

Medicines Act 1968 Advisory Bodies

Annual Reports 2009

Commission on Human Medicines

Advisory Board on the Registration of Homeopathic Products

British Pharmacopoeia Commission

Herbal Medicines Advisory Committee

Independent Review Panel for Advertising

Independent Review Panel for Borderline Products

Medicines and Healthcare products Regulatory Agency

**MEDICINES ACT 1968
ADVISORY BODIES ANNUAL REPORTS 2009**

**Presented to Parliament pursuant to Section 5(2) of
the Medicines Act 1968**

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FOREWORD BY THE PARLIAMENTARY UNDER SECRETARY OF STATE FOR QUALITY

It gives me great pleasure to present the Annual Reports for 2009 of the Medicines Act Advisory Bodies: Commission on Human Medicines; Advisory Board on the Registration of Homeopathic Products; the Herbal Medicines Advisory Committee, and British Pharmacopoeia Commission, along with a record of Members' interests in the pharmaceutical industry and code of practice. Also included in this volume are reports from the Independent Review Panel on the Advertising of Medicines and Independent Review Panel for Borderline Products.

On behalf of all Health Ministers I would like to thank the Chairmen and Members of all the Expert Committees whose professional expertise, commitment and hard work plays a vital role in ensuring that the medicines we take continue to meet the highest standards of safety, quality and efficacy.

Earl Howe

Commission on Human Medicines Annual Report 2009

TERMS OF REFERENCE

1. The Commission on Human Medicines was established in October 2005 under Section 2 of the Medicines Act 1968 (as amended) and replaced both the Medicines Commission and Committee on Safety of Medicines.
2. The functions of the Commission on Human Medicines are:
 - to advise the Health Ministers and the Licensing Authority (LA) on matters relating to human medicines products including giving advice in relation to the safety, quality and efficacy of human medicinal products where either the Commission thinks it appropriate or where it is asked to do so
 - to consider those applications that lead to LA action as appropriate (i.e. where the LA has a statutory duty to refer or chooses to do so)
 - to consider representations made (either in writing or at a hearing) by an applicant or by a licence or marketing authorisation holder in certain circumstances
 - to promote the collection and investigation of information relating to adverse reactions to human medicines for the purposes of enabling such advice to be given.

The Commission is, of course, similarly involved in respect of medicinal products to which relevant EC legislation applies.

MEMBERSHIP

3. Commissioners' details are listed at **Appendix I**. There are Expert Advisory Groups that report to the Commission, their remits and membership are listed at **Appendix II**.
4. The Commission wishes to record its gratitude and appreciation of the valuable work of its Expert Advisory Groups and Ad Hoc Groups:

1 November 2005 - 31 October 2009

Anti-Infectives, HIV and AIDS
Chaired by Dr Barbara Bannister

Biologicals and Vaccines (BVEAG)
Chaired by Dr Angela Thomas

Cardiovascular, Diabetes and Renal Medicines (CDREAG)
Chaired by Professor Henry Dargie

Chemistry, Pharmacy and Standards (CPSEAG)
Chaired by Professor Derek Calam

Clinical Trials (CTEAG)
Chaired by Professor Robert Lechler

Dermatology (DEAG)
Chaired by Professor David Gawkrödger

Gastrointestinal & Hepatology (GHEAG)
Chaired by Professor Michael Farthing

Medicines for Women's Health (MWHEAG)
Chaired by Dr Mary Armitage

Neurology and Pain Management (NPMEAG)
Chaired by Dr Michael Donaghy

Oncology and Haematology (OHEAG)
Chaired by Professor John Smyth

Paediatric Medicines (PMEAG)
Chaired by Professor Rosalind Smyth

Patient Information (PIEAG)
Chaired by Ms Joanne Rule

Pharmacovigilance (PEAG)
Chaired by Professor Munir Pirmohamed

Psychiatry & Old Age Psychiatry (POAPEAG)
Chaired by Professor Ken Woodhouse

Respiratory & Allergy (RAEAG)
Chaired by Professor Peter Helms

Rheumatology & Immunology (RIEAG)
Chaired by Professor Stuart Ralston

From November 2009

Anti-Infectives, HIV/AIDS & Hepatology
Chaired by Dr Barbara Bannister

Biologicals & Vaccines (BVEAG)
Chaired by Dr Angela Thomas

Cardiovascular, Diabetes, Renal & Respiratory & Allergy
(CDRRAEAG)
Chaired by Professor Colin Forfar

