOR HEALTH

I am pleased to introduce the annual reports for 1991 of the Medicines Commission, the Committee on Safety of Medicines, the Committee on Dental and Surgical Materials, the Committee on the Review of Medicines, the British Pharmacopoeia Commission and the Veterinary Products Committee. They are published together with a record of Members' interests in the pharmaceutical industry and the code of practice which apply when making their declarations.

The public often take for granted that medicines are safe, efficacious and of good quality. The work of the committees is crucial in ensuring that this is so. On behalf of all Ministers charged with responsibility for the Medicines Act, I am pleased to record our thanks to the committees for their help and advice and our appreciation of the considerable time and effort involved. I should particularly like to thank all those who over the years have been members of the Committee on the Review of Medicines and have helped to bring the Committee's work to a successful conclusion.



THE MEDICINES COMMISSION

ANNUAL REPORT FOR 1991

TERMS OF REFERENCE

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

MEMBERSHIP

2. A list of members during 1991 is at *Appendix II.*

MEETINGS

3. There were nine meetings of the Commission in 1991.

HEARINGS

Human medicines

4. The Commission held eight hearings and considered two written representations in respect of applications for new product licences. In three cases their advice was that a product licence should be granted and in a further three cases that a product licence should be granted subject to certain conditions being met. In four cases they advised that product licences should not be granted.

5. The Commission held one hearing and considered two written representations in respect of applications for reviewed or renewed product licences. In one case their advice was that a product licence should be granted for a limited range of indications; in the other two they advised that a product licence should not be granted.

Veterinary medicines

6. The Commission held seven hearings in respect of applications for reviewed product licences. In two cases the Commission advised that a product licence should be granted subject to certain conditions being met. In five cases they advised that product licences should not be granted.

7. The Commission also held a hearing concerning the proposed variation of a product licence. The Commission advised that the product licence should be varied.

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

COMMITTEES

Appointments

9. The Commission recommended Dr H E C Worthington for appointment to the British Pharmacopoeia Commission.

10. The Commission recommended Dr M Sharratt, Dr R J Heitzman, Dr N Bateman, Dr A Cooke and Dr R Richards for appointment to the Veterinary Products Committee.

Committee on the Review of Medicines

11. The Commission, in accordance with Section 3(2)(c) of the Medicines Act 1968, agreed to recommend to Ministers that the Committee on the Review of Medicines would no longer be required after March 1991 when it would complete the function assigned to it. Members of the Commission joined the Chairman in thanking the Chairman and members of the Committee for their excellent work.

OTHER MATTERS

European developments

12. The Commission were kept informed by Medicines Control Agency (MCA) officials of progress on a range of European Community (EC) initiatives aimed at harmonising and developing standards of safety and control in the pharmaceutical sector.

13. Negotiations on the Rational Use , Advertising and Homeopathics Directives were likely to be completed by the end of the year; and work was underway to implement the Extension Directives which would bring immunologicals, blood products and radiopharmaceuticals within the scope of EC law.

14. The Commission noted the progress of the EC Future Systems proposals for licensing medicines. The UK supported the principles underlying the proposals and would pursue a range of concerns in negotiations to ensure that the new arrangements were effective and maintained the highest standards of medicines control.

15. The Commission were also informed about the work of the EC Advisory Working Group on Inspection and Quality Control. Detailed guidelines on good manufacturing practice had been issued which drew heavily on the UK guide. Consultations were in progress on an EC Directive to implement the guidelines and an EC operations working group was to be set up to develop a scheme to assess compliance.

An additional criterion for licensing veterinary medicines

16. The Commission were informed about continuing political pressure for the introduction, for veterinary medicines, of an additional licensing criterion relating to such matters as social and economic implications and ethical considerations. They noted, with approval, the Government's view that such matters should have no part to play in a science-based licensing system.

Bovine Somatotrophin (BST) - current position

17. The Commission were informed that the European Community Council of Ministers had extended the moratorium on the use of BST products except in authorised field trials until 31 December 1991, in order to allow the EC Commission time to produce a report on the implications of licensing such products. At the end of the year the EC Commission had not produced a report, and it was not known what constraints, if any, would apply in future.

Veterinary Medicines Directorate

18. The Commission were kept informed of the progress being made by the Veterinary Medicines Directorate (VMD) since it had been launched as a Next Steps Agency on 2 April 1990.

Mid-year reports indicated that the VMD was progressing towards meeting its financial target of full cost recovery in 1990/91.

19. A significant improvement had been achieved in the processing of product licence applications, and the VMD was moving towards its target of dealing with all applications within 120 days "clock-time", ie excluding time taken by applicants to provide further information. Another major objective for the VMD was to increase public awareness of the licensing system for animal medicines. As part of this initiative the VMD had published an illustrative brochure of its work when it was launched as a Next Steps Agency.

20. The Commission were assured that there was no evidence that the increased fees in 1990/91 had significantly reduced the number of new applications. The review of product licences including licences of right was being financed by the graded annual fee and not by individual charges.

The British Pharmacopoeia into the 1990s

21. The Commission noted with interest the British Pharmacopoeia Commission's report "The British Pharmacopoeia into the 1990s" particularly the section concerning the European dimension. They considered that the European Pharmacopoeia was not at present sufficient for the needs of industry; the British Pharmacopoeia had a vital role which was likely to continue for the decade.

Publications

22. The Commission recommended the following for publication:

British Pharmacopoeia 1988:	*Amendments No 5*
	Addendum 1992
British Pharmacopoeia (Veterinary) 1985 :	*Amendments No 6*
	Addendum 1992

British Approved Names 1990: *Supplement No 2*

Supplement No 3

Supplement No 4

European Pharmacopoeia Approved Synonyms

REPORTS OF THE COMMITTEES

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

APPENDIX I MEDICINES COMMISSION TERMS OF REFERENCE

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

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

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

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

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

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

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

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

APPENDIX II

MEMBERSHIP OF THE MEDICINES COMMISSION 1 JANUARY 1991

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

* Term of office expired 31 December 1991

† Term of office expires 31 December 1993

APPENDIX III

REPRESENTATIONS CONSIDERED BY THE MEDICINES COMMISSION 1987-1991

	1987	1988	1989	1990	1991
Hearings	13	15	10	9	17
Written Representations	12	6	6	2	4

COMMITTEE ON SAFETY OF MEDICINES

ANNUAL REPORT FOR 1991

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 1991 is at the end of this report. Members are appointed for a three year period.

3. The Committee wishes to record its thanks to Professors D. R. Jones, S. T. Holgate and Drs R. T. Oliver, A. V. P. Mackay, P. D. Home and B. J. Kirby who attended and advised the Committee as external experts during the year. It also wishes to acknowledge the contributions of Professors R. A. C. Hughes, I. V. D. Weller, R. L. Souhami, R. W. F. Campbell, G. Nuki, J. R. Newton and Drs M. Corbel, R. Thorpe and T. Barrowcliffe to the deliberations of the Sub-Committees.

4. The Committee also wishes to record its appreciation of the valuable work of the Sub-Committees; for Safety Efficacy and Adverse Reactions under Professor M D Rawlins, Chemistry, Pharmacy and Standards under Professor A T Florence, Biologicals under Dr D A J Tyrrell and the Adverse Reactions Group of SEAR under Professor A M Breckenridge and its professional and administrative secretariat.

MEETINGS

5. The Committee held 12 meetings during 1991. Two day meetings were held in July and September to enable the Committee to complete its business.

6. The Sub-Committee on Safety, Efficacy and Adverse Reactions met 11 times and had to hold two day meetings in July and September mainly to cope with the much larger volume of abridged applications presented to it. The Sub- Committee on Chemistry, Pharmacy and Standards also met 11 times and dealt with a similar increased workload.

CONSIDERATION OF APPLICATIONS

7. The tables below provide a summary of applications and appeals for product licences (PLs) considered by the Committee during 1991:

8. The Committee considered and advised on a total of 300 product licence applications. Table A gives a breakdown between United Kingdom applications and those of the European Commission's Committee for Proprietary Medicinal Products (CPMP).

First consideration by CSM

Table A

		Grant Advised	Grant not Advised
(i)	CSM Advice on National Applications	Number of PLs	Number of PLs
	New Active Substances (NAS)	15 (35)	32 (65)
	Abridged	100 (39)	98 (52)

(ii)	CSM Reasoned Objections/Comments on CPMP Multistate/Concertation Applications	Number of PLs
	New Active Substances (NAS)	32 (28)
	Abridged	23 (11)

Note: 1990 figures given in brackets

Table B

CSM - ADVICE FOLLOWING HEARINGS AND WRITTEN REPRESENTATIONS 1991

24 Hearings scheduled (12 resolved without the need for a hearing).

19 Written Representations (includes three pre-hearings: the issues were resolved on each occasion, without the need for a hearing).

Analysis	Hearings:		
New Active Substances	Yes	= 8	(2)
	Yes on condition	= 3	(12)
	No	= 7	(5)
Abridged	Yes	= 4	(1)
	Yes on condition	= 0	(0)
	No	= 1	(1)
Adverse Reactions	Yes	= 0	(0)
	Yes on condition	= 0	(1)
	No	= 1	(0)
	Written Representations:		
New Active Substance	Yes	= 3	(1)
	Yes on condition	= 2	(8)
	No	= 0	(1)
Abridged	Yes	= 1	(0)
	Yes on condition	= 7	(3)
	No	= 6	(5)

Note: 1990 figures given in brackets

9. The total number of National Product Licence applications referred to the Committee for advice in 1991 was 28% greater than in the preceding year. Of the National Product Licence applications which were considered by the Committee in 1991, 47% were considered to be satisfactory for the grant of a licence at the first consideration.

10. Product licence (PL) applications for new active substances (UK and CPMP) accounted for 26% of all applications considered by the Committee in 1991. The number of abridged PL applications seen by the Committee was 116% higher than in the previous year.

11. 97 (25 NAS and 72 abridged) letters were written to companies informing them that the Committee was provisionally intending to advise against the grant of a PL. These detailed 1,560 (539 for NAS and 1021 for abridged) points of issue representing an average of 21.5 points per NAS application and 14 points per abridged application.

12. The Committee considered an average of 27 applications at its 11 full meetings in 1991, compared to 21 applications per meeting in 1990. The Committee held an additional special meeting at which only 1 item (a hearing) was considered in 1991 and this meeting has been excluded in making the calculation of the number of applications considered per meeting.

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

14. The Committee, noted with concern, that some companies presented data not previously seen by the Licensing Authority/Medicines Control Agency at hearings and in some cases were also seeking new indications from that previously applied for. The Committee wishes to record its concern that this practice makes it impossible for the Committee to assimilate and critically review new data at a hearing. Companies should note that the Committee will continue its practice of not considering new data at hearings where they have not been previously seen by the Licensing Authority/ Medicines Control Agency.

CONSIDERATION OF OTHER MATTERS

15. In addition to applications and appeals the Committee also considered and commented on papers of medical and pharmaceutical relevance. The total number of such papers considered in 1991 was 119, of which 60 dealt with adverse reactions associated with medicinal products (ADRs), 15 dealt with CPMP matters and the remainder were general information items.

Litigation

16. Litigation against the Committee continues in respect of opren and some benzodiazepines.

SAFETY OF MARKETED PRODUCTS

17. Newly introduced products (denoted by a black triangle symbol in data sheets, BNF, MIMS and advertisements) are under intensive surveillance by the Committee. At the beginning of 1991, 64 products were under intensive surveillance, over the year 30 drugs were removed from the list while 41 new products were added. A list of these drugs was sent to all doctors with the June issue of "Current Problems" to provide ready reference when reporting adverse reactions to the Committee.

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

Terodiline (Micturin)

Terodiline was licensed in the UK in 1986 for the treatment of urinary incontinence. By July 1991, the Committee had received 17 reports of ventricular tachycardia associated with terodiline, 13 of which were of the so called torsades de pointes variety. In addition, there were 3 reports of heart block and 4 of bradycardia. Following review of the safety of terodiline, the Chairman, on 25 July 1991, wrote to all the doctors and pharmacists warning them of the risks of serious cardiac adverse reactions associated with the use of terodiline. Four risk factors were identified and advice was given on patients in whom terodiline should not be used. Following this letter, the Committee received many further reports and by October there were a total of 69 reports of cardiac arrhythmias, including 14

cases of sudden or unexpected deaths, possibly associated with terodiline. On 13 September 1991, Kabi Pharmacia the licence holders withdrew terodiline worldwide pending further safety evaluation.

The UK Spontaneous Adverse Drug Reactions Reporting Scheme was the only reporting scheme in the world to identify this hazard associated with terodiline.

Quinolone anti-microbial agents

The Committee have received 26 reports of convulsions associated with the use of ciprofloxacin, one case with norfloxacin and one case with ofloxacin. This reaction can occur in patients with no previous history of convulsions. The licences for products containing ciprofloxacin, norfloxacin and ofloxacin have been varied to include appropriate warnings.

Clozapine (Clozaril)

Clozapine is indicated in the treatment of resistant schizophrenia in patients not responding to, or intolerant of, conventional treatment.

The use of clozapine is associated with a 2-3% risk of neutropenia leading to agranulocytosis. On the recommendations of the Committee, patients receiving clozapine are monitored closely by regular blood counts. The Company have set up a special scheme to provide this service - the Clozaril Patient Monitoring Service (CPMS). The Committee is pleased to report that the service is functioning efficiently. As at 31 December 1991, a total of 2337 patients had received clozapine and a total of 74 reported cases of neutropenia had occurred with one fatality.

Eight patients with clozapine-related convulsions have been reported in the UK. Only one patient had a previous history of epilepsy. Based on the available data, the Committee have recommended changes to the dose recommendations.

Chloraseptic

- see paragraph 6 of the 1990 report.

Following four reports of oedema of the epiglottis and/or larynx associated with use of Chloraseptic throat spray (1.4% phenol), the labelling of this product was amended in 1990 and an article was published in Current Problems No 28.

The Committee reviewed further reports of similar reactions in February 1991. Following discussion of the Committee's concerns with the company, it was agreed that the product should be reformulated so as to exclude phenol from the throat spray preparation. Chloraseptic mouthwash/gargle is still based on phenol but since November 1991 the active constituent of the throat spray is benzocaine.

Triazolam (Halcion)

Triazolam is a benzodiazepine which was first licensed for the treatment of insomnia in 1978. Its safety has been the subject of longstanding controversy following reports of psychiatric adverse reactions. A detailed review of all the available evidence was performed by the Committee in September 1991.

The Committee recommended that the drug be withdrawn urgently and this took place on 2nd October 1991. A letter was sent to all doctors, dentists and pharmacists informing them of the withdrawal. Action against product licences for triazolam is under appeal.

Fenoterol (Berotec)

- see paragraph 6 of the 1990 report.

At the request of the Committee, an application to introduce a low-dose 100 ug per puff formulation of fenoterol was considered in February. A licence was granted and the new preparation introduced in May. An article explaining the dosage changes was published in Current Problems 31. Use of the existing 200 ug formulation has been restricted to patients uncontrolled by use of lower doses. The maximum recommended dose of fenoterol is now 1600 ug per day.

Salmeterol (Serevent)

Salmeterol is a long-acting beta-2-agonist used in the treatment of asthma which was first marketed in December 1990. A review of its safety was undertaken by Committee following a substantial number of reports of suspected adverse reactions, including reports of worsening symptoms and fatal asthma attacks. The Committee concluded that there was insufficient evidence to implicate salmeterol in these suspected reactions, and this was reported in Current Problems 31. The Committee is continuing to monitor a large post-marketing study comparing salmeterol and salbutamol.

Beta-agonists

During 1991 the Committee considered evidence suggesting that the use of beta-agonists might be causally associated with an increase in asthma morbidity and mortality. The Committee set up a Working Party, which was announced in Current Problems 31, to review the available evidence and to make recommendations on licensing action. The Working Party will report its findings to the Committee early in 1992.

19. Two "Dear Doctor" letters from the Chairman were issued as follows:

"Terodiline (Micturin) & Adverse Cardiac Reactions" (dated 25 July 1991);

"Withdrawal of Triazolam" (dated 1 October 1991).

20. Two editions of Current Problems, the Committee's drug safety information bulletin for doctors, dentists and pharmacists were issued as follows:

Current Problems number 31 (June 1991) contained articles on:

1. Formation of a Working Party on Beta-agonists
2. Salmeterol
3. Fenoterol - new dosage recommendations
4. Multi-system adverse reactions following long-term flecainide therapy
5. Convulsions may occur in patients receiving clozapine
6. Diarrhoea, skin reactions and headache following omeprazole therapy
7. Genotoxicity of papaveretum and noscapine
8. New drugs under intensive surveillance by the CSM
9. Further information on Bjork-Shiley heart valves from the Medical Devices Directorate

Current Problems number 32 (October 1991) contained articles on:

1. Withdrawal of terodiline
2. Neutropenia and agranulocytosis with carbimazole
3. Convulsions due to quinolone antimicrobial agents
4. Pseudomembranous (antibiotic-associated) colitis and diarrhoea with cephalosporins
5. NSAID-related aseptic meningitis
6. NSAIDs and renal adverse reactions
7. Enquiries concerning the Current Problems bulletin
8. Neuromuscular toxicity in humans due to sheep dip poisoning - from the Veterinary Medicines Directorate
9. Notification of change of address

Reporting of suspected adverse reactions

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

22. The table below shows the number of reports received since 1981:

Reports of Suspected Adverse Reactions Received for Registration

1981	13,032
1982	10,922
1983	12,689
1984	12,163
1985	12,652
1986	15,527
1987	16,431

1988	19,022
1989	19,246
1990	18,084
1991	20,272

23. There has been an increase in the number of reports received this year in comparison with previous years. The Committee is actively examining ways of further encouraging reporting.

24. Currently, yellow slips can be found in the British National Formulary, the ABPI data sheet compendium and MIMS as well as the FPl0 prescription pads. An analysis of all reports received in 1991 is set out in the following table:

Reports of Suspected Adverse Reactions Received in 1991

Figures for 1990, where appropriate are shown in brackets.

	TOTAL	% OF TOTAL
Yellow Cards	6532 (5723)	32.2 (33.0)
BNF Slips	6935 (5621)	34.2 (32.4)
FPl0 Slips	2909 (3098)	14.4 (17.9)
ABPI	273 (287)	1.3 (1.6)
Industry	2786 (1809)	13.7 (10.4)
Anaesthetists	89 (85)	0.4 (0.5)
MIMS	344 (485)	1.7 (2.8)
Others	405 (217)	2.0 (1.2)

Hospital pharmacists reporting scheme

25. - see paragraph 6.5 of the 1990 Report

Following the success of a number of schemes in which pharmacists have encouraged doctors to report suspected ADRs, the Committee recognises the skills of hospital pharamacists in identifying ADRs. A pilot scheme of direct ADR reporting by hospital pharmacists, to the Committee, has commenced this year in Newcastle.

ADROIT adverse reactions computer system

26. - see paragraph 6.7 of the 1990 Report

A new computer system, ADROIT (Adverse Drug Reactions On-line Information Tracking) was introduced in June 1991 to support the monitoring of adverse drug reactions . The new system combines image storage on laser disk of ADR reports linked with a relational database. The system allows more rapid handling of ADR reports and greatly facilitates the analysis and assessment of ADR reports.

APPENDIX I

MEMBERSHIP OF THE COMMITTEE ON SAFETY OF MEDICINES

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

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

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

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

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

Professor R G Finch FRCP FRCPath
Professor of Infectious Diseases, City Hospital,
Nottingham

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

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

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

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

Dr W A Jerrett MB BCh FRCGP
General Practitioner, Glamorgan

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

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

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

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

Professor J M Midgley BSc MSc PhD CChem FRSC FRPharmS
Professor of Medical and Pharmaceutical Chemistry, University of Strathclyde

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

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

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

Dr D A J Tyrrell CBE MD DSc FRCP FRCPath FRS

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

NOTE
Term of office for all members expires 31 December 1992

APPENDIX II

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

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

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

Dr D H Calam MA DPhil CChem FRSC

Dr R T Calvert BSc PhD FRPharmS

Professor J E Carless BPharm MSc PhD MRPharmS

Dr A G Davidson BSc PhD MRPharmS

Professor D J Davies MSc PhD FRPharmS

Dr A L Davison PhD FIBiol

Professor F Fish OBE BPharm PhD FRPharmS

Professor D Ganderton BPharm PhD FRPharmS

Mr B Midcalf BPharm MRPharmS

Professor J M Midgley BSc MSc PhD CChem FRSC FRPharmS

Professor J M Newton BPharm PhD FPS

Professor M S Parker BSc MSc PhD FRPharmS MCPP FRSA

Professor J E Rees BPharm PhD FRPharmS

Professor G T Tucker BPharm PhD

NOTE
Term of office for all members expires 31 December 1992

APPENDIX III

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

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

* Dr Linda Beeley MA FRCP

Professor A T Birmingham BSc MB BS MRCS LRCP

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

Dr R L Carter MA DM DSc FRCPath

Professor D S Davies BSc PhD CChem FRSC

Dr P B Farmer MA DPhil

Professor R G Finch FRCP FRCPath

Professor S T Holgate BSc MD FRCP

* Professor C J Hull MBBS DA FCAnaes

Professor D R Jones BA MSc PhD

Dr B J Kirby MB FRCP

* Professor M J S Langman MD FRCP

Dr A V P MacKay MA BSc PhD MBChB FRCPsych FRCP

Professor A E M McLean BM PhD FRCPath

Professor B K Park BSc PhD

* Professor P A Routledge PhD FRCP

Professor C G Swift PhD FRCP

Dr G N Volans BSc MD FRCP

Dr D W Wall MB ChB(Hons) MRCP FRCGP

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

NOTE
Term of office for all members expires 31 December 1992

APPENDIX IV

SUB-COMMITTEE ON BIOLOGICALS

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

Professor J E Banatvala MA MD FRCPath DCH DPH

Dr E B Gingold BSc(Hons) MSc PhD

Professor K Gull BSc PhD

Professor G Janossy MD PhD MRCPath DSc

Dr S L Jeffcoate MB BChir PhD FRCPath

Professor J Melling MSc PhD FIBiol FRPharmS

Dr P Minor BA PhD

Dr R J Perry BSc PhD MRSC CChem - resigned 6 May 1991

Dr G C Schild BSc PhD FIBiol

Dr T J Snape BA PhD CChem MRSC - resigned 28 February 1991

Professor The Hon R S Tedder MA
MB B Chir MRCP MRCPath - appointed 21 November 1991

NOTE

Term of office for all members expires 31 December 1992

APPENDIX V

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

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

Professor J E Banatvala MA MD MRCP FRCPath

Dr C Bowie MRCP MFCM

Dr N Cavanagh MD MRCP

Dr P E M Fine VMD PhD

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

Dr C R Kennedy MD MRCP BA MBBS

Professor D G McDevitt DSc MD FRCP(Ed) FRCPI

Dr B W McGuiness MD FRCP DObst RCOG DCH RCPS

Professor S R Meadow MA DCh FRCP

Professor D L Miller MA FRCP FFCM DPH MD

Dr E Miller MB BS BSc

Dr P Minor BA PhD

Dr D Reid MD FRCP FFCM DPH

Dr D A J Tyrrell CBE MD DSc FRCP FRCPath FRS

NOTE

Term of office for all members expires 31 December 1992

COMMITTEE ON DENTAL AND SURGICAL MATERIALS

ANNUAL REPORT FOR 1991

INTRODUCTION

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

   a. *to give advice with regard to the safety, quality and efficacy in relation to human or animal use of substances or articles for dental or surgical use being:-*

      (i) instruments, apparatuses or appliances to which any provision of the Medicines Act 1968 is applicable or

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

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

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

COMMITTEE MEMBERSHIP

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

COMMITTEE ACTIVITIES

3. The Committee held five meetings during the year and held eight hearings against its provisional advice. The number of cases referred to the Committee is given in Appendix II.

4. A variety of topics were considered by the Committee during the year, on which it gave advice to the Licensing Authority. One new chemical entity was considered by the Committee, an antihistamine for topical application.

5. In addition, the Committee considered applications to the Committee for Proprietary Medicinal Products (CPMP) of the European Community in respect of a topical treatment for wounds and an unpreserved unit-dose eye drop for use in allergic eye disease. Further consideration was also given to a novel local treatment for periodontitis.

6. The Committee considered a number of ophthalmic products including a new combination of established active ingredients, presented in a novel container for optimised stability on storage. It also considered the issue of bioavailability and essential similarity for generic ophthalmic products.

7. Applications for a number of surgical materials and wound management products were considered. Following consideration of a number of absorbable sutures, some as part of the Review of Product Licences of Right, the Committee suggested that there was a need for guidelines for the assessment of suture performance testing.

8. Following previous consideration of yellow card reports of ocular adverse reactions, the Committee held hearings against provisional advice that product licences for a topical ophthalmic agent indicated for the treatment of glaucoma should be revoked. The Committee confirmed its advice to the Licensing Authority for those products with which adverse reactions had been associated.

9. The Committee considered the draft of a European Directive on Medical Devices. The Committee had in the past on several occasions expressed concern over the lack of adequate controls over a number of medical devices.

10. The Chairman wrote to the Minister for Health, copied to the Medicines Commission, to draw attention to the provisions in the Draft Directive for certain products currently regulated as pharmaceuticals, which were likely to receive a lesser degree of control under devices regulations.

11. The Committee also noted with concern the omission of 'chemical action' as an exclusion from the definition of a device previously adopted, and the resulting reduction of clarity of the borderline between medicines and devices.

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 CEng FIM MBES Hon MCORS
Head of Department of Materials
Dean of Engineering
Queen Mary and Westfield College
University of London

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

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

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

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

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

Professor G C Jenkins PhD MB BS FRCP(Edin) FRCPath
Professor of Haematology
University of London

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

Professor I D A Johnston MB MCh BOA 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 BPharm FRPharmS
Senior Lecturer in Pharmaceutics and Principal
Centre for Drug Formulation Studies
School of Pharmacy and Pharmacology
University of Bath

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

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

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

Professor D E M Taylor TD MB ChBEd FRCS FRCSEd
Department of Mechanical Engineering
Brunel University
Uxbridge

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

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

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

NOTE

Term of office for all members expires 31 December 1992.

Members appointed for specific meeting:-

July -

Dr A L Davison PhD FIBioL
Regional Pharmaceutical Microbiologist
St Bartholomew's Hospital

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

Professor M S Parker BSc MSc PhD FRPharmS MCPP FRSA
Head of Pharmacy Department
Dean of Faculty of Health
Brighton Polytechnic

September -

Dr P Minor BSc PhD
Head of Virology
National Institute for Biological Standards and Control

Professor M Rawlins BSc MD FRCP(London) FRCP(Edin)
Professor of Clinical Pharmacology
Newcastle University

APPENDIX II

TABLE A
FIRST CONSIDERATION OF APPLICATIONS FOR PRODUCT LICENCES BY CDSM

	Grant Advised in Accordance with Applications:	Grant Advised Other than in Accordance With Applications:	Grant Not Advised:	TOTAL
Abridged:	-	8	17	25 *
New Active Substance (NAS):	-	-	2	2
CPMP:	-	-	4	4 **
Review:	-	4	2	6
Renewal:	-	-	1	1
TOTALS	-	**12**	**26**	**38**

* 1 application was withdrawn following Committee advice.
** Reasoned objections were raised by the Committee.

TABLE B
CDSM - ADVICE ON APPLICATIONS FOR PRODUCT LICENCES FOLLOWING APPEALS:

	Grant Advised in Accordance with Applications:	Grant Advised Other than in Accordance With Applications:	Grant Not Advised:	TOTAL
	H : W	H : W	H : W	H : W
Abridged:	- : -	1 : 1	1 : 1	2 : 2
New Active Substance (NAS):	- : -	- : -	- : -	- : -
CPMP:	- : -	- : -	- : -	- : -
Review:	- : 2	- : 1	- : 1	- : 4
Renewal:	- : -	- : -	1 : 1	1 : 1
TOTALS	**- : 2**	**1 : 2**	**2 : 3**	**3 : 7**

(H = Hearing)
(W = Written Representaton)

TABLE C

CDSM - ADVICE ON PROPOSALS MADE BY THE LICENSING AUTHORITY - FOLLOWING APPEAL

	Proposal Endorsed	Proposal Not Endorsed	Total
	H : W	H : W	H : W
Revocation of Licence:	3 : -	2 : -	5 : -

(H = Hearing)
(W = Written Representation)

TABLE D

APPLICATIONS OUTSTANDING - SUBJECT TO SECTION 21(1) ACTION*

	Abridged	New Active Substance	CPMP	Review	Renewal	TOTAL
1991	16	2	-	2	1	21 +
Pre-1991	6	3	2	2	-	13
TOTAL	22	5	2	4	1	34

+ Excludes 4 cases relating to applications involving CPMP and 1 Abridged application which was withdrawn by the applicant.

TABLE E

ADVICE ON EXISTING LICENCES

Variations Determined: Nil

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

APPENDIX III

COMMITTEE ON DENTAL AND SURGICAL MATERIALS

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

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

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

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

iv. certain vaginal and tubal contraceptives;

v. 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;

vi. contact lens fluids;

vii. certain medicines placed in the eye;

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

COMMITTEE ON THE REVIEW OF MEDICINES

ANNUAL REPORT FOR 1991

INTRODUCTION

1. The Committee on the Review of Medicines (CRM) was established in 1975 under section 4 of the Medicines Act 1968 ("the Act") and was disestablished by the Medicines (Committee on the Review of Medicines) (Revocation) Order 1992 having completed its work. Its terms of reference were:

"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 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 was concerned mainly with medicines which were already on the market when the Act came into force and which had been granted Product Licences of Right (PLRs). Unless the type of product was subject to one of the exemptions specified in the EEC pharmaceutical directives, all products with PLRs had to be reviewed so as to ensure that they met standards imposed by those directives. The principal directives relevant to medicinal 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 convened their final meeting in March 1991. They held 2 hearings and considered 6 written representations against their provisional advice.

   The Committee also considered one application referred to them. Details are given at Appendix II.

5. The Minister of State for Health, Mrs Virginia Bottomley MP, congratulated past and present members on a notable achievement of which they could justifiably be proud.

HISTORY OF THE REVIEW

6. A brief history of the review of medicines is given at Appendix III

APPENDIX I

MEMBERSHIP OF THE COMMITTEE ON THE REVIEW OF MEDICINES

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

APPENDIX II

1. COMMITTEE PROCEEDINGS 1991

1.1 Referred to CRM for advice under section 20 (3) * of the Act

a. applications	1
b. written representations (following notification under section 21(1)*)	6
c. hearings (following notification under section 21 (1) *)	2
Total	**9**

1.2 Advice given to the Licensing Authority following referral

a. licence should be granted with amendment to the application (as accepted by the applicant)	5
b. CRM unable to recommend that a reviewed product licence should be granted	3

1.3

Provisional advice that a reviewed product licence should not be granted+	1
Total	**9**

2. COMMITTEE PROCEEDINGS 1987 - 1991

Referred to CRM for advice:	**1987**	**1988**	**1989**	**1990**	**1991**
Applications	52	45	51	28	1
Written Representations	22	19	23	14	6
Hearings	12	8	16	10	2
Advice:					
Licence should be granted	1	nil	11	4	nil
Licence should be granted with amendment	29	40	24	19	5
Licence should not be granted	56	32	55	29	4

Notes

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

\+ As the Committee would not be sitting again following this provisional advice, the applicant was given the opportunity to make representations to the Committee on the Safety of Medicines.

APPENDIX III THE REVIEW OF MEDICINES

1. When the Medicines Act (1968) came into force on 1 September 1971 the Licensing Authority (LA) granted a Product Licence of Right (PLR) for all products already available for sale at that date. There were 39,035 such PLRs. Review of these products became a requirement following European Community Directives (EC 65/6 and 75/318). The LA set up the Committee on the Review of Medicines (CRM) in 1975 to give advice when requested on the safety, quality and efficacy of any substance or article with a PLR. The Committee on Dental and Surgical Materials (CDSM) considered those PLRs within its area of expertise.

2. Homeopathic products, blood products, vaccines toxins and sera, and radiopharmaceuticals, which accounted for some 6000 of the PLRs, were specifically excluded by the directives from review. The remaining PLRs had to be reviewed and either full product licences granted or the PLRs allowed to lapse and the products taken off the market.

3. At first, the Review was arranged into approximately 30 therapeutic categories and separate expert subcommittees were set up for some of these. The active ingredients were considered initially, to review claims for efficacy, dosage, the need for warnings, contraindications and adverse effects, for any necessary restrictions on advertising and labelling, and to produce guidelines on the quality aspects. Definitive recommendations for the active ingredients were produced and then applied to individual products.

4. The second stage began in 1979 and allowed the Committee to consider individual products at a much earlier stage and considerably increased the rate of reviewing applications. Also at this time large volume parenteral fluids were looked at in view of quality concerns; the use of phenacetin was banned, bromides were disallowed and recommendations for barbiturates and benzodiazepines were published. In addition, a procedure was set up to bring to the attention of the Committee as quickly as possible products where lack of both safety or efficacy could present problems . Examples included aerosol products containing neomycin, bismuth

salts, products containing metals such as arsenic, mercury, antimony, tin and lead and other ingredients such as borax and camphor.

5. Phase three, known as the cyclical review, staggered the submission of applications to distribute the workload as evenly as possible across companies and introduced other changes to the procedures and approach. These measures and negotiating with companies to remove unsubstantiated claims, reduce the number of active ingredients and improve labelling and information, enabled more rapid progress to be made.

6. Of the 34,139 PLRs which had been eligible for review at the outset, applications were received in respect of just under 6,300 and a little under 5,300 reviewed licences were granted. In achieving these results the Licensing Authority was indebted to the CRM under the Chairmanship of Sir Eric Scowen, Professor O L Wade, Professor A W Asscher and Professor D H Lawson, and the CDSM under the Chairmanship of Professor C A Cawson, Professor Dame Rosalinde Hurley and Professor C L Berry.

BRITISH PHARMACOPOEIA COMMISSION

ANNUAL REPORT FOR 1991

Introduction

1. The British Pharmacopoeia Commission, appointed under Section 4 of the Medicines Act 1968, is responsible under Section 99(1) of the Act for preparing new editions of the British Pharmacopoeia and the British Pharmacopoeia (Veterinary) and for keeping these up to date. It provides advice to the United Kingdom delegation to the European Pharmacopoeia Commission (of which the United Kingdom is a member by virtue of its obligations under the Convention on the Elaboration of a European Pharmacopoeia, Treaty Series No 32: 1974) and selects British Approved Names under Section 100 of the Medicines Act. The membership of the Commission during 1991 is given in Appendix I.

2. The *Addendum 1991* to the *British Pharmacopoeia 1988* was published in January and the second and third supplements to *British Approved Names 1990* were published in February and August respectively.

3. The British Pharmacopoeia Commission, which met five times during 1991, has appointed twelve Committees and seven Consultative Groups to assist it in its work. There were sixteen meetings of Committees and Groups throughout the year and two additional *ad hoc* meetings on specialised topics. Membership of the Committees and Groups is given in Appendix II. The Commission expresses its gratitude for the invaluable contribution made by these members towards the maintenance and improvement of standards in the British Pharmacopoeia.

4. In October the Commission was advised that, in order to concentrate responsibility for laboratory services within a single Business of the Medicines Control Agency, management of the Pharmacopoeial Laboratory was to be transferred to the Inspection and Enforcement Business (Business D) within the Agency. Responsibility for the Commission's Secretariat was to be transferred to the New Drugs and European Licensing Business (Business A). These changes were effected on 1 November.

5. The Commission noted with pleasure the following awards and appointments made to members and former members of the Commission and its committees: Professor A O Betts, member of Commission, Fellow of The Royal Veterinary College; Dr. D J G Davies, member of the Pharmacy Committee, Professor of Pharmaceutics at the University of Bath; Professor F Fish, member of Commission, Honorary Fellow of the School of Pharmacy of the University of London; Professor J M Midgley, member of Commission, co-opted to the Council of the Royal Pharmaceutical Society of Great Britain; Professor G F Phillips, member of Commission, Honorary Member of the Royal Pharmaceutical Society of Great Britain; Dr. L E Ramsay, member of Commission, Professor of Clinical Pharmacology and Therapeutics at the University of Sheffield; Dr. J W G Smith, former member of Commission and the Committee on Immunological Products, a Knighthood in the Queen's Birthday Honours List; Dr. A H Thomas, member of the Antibiotics Committee, distinguished service award of the Analytical Division of the Royal Society of Chemistry; Mr. T D Turner, member of the Surgical Dressings Committee, the Charter Silver Medal for 1991 of the Royal Pharmaceutical Society of Great Britain.

6. With regret the Commission noted the deaths of Mr. K Bailey (former member of Committee B: Medicinal Chemicals) and Dr. D Watt (former member of Committee B: Medicinal Chemicals).

7. Dr. A R Rogers retired as Secretary and Scientific Director at the end of October after 28 years of distinguished association with the British Pharmacopoeia Commission. Dr. Rogers first contributed to the work of the British Pharmacopoeia in 1963 as a member of one of the synthetic drugs committees, later becoming its chairman. He served as a member of the British Pharmacopoeia Commission from 1978 to 1983 before joining the Secretariat in 1984. Early in 1988, Dr. Rogers was appointed as Secretary and Scientific Director, a position he held with enthusiasm and distinction.

8. Following the retirement of Dr. Rogers, Dr. R C Hutton was appointed as Secretary to the British Pharmacopoeia Commission. Dr. Hutton was formerly a senior member of the Medicines Inspectorate with responsibility for the UK Medicines Testing Scheme.

British Pharmacopoeia 1988

9. The *Addendum 1991* to the *British Pharmacopoeia 1988* was published in January and came into effect on 1 July 1991. *Amendments No 5* were issued also with effect from 1 July 1991. The Addendum costs £26.00 and is available from HMSO Publications Centre, from Government Bookshops or from the Pharmaceutical Press (ISBN 0 11 321311 5). *Amendments No 5* are supplied free of charge to registered purchasers of the British Pharmacopoeia or may be purchased separately as above (ISBN 0 11 321431 6, price £1.50).

10. The Addendum includes fourteen monographs that are new to the British Pharmacopoeia and a considerable number of amended texts. Although the new monograph for Chlortetracycline Ointment uses a microbiological assay, it is intended that the assays of many tetracycline antibiotic preparations will be replaced by liquid chromatographic methods in the future. Procedures for carrying out the test for uniformity of content of active ingredient have been added to a further number of monographs for capsules and tablets. The use of radioactive uranyl acetate as a reagent in identification tests for sodium has been deleted from a further number of monographs. A gas chromatographic method coupled to mass spectrometry to limit the content of 2,3,7,8-tetrachlorodibenzo-*p*-dioxin has been included in the monograph for Hexachlorophane. It is the first time that this combination technique has been used in the British Pharmacopoeia.

British Pharmacopoeia (Veterinary) 1985

11. *Amendments No 6* to the *British Pharmacopoeia (Veterinary) 1985* were published with an effective date of 1 July 1991. *Amendments No 6* may be purchased from HMSO Publications Centre or from bookshops (ISBN 0 11 321432 4, price £2.15).

Policy

12. The Commission continued its review of the purpose and functions of the Pharmacopoeia to which reference was made in the Annual Report for 1990. As part of this review, the British Pharmacopoeia Commission issued a policy statement in July about its present and future role in the control of medicines. In this statement, entitled *'The British Pharmacopoeia into the 1990s'*, the Commission defined its mission to provide objective and public standards of quality for medicines and described how this mission was realised through publication of the British Pharmacopoeia and participation in the work of the European Pharmacopoeia. The relationship between product licensing, inspection and the pharmacopoeia was explored and the Pharmacopoeia's contribution to the overall system of control of medicines was explained. The policy statement has been made available to users of the Pharmacopoeia both within the United Kingdom and overseas.

13. During the latter part of the year, the Commission gave preliminary consideration as to how the objectives described in the statement might best be achieved within the context of the revised arrangements for management of the Secretariat and Laboratory.

14. A declared policy of the Commission is to reduce reliance on test methods involving animals wherever this is compatible with its primary objective of providing satisfactory pharmacopoeial standards. In pursuance of this policy the Commission gave further thought to the small number of monographs for biological materials and antibiotics in which the test for abnormal toxicity had been retained following the systematic review that had been carried out for the *British Pharmacopoeia 1988*. After careful consideration, the Commission agreed that the test should no longer be included in the monographs for these materials. It was the opinion of the Commission that, in the current state of knowledge and widespread use of good pharmaceutical manufacturing practice, the test for abnormal toxicity contributes nothing to the monographs in question. With respect to a grossly contaminated product it is believed that the 'rational considerations' statement within the General Notice on Official Standards will provide an adequate basis for judging compliance. The test for abnormal toxicity will be deleted, therefore, from all monographs for biological materials, antibiotics and their preparations that are the direct responsibility of the British Pharmacopoeia Commission by means of the *Addendum 1992*.

European Pharmacopoeia

15. The European Pharmacopoeia Commission met on three occasions during 1991. In addition, fifty-seven meetings of its Groups of Experts were held.

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

17. Monographs in the fourteenth fascicule of the second edition of the European Pharmacopoeia were implemented on 1 January 1991 and appeared in edited form in the *British Pharmacopoeia 1988 Addendum 1991*. Notice was given that monographs and other texts in the fifteenth fascicule, which was published during the year, were to be implemented on 1 January 1992.

18. Good progress continues to be made with the elaboration of monographs by means of the adaptation of monographs from national pharmacopoeias. The first five monographs elaborated using this procedure were published in the fifteenth fascicule of the second edition of the European Pharmacopoeia.

19. During the year, continuing discussions among representatives of the European Pharmacopoeia Commission, drug regulators from the European Community and European Free Trade Association (EFTA) countries, representatives of the EC Commission and of the European pharmaceutical and chemical industry organisations were held with regard to the 'transparency' of monographs and the proposed procedure for the certification of suitability of monographs of the European Pharmacopoeia. The main feature of 'transparency' would be the naming of impurities known to be limited by a monograph. This is expected to increase the usefulness of monographs to licensing authorities.

20. Discussions were also held by the European Pharmacopoeia Commission with the *Comité Européen de Normalisation* (CEN) and the Commission of the European Communities with a view to establishing a memorandum of understanding with regard to the responsibilities for standardisation of medical devices.

21. Secretaries of European national pharmacopoeial authorities met twice to discuss matters of mutual concern and to promote and further the harmonisation of standards.

List of names

22. 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 1991 on the recommendation of the Medicines Commission.

23. 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.

24. During the year *Supplement Nos 2* and *3* to *British Approved Names 1990* were prepared and published on the recommendation of the Medicines Commission; 52 names were thereby added to the list.

25. The British Pharmacopoeia Commission continued to participate in the work of the World Health Organization in issuing nonproprietary names for medicinal substances. It also co-operated with authorities engaged in nomenclature work in other countries, in particular with the United States Adopted Names Council. In April, the secretary to the Commission's Nomenclature Committee attended the WHO consultations that led to the publication during the year of further lists (Nos 64 and 65) of proposed International Nonproprietary Names.

26. The year saw the adoption by the World Health Organization of a form of nonproprietary nomenclature for monoclonal antibodies suitable for use by health professionals. The scheme focusses on the generic suffix *-mab*; other letters in the name relate to the intended action and the animal source. Thus, in the name *nebacumab* the syllable *-bac-* indicates antibacterial action and the letter *u* indicates that the antibody is of human origin. The scheme was evolved with the support of the British Pharmacopoeia Commission and other co-operating national nomenclature agencies.

Pharmacopoeial laboratory

27. Evaluation and, where necessary, adaptation of test methods proposed to the Commission remained an important aspect of the work of the Laboratory. Changes in working practices made in the previous year resulted in the preparation of an increased number of monographs for the *Addendum 1992*. Organisation of staff and working practices were kept under review to improve efficiency yet further.

28. Support continued to be provided to UK members of European Pharmacopoeia Groups of Experts. Laboratory staff had direct involvement through membership of three of these groups and supplied substitutes for others on occasion.

29. The demand for British Pharmacopoeia Chemical Reference Substances (BPCRS) remained constant. Computerisation of the processing of orders improved operational efficiency.

30. To support the *Addendum 1991* an additional thirteen reference materials were established. Seven existing reference materials were re-evaluated to ascertain their suitability in procedures other than those for which they were originally established. This work was in addition to the continuing BPCRS monitoring programme. During the process thirty current reference substances were replaced either because of exhausted stock or unsuitability for new applications.

Liaison with other organisations

31. The British Pharmacopoeia Commission is again pleased to acknowledge the valuable support for its work provided by members of staff of the National Institute for Biological Standards and Control and staff of the Central Veterinary Laboratory, Weybridge. Significant contributions have been made covering a wide range of topics including antibiotics, hormones, immunological and other products. In addition, staff of the Medicines Testing Laboratory, Edinburgh, have again provided a considerable amount of helpful advice and comment.

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

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

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

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

* W G Allen MRCVS
A Veterinary Surgeon

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

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

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

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

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

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

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

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

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

* J M Midgley BSc MSc PhD FRPharmS CChem FRSC
Professor of Pharmaceutical and Medicinal Chemistry in the University of Strathclyde

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

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

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

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

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

\# A R Rogers BPharm BSc PhD FRPharmS CChem FRSC
Secretary and Scientific Director

† Term of office ended 31 December 1991
* Term of office ends 31 December 1993
Δ Term of office ends 31 December 1995
\# Retired 31 October 1991

APPENDIX II

BRITISH PHARMACOPOEIA COMMISSION

Membership of Committees and Groups

COMMITTEES

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

CONSULTATIVE GROUPS

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

APPENDIX III

EUROPEAN PHARMACOPOEIA COMMISSION

UNITED KINGDOM DELEGATION: D Ganderton *(Head of delegation)*
D H Calam
A R Rogers

Alternates: R C Hutton
M L Rabouhans
B A Wills

MEMBERS OF GROUPS OF EXPERTS FROM THE UNITED KINGDOM:

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

VETERINARY PRODUCTS COMMITTEE

ANNUAL REPORT 1991

TERMS OF REFERENCE

1. The Veterinary Products Committee was established in 1970 under Section 4 of the Medicines Act 1968. Its terms of reference are:

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

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

MEETINGS

2. The Committee held 11 meetings during 1991.

MEMBERSHIP

3. A list of members is provided at Appendix 1. Dr. Sharratt resigned during the year. Professor Richards joined the Committee in November to strengthen the expertise in the area of fish medicine. Professor Gettinby attended as a consultant to provide advice on statistics in connection with specific applications.

4. Members' current interests are provided at the Annex.

PRODUCTS AND PRODUCT GROUPS

Number of applications

5. During 1991, 68 applications for product licences and animal test certificates were referred to the Committee for detailed consideration of which 36 were recommended for refusal. The Committee considered formal representations in respect of 15 applications, 10 of which were made orally, and refusal was recommended in 8 cases.

Review of veterinary products

6. The Committee continued to provide advice on the review of veterinary medicinal products. The review is a requirement under the Veterinary Medicines Directive 81/851/EEC. Product groups initially considered by the Committee during 1991 included hormones, corticosteroids and sheep dips. The Committee was concerned that inadequate toxicological data were provided for several corticosteroid products which were widely used in food-producing animals and could recommend the use of these products in companion animals only. Further information was requested from the companies concerned to support use in food-producing species.

Sheep dips

7. The Committee considered a summary of all reported adverse reactions in humans associated with the use of organophosphorus sheep dips between 1984 and 1991. The Committee were also informed of the results of a survey carried out by the Health and Safety Executive (HSE) on existing sheep dipping practice in the farming community. The survey was intended as an initial small scale study only, was limited by a number of factors and the data were insufficient to draw a conclusion. However, the study was used to help in directing future HSE research on operator exposure to sheep dips. The Committee considered that existing labelling of products was inadequate and agreed there was a need for clear and practical recommendations on protective clothing to be worn by those using these products.

The Committee commented on an advisory note for farmers on the safe handling and disposal of sheep dips. The note had been prepared by the secretariat with assistance from representatives of the Department of the Environment, the National Rivers Authority, the Health and Safety Executive, the Working Party on the Disposal of Pesticides and manufacturers of sheep dip products. The Committee also noted the HSE leaflet entitled "Sheep Dipping - Protect your Health".

As part of the review of veterinary products, the Committee completed the initial phase of its review of sheep dip products. The Committee concluded that there was no clear evidence that sheep dips caused an unacceptable risk to human health when used in accordance with the label instructions. However, the Committee considered that certain aspects of the products and their conditions of use required further evaluation, in particular:

- the level of purity of the active ingredients

- the toxicity of other ingredients and solvents in the product formulations
- further operator monitoring studies on workers using the dips
- the persistence of residues in the fleece in relation to its subsequent handling.

The companies concerned have been asked to supply further data on these aspects so that the review can be completed by the end of 1992.

Immunological products

8. The Committee was informed of the implementation of new procedures for the post-licensing monitoring of immunological products. This would involve product related quality control/ quality assurance inspection and replace the existing batch testing arrangements.

Bovine somatotropin (BST)

9. The Committee was informed that the European Community Council of Ministers had agreed to extend the moratorium on the use of BST until the end of 1991.

The Committee provided advice for officials attending the European Commission's Committee for Veterinary Medicinal Products in connection with the consideration of the two applications for BST products under Directive 87/22/EEC.

Aquagard

10. An interim report on the use of this product was considered. The product contains dichlorvos and is used for the treatment of sea lice infestation in salmon. The Committee were informed that there appeared to be under-reporting to the River Authorities of discharges of Aquagard and it was agreed that prescribing veterinarians should be encouraged to inform the authorities when the product was used so that discharges could be monitored.

The Committee recommended that an animal test certificate could be granted, subject to certain conditions, for a product containing azamethiphos, an organophosphorus compound, for tests on sea lice infestation in salmon.

Mineral hydrocarbons

11. Following further comments by members, the Committee confirmed the advice to Ministers which was detailed in the report for 1990.

RESIDUES

Report of the Working Party on Veterinary Residues in Animal Products

12. The Committee considered the report of this working party for the period 1986 to 1990 and agreed a statement to be included as an appendix to the report. This report is to be published in 1992 by Her Majesty's Stationery Office in the Food Surveillance Paper series.

Natural steroid hormones

13. The Committee agreed that there were sufficient data to show that the natural steroid hormones used for permitted therapeutic and zootechnical purposes were not genotoxic and that their carcinogenic activity was secondary to their hormonal effects. As these are endogenous compounds it was considered unnecessary to set Maximum Residue Limits (MRLs) for these substances. To determine withdrawal times, residues studies should examine the decay of the substance in edible tissues to determine the time point when either the levels were comparable with similar concurrent controls or matched the levels yet to be adopted in the European Community.

Framycetin

14. The Committee agreed an MRL of 0.5 mg/kg for meat for framycetin, an aminoglycoside antibiotic related to neomycin.

Ceftiofur

15. The Committee agreed MRLs of 10 mg/kg for kidney and 0.5 mg/kg for milk for ceftiofur, a cephalosporin antibiotic.

SUSPECTED ADVERSE REACTIONS SURVEILLANCE SCHEME

16. The Committee received quarterly reports of the Licensing Authority's activities under the Suspected Adverse Reaction Surveillance Scheme. Reports of suspected adverse reactions to veterinary products were received from pharmaceutical companies and through voluntary reporting by veterinary surgeons and the general public under the "yellow form" arrangements. The Committee commended efforts by the secretariat to improve communications with those reporting reactions. A total of 353 reports were received during 1991 and investigated. 19 of these reports were associated with the use of unlicensed medicines, and the balance of 334 reports involved 141 licensed products.

The number of reports involving cattle and dogs increased. In both species problems with anti-inflammatory products, including non-steroidal anti-inflammatory drugs, and anti-microbials were significant. The unlicensed use of monensin in sheep was associated with reports of toxicity, some of which were attributable to feed mixing errors. Where reports of feed mixing errors were received, relevant information was passed on to the Royal Pharmaceutical Society of Great Britain which has the responsibility for inspection of manufacturers of medicated feed.

17. The scheme also receives reports of human reactions associated with the use or administration of veterinary products. The Committee was informed of the establishment of an appraisal panel to assess these reports. The panel consists of doctors, veterinarians and scientists from the Department of Health, the Health and Safety Executive and the Veterinary Medicines Directorate. All human reactions will be assessed by the panel which will report to the Committee.

209 reports of suspected human adverse reactions were received in 1991 from companies, the National Poisons Information Service and other sources. 141 of these reports were associated with sheep dip products.

EUROPEAN COMMUNITY

Council Regulation (EEC) No. 2377/90

18. The Committee was informed that this regulation laid down a Community procedure for the establishment of MRLs for ingredients of veterinary medicinal products in foodstuffs of animal origin. The regulation is binding on Member States and comes into force on 1 January 1992. The effect of the regulation is that new active substances intended for food-producing species must have a Community MRL before a product licence can be issued. Active substances in currently licensed products must have a Community MRL by 1997 and a call-up procedure is in force. Applications for MRLs will be considered by the European Commission's Committee for Veterinary Medicinal Products (CVMP) and the VPC would be consulted to provide advice for officials attending the CVMP.

The Committee noted The Animals, Meat and Meat Products (Examination for Residues and Maximum Residue Limits) Regulations 1991 (SI 1991 No 2843) which come into force on 8 January 1992.

Implementation of Directive 90/676/EEC

19. The Committee was informed of changes to UK law which would be necessary to implement Council Directive 90/676/EEC, and of the Government's provisional plans for dealing with these. The Directive updates existing Community law on licensing veterinary medicines, and introduces controls on their distribution. In particular it makes it clear (in accordance with existing UK practice) that the safety criterion includes environmental safety, and requires member states to take account when issuing licences of MRLs established by the Community.

Homeopathic products

20. The Committee was informed of the current UK law on the supply of homeopathic products for veterinary use and of the implications of a Commission proposal for a Community directive on these matters. Under this directive it was proposed that products sold for specific therapeutic purposes would require a full product licence (as now), but that other products could be registered in accordance with a new simplified procedure.

OTHER MATTERS

Malachite green

21. The Committee considered the use of malachite green in fish farming and noted with concern there was no currently licensed product containing this substance. At present malachite green appears to be the only effective treatment for proliferative kidney disease in trout but only in the early stages of the disease. Because fish are treated only in their first year of life, the Committee thought it extremely unlikely that detectable residues would be found in fish intended for human consumption. The report of the Working Party on Veterinary Residues in Animal Products included results from samples of farmed fish which had been analysed for malachite green and no residues of this substance were detected using an analytical method with a limit of determination of 0.02 mg/kg. The Committee noted that published studies suggested that the substance was mutagenic, carcinogenic and teratogenic although the studies had been carried out some time ago with malachite green of doubtful provenance. The Committee recommended that the substance should be tested for mutagenicity using

the strategy recommended by the Department of Health Committee on Mutagenicity. The Committee welcomed the news that the European Community was funding research on the ecotoxicity of malachite green and asked to be kept informed on the progress of all studies on this material.

Control of Substances Hazardous to Health (COSHH) Regulations

22. The Committee was informed of these regulations and noted the application of COSHH to veterinary medicines. It concluded that there should be full cooperation with the Health and Safety Executive (HSE) to ensure that the HSE can fulfil its statutory role as the enforcing authority for the COSHH Regulations and relevant sections of the Health and Safety at Work Act 1974.

EXTERNAL ISSUES

Expert Group on Animal Feedingstuffs

23. The Committee considered and agreed a submission to the Expert Group on Animal Feedingstuffs. This group was to report to Ministers on all aspects of animal feedingstuffs and the Committee's submission covered the controls on the use of medicated animal feedingstuffs.

Press briefing

24. At the end of each meeting, The Committee approved a summary of its proceedings for use in response to press enquiries.

Release of VPC papers

25. In 1990, MAFF Ministers accepted the Committee's advice that some papers coming before it could be made available to interested members of the public following consideration by the Committee. In 1991 the following six papers were made available -

a) Veterinary Medicines Directorate R and D Strategy Paper

b) Vitamin A

c) Toxicity Assessment: Natural Steroid Hormones

d) Natural Steroid Hormones: Supplementary Guidelines

e) COSHH Regulations: Application to Veterinary Medicines

f) Regulation of Veterinary Homeopathic Products

ACKNOWLEDGEMENTS

26. The Committee was grateful for advice it received from the Advisory Committee on Pesticides and 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 thanked the scientific and administrative secretariat in the Veterinary Medicines Directorate. The Committee was also grateful for advice received from officials of the Department of Health, the Department of the Environment and the Health and Safety Executive.

APPENDIX I

VETERINARY PRODUCTS COMMITTEE MEMBERS 1991

Chairman

Professor J Armour CBE* PhD, Dr hc (Utrecht), MRCVS, FRSE	*Vice Principal, University of Glasgow*

Members

Professor J P Arbuthnott** PhD, ScD, MRIA, FI Biol	*Vice-Chancellor, Strathclyde University*
Professor PM Biggs CBE* DSc, Dr hc (Liege), DVM (hc) (Munich), FRC Path, C Biol, FI Biol, FRCVS, FRS	*Visiting Professor in Microbiology at the Royal Veterinary College, London*
Professor J W Bridges** BSc, PhD, MRC Path, C Chem, FRCS, C Biol, FI Biol, M Inst Eng Sci	*Professor of Toxicology and Director of the Robens Institute, University of Surrey*
Professor J Brown** BSc, MSc, PhD, FR PharmS, C Chem, FRSC, C Biol, FI Biol	*Professor of Pharmaceutical Chemistry Sunderland Polytechnic*
Mr D S Collins** MVB, C Biol, MI Biol, DVPH (MH) MRCVS	*Veterinarian, Consultant in Veterinary Public Health*
Mr P Crossman** B Vet Med, MSc, MRCVS	*Practising Veterinary Surgeon, Chichester, West Sussex*
Professor S Denyer** B Pharm, PhD, MR PharmS	*Professor of Pharmacy and Head of Department of Pharmacy, Brighton Polytechnic*
Miss K Gibson* BVMS, MRCVS	*Practising Veterinary Surgeon, Edinburgh*
Dr R J Heitzman* BSc, PhD	*Private consultant working for FAO/WHO, EEC, International Atomic Energy Agency and UN Development Programme*
Professor D E Jacobs** BVMS, PhD, MRCVS	*Department of Veterinary Pathology, Royal Veterinary College, University of London*

Veterinary Products Committee

Professor G E Lamming OBE* DSc, PhD, MA, BSc, BSc(Agric), FI Biol, NDA BSc, Hon Assoc RCVS	*Department of Physiology and Environmental Science, University of Nottingham*
Professor P Lees** B Pharm, PhD, Hon Assoc RCVS C Biol, FI Biol, Dr hc (Gent)	*Department of Veterinary Basic Sciences, Royal Veterinary College, University of London*
Dr K A Linklater** BVMS, PhD, FRCVS	*Director of SAC Veterinary Services Edinburgh, Scotland*
Professor R Richards* BA, MA, Vet MB, PhD, MRCVS	*Deputy Director, Institute of Aquaculture University of Stirling*
Dr M Sharratt++ BSc, MSc, PhD, MB, ChB FRC Path, FFOM	*Former Toxicology Advisor and Deputy Head of British Petroleum Group Occupational Health Centre*
Professor I K M Smith* MSc, PhD, MRCVS	*Department of Veterinary Pathology Royal Veterinary College, University of London*
Dr S Venitt** BSc, PhD	*Team Leader, Molecular Carcinogenesis Section Institute of Cancer Research*
Professor G Gettinby+ BSc, PhD	*Department of Statistics and Modelling Science University of Strathclyde*

* Term of office expires 31.12.95

** Term of office expires 31.12.93

\+ Attended as a consultant

++ Resigned during the year

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

* Excluding the British Pharmacopoeia Commission and its Committees

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

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

4. In this code, "pharmaceutical industry" means

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

b. trade associations representing companies involved with such products;

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

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

5. In this code, "the Department" means the Department of Health or in the case of the Veterinary Products Committee, the Ministry of Agriculture, Fisheries and Food.

DIFFERENT TYPES OF INTEREST

6. The following is intended as a guide to the kinds of interests which should be declared. Where a member is uncertain as to whether an interest should be declared he or she should seek guidance from the Department or, where it may concern

a particular product which is to be considered at a meeting, from the Chairman at that meeting. If members have interests not specified in these notes but which they believe could be regarded as influencing their advice they should declare them. However, neither members nor the Department are under an obligation to search out links between one company and another, for example where a company with which a member is connected has an interest in a pharmaceutical company of which the member is not aware and could not reasonably be expected to be aware.

Personal interests

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

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

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

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

Non-personal interests

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

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

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

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

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

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

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

DECLARATION OF INTERESTS

Declaration of interests to the Department

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

Special position of Chairmen

10. It is not appropriate for the Chairmen of the Medicines Commission and the Section 4 Committees to have any current personal interests in the pharmaceutical industry.

The position of Sub-Committee Chairmen is the same as for all other members, since Sub-Committees report to the main Committee rather than giving advice in their own right.

Declaration of interests at meetings and participation by members

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

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

b. A member must declare a personal non-specific interest if he or she has a current personal interest in the pharmaceutical company concerned which does not relate specifically to the product under discussion. The member shall take no part in the proceedings as they relate to the product, except, at the Chairman's discretion, to answer questions from other members.

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

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

12. The examples of "personal", "non-personal" and "current" interests given in the previous paragraphs should be read in the context of paragraphs 6,7, and 8. "Taking part in the proceedings" includes both speaking and voting. A member who is in any doubt as to whether he or she has an interest which should be declared, or whether to take part in the proceedings,

should ask the Chairman for guidance. The Chairman has the power to determine whether or not a member with an interest shall take part in the proceedings.

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

RECORD OF INTERESTS

14. A record is kept in the Department of

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

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

PUBLICATION

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

MEDICINES COMMISSION

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

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor Rosalinde Hurley (Chairman)	None		None		
Professor I D Aitken	Moredun Animal Health Limited	Director and Fee	None		
Mr M J S Butler	None		None		
Dr M G Carter	ICI plc	Salary and Shareholder			
Professor J G Collee	None		None		
Professor P F D'Arcy	None		None		
Professor A D Dayan	Boots Glaxo ICI	} Shareholding	None		
	S K Beecham Ltd Immunology Ltd M L Laboratories Ltd Ortho Ltd Pfizer Ltd	} Consultancy	None		

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

Annex 1

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor A D Dayan (continued)	Sterling Winthrop Ltd Syntex Ltd Wyeth Ltd	Consultancy	None		
Dr S M Gore	Glaxo Cambridge Lung Surfactants Ltd	Shareholder	Vestar	Consultancy Fee	No
	Healthcare Education Services Ltd Wellcome Sandoz	Fee			
	Immunology Ltd	Statistical Consultancy (Fee to BSU Research Fund)			
Miss Joan Greenleaf	David Bull Laboratories Innovex Ltd	Consultancy	None		
Mr B D Hoskin	ICI plc	Shareholding	None		
	Wellcome plc	Shareholding, Pension			
	Secto Company Ltd	Consultancy (short term)			
Professor C N Hudson	None		None		
Professor T M Jones	Wellcome plc	Director and Shareholder	None		

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor D G McDevitt	Drug Development (Scotland) Ltd	Director (ex-offico)	Abbot Laboratories	Research Grant	Yes
	3M Healthcare	Consultancy	Bayer	Support for Research Pharmacist	Yes
			Boehringer Ingelheim	Support for	Yes
			Glaxo	Research	Yes
			Smith Kline Beecham	Fellow	Yes
			Ciba-Geigy	Support for Research Computer Programmer	Yes
			ICI		Yes
			Janssen		No
			Lederle		Yes
			Merck Sharp & Dohme	Research	Yes
			Pfizer	Grants	Yes
			Rhone-Poulenc Rorer		Yes
			G D Searle		Yes
			Servier		
			Squibb		Yes
			3M Healthcare		Yes
Dr P C Pietroni	None		None		
Professor P M Reilly	None		Schering Health	Research	Yes
			Convatex (UK)	Grant to	Yes
			Gallen	Members of	Yes
			Bessalar	Department to	No
			M S D	support their	No
			Stuart	research in a	No
			Boots plc	specific project	No

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
Professor P M Reilly (cont'd)			Eli-Lilly/RCGP	using their product	No
Dr A G Renwick	International Sweetners Association	Consultancy in relation to intense sweetners only	Bayer	Support for research project plus income from drug assay work	Yes
			Ciba-Geigy	Support of Research Projects	Yes
			Fisons	Support of research projects and technical staff	Yes
			Warner Lambert	Income from drug assay work	Yes
			Boots ICI Roche	Support for Completed research projects	No
Professor John Rhodes	Smith Kline Beecham Tillotts Pharm AG Norwich Eaton (USA) Farmitalia Carlo Erba Ltd	Consultancy	Smith Kline Beecham Tillotts Pharm AG Norwich Eaton (USA) Farmitalia Carlo Erba Ltd Pharmacia-Leo (Kabi-Pharmacia)	Finance for Research Staff	Yes Yes Yes Yes Yes

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor P S J Spencer	Glaxo Group Boots Research May & Baker (now Rorer Rhone-Poulenc)	Shareholder Project Grant Holder Consultancy	None		
Mr G C Tuck	Miles Ltd	Company Secretary and Legal Director (Salaried)	None		
Professor D W Vere	Rhone-Poulenc UK	Consultancy	Sandoz	Grant to Department	No
Dr D R Williams	None		None		
Mr H C Wilson	None		None		

COMMITTEE ON SAFETY OF MEDICINES

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

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
Professor A W Asscher (Chairman)	None		Action Research Agricultural & Food Research Council AMI Healthcare AO-Stiftung. ASIF-Foundation Arthritis & Rheumatism Council Bayer (UK) Ltd Beechams Blood Pressure Research Trust Boots Breast Cancer Research Trust Bristol Myers Pharmaceuticals British American Tobacco Co Ltd British Digestive Foundation British Heart Foundation British Lung Foundation British Telecom British Thoracic Society Cancer Research Campaign Cardiovascular Research Foundation (Geneva) Chest Heart & Stroke Association Ciba-Geigy Ltd City & Hackney Health Authority Commission of the European Communities Crawley & Jersey Research Trust Department of Health Draco	The Dean (Professor Asscher) is Chief Executive of the Medical School, which has 23 departments. The grants listed refer to grants made to individual departments. None of them is payable to the Dean since he heads the School's administration	Yes

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
Professor A W Asscher (continued)			E.R. Squibb & Sons Farmitalia Carlo Erba Fisons Pharmaceutical Glaxo (UK) Glaxo (USA) Glaxo Institute for Molecular Biology SA Glaxo Labs & Cardiac Research Fund Guide Dogs for the Blind Association Hayward Foundation Health Education Authority Healthpromotion Trust Home Office-Information Technology Div ICI Ileostomy Association Knoll Leukaemia Research Fund Leverhulme Trust Lewis Family Charitable Trust Lithox System Marrow Environment Project Max Reinhardt Charitable Trust May & Baker Medical Research Committee Medical Research Council Mental Health Foundation Merck, Sharp & Dohme Milupa Ltd Ministry of Agriculture Fisheries & Food		

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor A W Asscher (continued)			Ministry of Defence National Association for Colitis & Crohn's Diseases National Kidney Research Trust Neurosciences Research Foundation (AMH) Pfizer Pharmax Ltd Proctor & Gamble Co Ltd Research into Ageing Rhone Poulenc Roche Products Ltd Royal Gist-Brocades NV Royal National Institute for the Deaf Royal Ottawa Hospital Sandoz Forschungsinstitut Sandoz Ltd Schwarz Pharma Spa Science & Engineering Research Council G.D. Searle & Co Ltd Seven Seas Ltd Sir Halley Stewart Trust Sir Jules Thorn Charitble Trust South West Thames RHA South West Thames RHA (LRS) St Bartholomew's Hospital Sterling Winthrop Group Ltd TCET Ltd The Priory Hospital UPSA Medica Wandsworth Health Authority		

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
Professor A W Asscher (continued)			Wellcome Trust World Health Organisation Zyma (UK) Ltd		
Professor C L Berry	None		None		
Professor S S Bleehen	Steifel Labs (UK) Advisory Board (Fee)	Skin Forum	Unilever Research	Research Grant	Yes
	Sandoz	Research Grant	Roche	Grant to Department	Yes
			Galderma	Grant to Department	No
Professor T G Booth	Wellcome PLC	Share Holder	Boots PLC	Staff Funding	Yes
	Scholl (UK) Ltd Convatec Ltd	Consultancy and Fee Paid Work	AAH Pharmaceuticals Ltd Glaxo Pharmaceuticals Ltd Allen and Hanburys Boots	Grant, Support for Chair. Research Support Staffing Funding.	Yes
Professor A M Breckenridge	Smith Kline & Beecham	Consultancy	Boehringer Mannheim Glaxo Pharmaceuticals ICI Kirby Warrick Pharmaceuticals Organon Labs Ltd Parke Davis Research Labs Pfizer Ltd Sandoz Pharmaceuticals Schering Health Care Ltd	Research Grants to Members of Department to support their research.	Yes

Annex 1

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor R G Finch	Amgen Bayer Bristol Myers/Squibb Centocor Daiichi ICI Rhone-Poulenc Smith Kline Beecham Vestar	Consultancy	Merrell Dow/Marion Wellcome Trust	Departmental Research Grants	Yes
Professor A T Florence	Napp Controlled Therapeutics (Scotland) Syntex Research Centre, Edinburgh	Consultancy	L'Oreal Syntex	Research Studentship supervised by Professor Florence	Yes
			Abbott Astra Bayer B P Chemicals Boehringer Ingelheim Burroughs Welcome Ciba-Geigy Daiichi Seiyaku (Japan) E.I. Dupont de Nemours FMC Corporation Glaxo Group Research Ltd Glaxo (Verona and Australia) ICI L'Oreal MSD Novo Nordisk Orstram	Research Grants, travel grants, gifts of research materials and equipment to departments and individuals in the School of Pharmacy, University of London	Yes

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor A T Florence (cont'd)			Parke Davis Rhone-Poulenc Roussel Sandoz Sederma Smith Kline Beecham Syntex Tocris Neuramin Warner Lambert (UK)	of which Professor Florence is Dean.	
Professor E C Gordon-Smith	None		Sandoz	Clinical Trial and Funding for Data Manager	Yes
Professor F Harris	None		Allen & Hanbury's Amersham International Astra Pharmaceuticals Bayer (UK) Beecham Wulfing Boehringer Manheim Boots Co. plc British Biotechnology Celltech Limited Ciba, Geigy, Sandoz, UpJohn Ltd, Shire Pharmaceuticals Duphar Lab Ltd Eli Lilley & Co (USA) Farmitalia Fisons Pharmaceutical Glaxo Group Research Ltd Glaxo Laboratories ICI	Research Grants, and Student-ships to Depart-ments of the School in the University of Leicester for which Professor Harris is Dean.	Yes

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor F Harris (Cont'd)			Janssen Pharmaceutical Johnson & Johnson 3M Health Care Ltd Mercke Sharp & Dohme Merrell Dow Nycomed (UK) Ltd Parke Davis & Co Pfizer/Shiley Pharmacia Ltd Rhone Pulenc Rore Scherig Healthcare Senofi U.K. Smith & Nephew Pharmaceuticals Smith Kline Animal Squibb Europe Stuart Pharmaceuticals Unilever Research UpJohn Ltd Wyeth Labs		
Professor H S Jacobs	Serono Novo-Nordisk	Consultancy	Serono Organon	Sponsored Research	Yes No
	Glaxo	Shareholder			
Dr W A Jerrett	None		None		
Professor M J S Langman	Merck Sharpe Dohme (now lapsed) Wellcome	Consultancy	Astra Boots Ciba Geigy Glaxo Smith Kline Beecham Syntlelabo	Support for Departmental Research Activities	Yes No

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		Bristol Myers Squibb Hoechst (UK) Ltd	Post Marketing Surveillance Analysis	Yes
Mr F E Loeffler	None		None		
Professor A E M McLean	Delta Biotechnology UPSA (France) Riker 3M Healthcare Mutract (Isle of Man) Roussel Ltd Smith & Nephew Ltd Ferrosan (Denmark)	Consultancy	Sterling Winthrop Rhone-Poulence Roussel UCLAF (France)	Research Grant and Fees for PhD Studentships	Yes
	British Technology Group	Patent Royalties			
Professor J M Midgley	Convatec Wound Healing Research Institute Daiichi Mitsubishi Kasei UPSA	Consultancy	Glaxo Research Welcome Foundation	Endowed Lectureship Research	Yes Yes
	Rhone-Poulenc-Rorer Allergan	Research Grants			
Dr S A Montgomery	Smith Kline Beecham Novo Jouveinal Organon Duphar Merck Wyeth Almirall	Lectures/Advice	Bayer Janssen Glaxo Merrill Dow Lilly	Contributions to Support Research Staff Costs Contributions to Support Research Staff Costs	Yes No

Annex 1

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Dr C M Oakley	None		None		
Professor M D Rawlins	None		Astra Werke Degussa Bayer (UK) Boots Squibb Bristol Myers Janssen Welcome	Departmental Research Grants	Yes
Dr D A J Tyrrell	Glaxo Research Janssen Research	Consultancy	None		
Professor M P Vessey	Novo-Nordisk	Consultancy	Ciba-Geigy Parke-Davis Upjohn	Clinical Trial	Yes
			Schering	Epidemological Study	No
			Bayer	Member of Advisory Group on Acarbose	Yes
			Smith Kline Beeham	Research Grant	Yes

COMMITTEE ON SAFETY OF MEDICINES

SUB COMMITTEE ON SAFETY, EFFICACY AND ADVERSE REACTIONS

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

	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
MEMBER	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Dr L Beeley	None		None		
Professor A T Birmingham	Wellcome Research Labs. Welcome Foundation	Consultancy Member of Protocol Review Committee	Alza, Abbott, Amersham, Boehringer, Boots, Celltech, Delta, Glaxo, ICI, Johnson & Johnson, Janssen, Merck, Sharp & Dohme, Merrell-Dow, Pharmafood, Proctor & Gamble, Reckitt & Colman, Roussel, Smith Kline Beecham, Squibb, Syntex, Syntex/, UCB	Various Support for staff, Studentships, grants and contracts: for equipment and consumable costs	Yes

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor A T Birmingham (Cont'd)			Upjohn Wyeth/ 3-M	}	
Professor A M Breckenridge	(see entry under Committee on Safety of Medicines}				
Dr R L Carter	ICI	Shareholder	None		
Professor D S Davies	ICI	Shareholder Boots	Astra/Draco	}	
	M L Laboratories	Non Executive Director	Daiichi Dompe Glaxo	} Commissioned Research, Fellowships,	
	Clinical & Biochemical Pharmacology Limited	} Director	Hoechst M L Laboratories Merck Sharp & Dohme Pfizer Proctor & Gamble Rhone-Poulenc Rorer Roche Wellcome Foundation	} Grants & Consultancy	Yes
			Abbott Astra Otsuka	} Commissioned Research	No
Dr P B Farmer	None		Ciba-Geigy	Research Collaboration	Yes
Professor R G Finch	(see entry under Committee on Safety of Medicines)				

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor S T Holgate	Laboratories Almiral Ciba-Geigy Fisons ICI 3M Riker Roche (UK) Burroughs Wellcome (UK)	Consultancy	Allen Hanbury Astra Pharma Boehringer Ingelheim Boehringer Manheim Ciba-Geigy Fisons Fujisawa Glaxo ICI Laboratories Almiral Lipha Merrell Dow Norton (Harris) Sandoz Schering-Plough Takeda	Research Grants & Clinical Trials	Yes
Professor C J Hull	Janssen Pharmaceuticals Wellcome	Consultancy	Janssen Pharmaceuticals Organon Teknica	Departmental Research Project	Yes
Professor D R Jones	Wellcome Foundation ICI	Consultancy	Glaxo Fisons	Student prizes for MSc Course	Yes
Dr B J Kirby	None		None		
Professor M J S Langman	(see entry under Committee on Safety of Medicines)				
Dr A V P Mackay	None		Scotia Pharmaceuticals	Research Grant to a Colleague	Yes

Annex 1

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor A E M McLean	(see entry under Committee on Safety of Medicines)				
Professor B K Park	Lederle	Consultancy	Schering Boots Park-Davis / Warner Lambert Sanofi	Postgraduate Studentships & Research Grants	Yes
Professor M D Rawlins (Chairman)	(see entry under Committee on Safety of Medicines)				
Professor P A Routledge	Sanofi	Fee for Lecture	Glaxo	Clinical Trial	No
			Dow Corning	Analytical Work	No
			Wellcome	Drug Analysis	No
			Cardiff Clinical Trials Unit	Consultancy Work and Pharmacokinetic Reports	Yes
Professor C G Swift	None		Astra		Yes
			Boots		No
			ICI		Yes
			Labs for Applied Biology	Departmental Research Grants	No
			Rhone-Poulenc		No
			Rorer		Yes
			Smith Kline Beecham		No
			Sode Pharm Ltd		No
			Welcome		Yes

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Dr G N Volans	Boots	Expert Reports	Bayer Glaxo LERS-Synthilabo Lilly E Merck Kabi Pharmacia	Research	Yes
			Boots Boehringer Dista Duphar Glaxo Hoechst Sanofi-Winthrop Servier Welcome	Assays for Various Drugs	Yes
			Boots ICI May & Baker Schering-Plough Squibb Servier Stiefal	Information Searches & Report Preparation	Yes
Dr D W Wall	None		None		

COMMITTEE ON SAFETY OF MEDICINES

SUB COMMITTEE ON CHEMISTRY, PHARMACY AND STANDARDS

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

	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
MEMBER	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor J R Brown	Merck Schering-Plough Jouveinol Salix	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		
Professor D J G Davies	Smith & Nephew Pharms	Royalty Payment on Pryme Care Product & Fees for occasional Development Work	Abatron Ltd A K G Westalia Allergan Inc Allergan Optical Bausch & Lomb Boots Celltech Contactasol Bayer Controlled Therapeutics Cyanamid Eschmann Bros & Walsh Glaxo Group Research Harris Pharmaceuticals	Research Projects, Studies and Studentships	Yes
	Co-ordinated Drug Development Ltd	Director and Shareholder			
	Smith & Nephew Controlled Therapeutics Ltd	Royalty Payments			

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

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Mr B Midcalf	None		None		
Professor J M Midgley	(See entry under Committee on Safety of Medicines)				
Professor J M Newton	Cyanamid H N Norton	Consultancy	Boehringer Ingelheim BTG FMC Corporation Glaxo 3M Health care H N Norton Rhone Poulence Rorer Roussel Syntex Welcome	Research Support	Yes
			ICI Pharmaceuticals	Research Support	No
Professor M S Parker	None		None		
Professor J E Rees	Abbott Glaxo Controlled Therapeutics Inc. Allergan Optical Baush & Lomb	Share Holder Licence agreement relating to a new contact lens disinfection system	Allergan Optical Controlled Therapeutics Co-ordinated Drug Development Cyanamid Boots Abatron		
	Welcome	Expert Witness	Alliance Tech & Development Cilovision		
	Boots AAH Pharmaceuticals	Equipment Donational Meetings Sponsorship			

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
Professor J E Rees (Cont'd)	Pfizer	Fee as advisor for annual Pfizer academic awards	Glaxo Research Harris Hoechst Smith & Nephew Squibbderm	Research & Study Grants and Consultancies to Departments	Yes
	Hadley-Hutt	Research Grant	Sanflon Rhone Poulenc Rorer Wessex Medical Universiti Sains, Malaysia		
Professor G T Tucker	Napp S K Beecham Upjohn Rhone-Poulenc-Rorer Innovata Biomedica Astra (Sweden)	Consultancy	Glaxo Group Research	Research Studentship	Yes

COMMITTEE ON SAFETY OF MEDICINES

SUB COMMITTEE ON BIOLOGICALS

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

	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
MEMBER	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor J E Banatvala	Smith Kline Beecham Roche Products	Research Studies	Abbot Diagnostics Amerlite Diagnostics British Biotechnology Merieux Smith Kline Beecham Wellcome Foundation	Sponsorship Costs	Yes
			Smith Kline Beecham Welcome Foundation	Research Funding	Yes
Dr E B Gingold	None		None		
Professor K Gull	British Biotechnology Kent Life Science Director	Consultancy	Proteus	Lectureship	Yes
Professor G Janossy	None		Sandoz	Grant	Yes
Dr S L Jeffcoate	None		None		
Professor J Melling	None		Amerlite Diagnostics Amersham International Akzo (Organon) Ltd Bayer BASF Behringwerke Beki Barn AB	All Services Contract Patent Patent Patent Patent/Contract Patent	

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor J Melling (cont'd)			Bioscot	Safe Deposit	
			Biomerieux	Patent	
			Bioferon	Patent	
			Boehringer Mannhein	Patent	Yes
			Boehringer Ingelheim	Patent	
			British Biotechnology	Supply	
			British Novo	Safe Deposit	
			Bunge (Australia) (Pty) Ltd	Patent	
			Cambridge Research Biochemicals	Supply	
			Celltech	All Services	
			Convatec	All Services	
			Ciba-Geigy AG	Patent	
			Delta Biotechnology	All Services	
			Diosynth SA (Organon)	Contract/Patent	
			Degussa	Patent	
			Evans Medical	Contract	
			Farmitalia Carlo Erba	Patent/Supply	
			Fisons	Training/Supply	
			Glaxo	All Services	
			Genzyme	Contract	
			Hoechst AG	Patent	
			Hoffman La Roche	Patent/Supply	
			ICI	Supply	
			Immuno	Sales	
			Immunology	All Services	
			Ingensa	Patent	
			Innogenetics	Patent	
			Interprise	Patent	
			Intervet	Contract	
			Ire Medgenix	Patent/Supply	
			Ire Celltarg	Patent	
			Nordisk Gentofte	All Services	
			Orpegen	Patent	

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor J Melling (Cont'd)			Otto Nordwald AG	Supply/Patent	
			Oxford Virology	Contract	
			Pitman Moore	All Services	
			Pharma Biotechnologie	Patent	
			Porton Products	All Services, Sales	
			Progen Biotechnik	Patent /Contract	
			Rhone Poulenc	Supply	
			Sandox	All Services	
			Sanofi	Contract/Supply	
			Schering AG	Patent	Yes
			Serotec	Contract	
			Serono	All Services	
			Smith Kline Beecham	All Services	
			Squibb Surgicare	Supply	
			Stabilgen	Patent	
			Upjohn	Training/Supply	
			Wellcome	All Services & Sales	
			Vuman Ltd	Safe Deposit	
			Xenova	All Services	

DEFINITIONS

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

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

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

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

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

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

7. Sales — Sale of products produced by CAMR

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

COMMITTEE ON SAFETY OF MEDICINES

SUB COMMITTEE ON ADVERSE REACTIONS TO VACCINES AND IMMUNISATION

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

	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
MEMBER	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor J E Banatvala	Smithkline Beecham Roche Products Ltd	Research Studies	Abbot Diagnostics Amerlite Diagnostics British Biotechnology Merieux Smith Kline Beecham Wellcome Foundation	Sponsorship Costs	Yes
			Smith Kline Beecham Welcome Foundation	Research Funds	Yes
Dr C Bowie	None		None		
Professor A M Breckenridge (Chairman)	(see entry under Committee on Safety of Medicines)				
Dr N Cavanagh	None		None		
Dr P Fine	Pasteur/Merieux	Member of Scientific review Committee on pertussis vaccines	None		
Professor F Harris	(see entry under Committee on Safety of Medicines)		None		
Dr C R Kennedy	None		None		

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor D G McDevitt	Drug Development, Scotland 3M Health Care	Director (Ex-officio) Consultancy	Abbott, Bayer, Boehringer Ingelheim, Ciba Geigy, Glaxo, ICI, Janssen, Lederle, Merck Sharp & Dohme, Pfizer, Rhone-Poulenc (Rorer), G D Searle, Smith Kline Beecham, Squibb	Research Grants	Yes
Dr B W McGuinnes	None		Leo Laboratories, Bayer, Glaxo, Lilly, Astra	Research Support	Yes
Professor S R Meadow	Boots	Share Holder	None		
Professor D L Miller	None		None		
Dr E Miller	None		None		
Dr P Minor	None		None		
Dr D Reid	None		Smith Kline & Beecham	Salary of Staff	Yes
Dr D A J Tyrrell	(see entry under Committee on Safety of Medicines)				

COMMITTEE ON DENTAL AND SURGICAL MATERIALS

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 C L Berry (Chairman)	None		None		
Professor W Bonfield	None		Johnson & Johnson Orthopaedic	Grant	Yes
Mr R J Buckley	Bausch & Lomb	Member of B&L International Research Committee (travel Grant)	None		
Professor H D Edmondson	None		Astra		
			Pharmaceuticals Ltd	} Expert	Yes
			Straumann Corvent	} Opinion	Yes
			Britcair (SKF Ltd)	}	Yes
Mr J A Elias	None		None		
Professor M Elstein	None		Schering Healthcare	}	Yes
			Organon International	} Research	Yes
			London International	} Studies and	Yes
			Femcare	} Clinical Trials	Yes
			Leiras	}	Yes
			Conrad USA/Aid	}	Yes
			Ortho Cilag	}	Yes

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
Professor M Elstein (continued)			Wyeth - Ayerst	}	Yes
			Medgenix	} Research	Yes
			Colombia	} Studies and	Yes
			Roussel Laboratories	} Clinical	Yes
			Norwich-Eaton	} Trials	Yes
			Johnson & Johnson	}	Yes
			Novo Nordisk	}	Yes
			Remer Chemicals	}	Yes
			Quintiles	}	Yes
Mr J Howe	None		None		
Professor G C Jenkins	None		None		
Professor R B Johns	NobelPharma	Grant	None		
Professor I D A Johnston	None		Cow & Gate	Research	Yes
Dr J R Larke	Pilkington Vision Care	Consultancy	None		
Mr B J Meakin	Co-ordinated Drug Development	Director, Share Holder	Smith & Nephew	} Research	No
			Wessex Medical	} Contracts	Yes
	Smith & Nephew	Royalty Fees	E R Squibb	} Awarded	No
	Controlled Therapeutics inc	Patent Holder for University of Bath	Fisons Pharms	} to University	No
			Duplex	} of Bath	No
	Glaxo Group Research	Consultancy	Roussel	} (No involvement)	Yes
	Alliance Technology & Development	Consultancy	Hoechst UK	}	Yes
			Cyanamid UK	}	No
	Cibavision	Research Contract & Consultancy	Eschmann Bros & Walsh	}	Yes
	Bausch & Lomb (USA)	Consultancy			

Annex 1

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
Mr B J Meakin (cont'd)	Allergan Optical	Consultancy (Lapsed)	Harris Pharmaceuticals	Research	No
			Abatron Ltd	Contracts	Yes
			Sauflon Pharmaceuticals	Awarded to	Yes
			Glaxo Group Research	University	Yes
			Smith & Nephew	of Bath	Yes
			Madden & Layman	(Personal involvement in Direction of work)	Yes
Mr B Midcalf	None		Kabi Vitrum	Loan to University	Yes
			Polymedica Industries	Provision of Materials	Yes
Professor C Scully	Blendax/ Proctor & Gamble	Consultancy/ Research Grant	None		
	Vitabiotics	Grant			
	3M Health Care	Grant			
	Wyeth Laboratories	Grant			
Miss A B Sutherland	Johnson & Johnson	Share Holding	None		
Professor D E M Taylor	Geistlich Sons Pharmaceuticals	Consultancy	Davis & Geck	Grant in	Yes
			Ethicon	Kind	Yes
			Sutures (UK)	Research	Yes
			Autosuture	Co-operation	Yes

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Mr T D Turner	Johnson & Johnson Seton Polymedica UK Ltd	} Consultancy	None		
Professor B Whiting	None		None		
Professor E G Woodward	None		Ciba Vision Bausch & Lomb Johnson & Johnson Smith & Nephew	} Research } Support } } Research	Yes Yes Yes Yes

COMMITTEE ON THE REVIEW OF MEDICINES

MEMBERS DECLARED 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	Shareholder	None		
Professor C J Bulpitt	Wellcome Foundation Ltd	Wellcome Protocol Review Committee Consultancy fee	ICI Ltd E Merck Ltd Pfizer Ltd Merck Sharp & Dohme Ltd	Departmental Grants	Yes
Professor J E Carless	None		None		
Mr W M Darling	None		None		
Professor F Fish	None		None		
Professor F Harris	None		Squibb Europe Glaxo Group Research Ltd Fisons Pharmaceutical Bayer UK Ltd Shire Pharmaceuticals Beecham Wulfing Gist Brocades Delft Unilever Research Ltd Upjohn Ltd Ciba Geigy Sandoz	Research grants to Departments	

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
Professor F Harris (cont)			Janssen Pharmaceuticals Ltd Amersham International Boehringer Mannheim Pharmacia Ltd Allen & Hanbury's Merck Sharp & Dohme Neuroscience Research Centre Leo Labs Ltd Smith Kline 1982 Foundation Pfizer Ltd ICI Schwarz Pharmaceuticals Abbot Laboratories UCB Pharmaceuticals Merrell Dow Medisure Vox Healthcare Farmitalia Carlo Erba Bristol Myers Astra Pharmaceuticals Roussel Laboratories Delta Biotech	in the University of Leicester School of Medicine of which the member is Dean	Yes
Professor J G R Howie	Glaxo	Occasional lecturing fees - not product related	None		
Dr B J Kirby	None		None		
Professor D H Lawson (Chairman)	None		None		

Annex 1

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Professor R M Mackie	None		None		
Dr A McKnight	Schering Health Care Ltd	Research Funding	None		
Professor J M Midgley	Convatech (Bristol-Meyers Squibb)	Consultancy Granuflex Dressing	Rhone-Poulenc Ltd	Research support	Yes
			Roche Products Ltd	Visiting Professor	Yes
Dr A T Proudfoot	None		None		
Dr L E Ramsay	None		Servier Laboratories Abbot Laboratories Beechams Laboratories	Research	Yes

VETERINARY PRODUCTS COMMITTEE

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

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
Professor J Armour (Chairman)	Merck Research Laboratories	Parasitology Consultancy	None		
Professor J P Arbuthnott	SmithKline Beecham	Consultancy, Fees; Anti-Infectives Research Grant	SmithKline Beecham	} Research	Yes
Professor P M Biggs	Hoechst UK Ltd	Consultancy	None		
Professor J W Bridges	None		None		
Professor J Brown	Merck Schering Plough Jouveinal	Consultancy Consultancy Consultancy	Serono Glaxo	Consultancy Grants	No Yes
Mr D S Collins	None		None		
Mr P J Crossman	None		None		
Professor S P Denyer	Amersham International SmithKline Beecham Rhone-Poulenc Glaxo	Consultancy, Research Grants Research Support Consultancy Research Support	Ciba-Geigy Glaxo Upjohn Loveridge Europharm Britcair Custom	} Research } Support } } } Contract } Research }	Yes Yes Yes Yes Yes Yes Yes

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	WHETHER CURRENT
Miss K Gibson	None		None		
Dr R J Heitzman	None		None		
Professor D E Jacobs	Sorex Ltd	Consultancy	Bayer		
	Pfizer Ltd	Fees (Anthemintics)	Coopers Pitman-Moore	}	Yes
			Hoechst	}	Yes
			Pfizer	} Support for	Yes
			SmithKline Beecham	} Research	Yes
			Temana	}	Yes
			MSD Agvet	}	Yes
Professor G E Lamming	None		Ciba-Geigy	}	Yes
			Pfizer	} Support for	Yes
			Hoechst UK Ltd	} Research	Yes
			Pfizer	}	Yes
			Glaxo	}	Yes
			Lilly	} Material for	Yes
			Intervet	} Research	Yes
			Upjohn	} projects	Yes
			SmithKline Beecham	}	Yes
Professor P Lees	Norbrook Laboratories Ltd	Consultancy	Rycovet (Grampian Holdings)	}	Yes
			Norbrook Laboratories Ltd	}	No
			Vetoquinol Ltd	} Support for	Yes
			Panpharma Ltd	} Research	No
			American Cyanamid	}	No
			Schering Plough/Essex	}	Yes
			Boehringer Ingleheim	}	No
			Intervet	}	Yes

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
Dr K A Linklater	None		Coopers Animal Health		Yes
			Pitman-Moore		Yes
			Hoechst (UK) Ltd	Commercial	Yes
			Janssen Animal Health	Consultancy	Yes
			MSD Agvet		Yes
			Pfizer Ltd		Yes
			Intervet UK Ltd		Yes
Dr M Sharratt	ICI	Shareholder	None		
Professor I K M Smith	Duphar Ltd	Consultancy	Duphar	Support for	Yes
			Bayer Ltd	Research	Yes
Dr S Venitt	None		None		