Chemistry, Pharmacy and Standards (CPSEAG)
Chaired by Professor Derek Calam

Clinical Trials (CTEAG)
Chaired by Professor Robert Lechler

Dermatology, Rheumatology, Gastroenterology & Immunology
Vacant

Medicines for Women's Health (MWHEAG)
Chaired by Dr Mary Armitage

Neurology, Pain & Psychiatry (NPPEAG)
Chaired by Dr Michael Donaghy

Oncology and Haematology (OHEAG)
Vacant

Paediatric Medicines (PMEAG)
Chaired by Professor Rosalind Smyth

Patient Information (PIEAG)
Vacant

Pharmacovigilance (PEAG)
Chaired by Professor Munir Pirmohamed

Ad Hoc and Working Groups 2009

Bioequivalence Ad Hoc Group
Chaired by Professor Ian Weller

Mixing of Medicines Working Group
Chaired by Professor Derek Calam

Coughs and Colds Working Group
Chaired by Professor Rosalind Smyth

Nicotine Replacement Therapy Working Group (NRT WG)
Chaired by Professor Ian Weller

Pseudoephedrine Ad Hoc Group
Chaired by Professor Roger Walker

Pharmacy Supply Usage Modelling and Antibiotic Resistance (PUMAR) Ad Hoc Group
Chaired by Dr Barbara Bannister

5. The Commission also notes with great pleasure the extent of its influence and congratulates those Commissioners chairing Committee on Human Medicinal Products (CHMP) Scientific Advisory Groups, namely Dr Barbara Bannister (Anti-Infectives), Professor Henry Dargie (Cardiovascular), Dr Michael Donaghy (Clinical Neuro-Sciences), Professor Ian Weller (HIV/Viral Diseases) and from its external panel of experts, Professor Edwin Gale (Diabetes/Endocrinology) and to Professor Jonathan Ledermann (member of the Oncology SAG). The CHMP is the medicines regulatory body for all EU member states.
6. The Commission wishes to record its gratitude to those members of the External Advisory Panel who attended meetings or provided written advice to the Commission and its Expert Advisory Groups during the course of the year. Members' names are listed at the end of this report, **Appendix III**.

MEETINGS

7. The Commission held 11 meetings during 2009. Two-day meetings were held in May, June and September. One-day meetings normally lasted between five and six hours. Meetings are held at the Medicines and Healthcare products Regulatory Agency (MHRA), Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

SECRETARIAT

8. The Commission's secretariat is based at the MHRA. A list of the support staff is at **Appendix IV**. The Commission also wishes to place on record its indebtedness and gratitude to the excellent professional and administrative staff of the MHRA concerned with the business of the Commission and its Expert Advisory Groups.

COSTS

9. For each meeting they attend, Commissioners are paid a fee of £275 per day (Chairman's fees are £400 per day). In respect of the Expert Advisory Groups, members receive £150 per day and Chair £275 per day. Travel and subsistence are also payable within Department of Health guidelines.
10. The Commission considered and advised on a total of 85 applications for marketing authorisations. The table below shows the outcome for national/mutual recognition/ decentralised/ centralised applications for new active substances and abridged applications at first consideration (ie before appeals).

FIRST CONSIDERATION BY THE COMMISSION

Commission Advice on Applications for National Marketing Authorisations/ Mutual Recognition/ Decentralised and Centralised Applications

| | Grant advised | Grant not advised |
|-----------------------|---------------|-------------------|
| New Active Substances | 4 | 13 |
| Abridged Applications | 1 | 67 |

11. The Commission was extensively involved in applications made through the European centralised procedure. Included in the total number in the table above of applications seen by the Commission were 17 new active substances covering 13 centralised marketing authorisations.

APPEALS

12. The Commission considered a total of eight pre-hearings covering 19 applications. Of these, 14, applications were approved at the pre-hearing stage provided the product particulars were amended. One product covering one application received an oral hearing and was not approved. Two applications are undergoing ongoing data assessment. Following the remaining pre-hearing (which covered two applications), the Commission suggested that there should be a clarification meeting between the company and the MHRA so that the MHRA could explain the issues in more detail.
13. The Commission considered an average of eight applications at each of its 11 meetings in this period, in addition to clinical trial applications, appeals, reclassifications, pharmacovigilance data and other matters.

EXTERNAL STAKEHOLDERS

14. In March, the Commission held one of its regular meetings with industry representatives and discussed issues of mutual interest which included:
- revised pharmacovigilance proposals contained in the EU pharmaceutical package
 - recommendations on the Royal College of Physicians report on 'Innovating for Health'
 - UK Industry views on stratified diseases/ personalised medicine
 - the EU guideline on the investigation of bioequivalence
 - UK policy on the promotion of clinical trials
 - a BIA regulatory affairs committee one day workshop on the use of safety biomarkers.
15. The Commission received representatives from the Chief Medical Officer's office, the NHS Purchasing and Supply Agency, the Department of Health, the European Medicines Agency and the London School of Economics.

REAPPOINTMENT

16. In October 2009, the majority of Commissioners' terms of appointment came to an end. The following new appointments to the Commission were made:

Mrs Alison Bowser
Lay representative

Dr J Colin Forfar BSc(Hons) MBChB PhD MD MA FRCP
Consultant Physician and Cardiologist, John Radcliffe
Hospital, Oxford

Professor Rosalind Smyth MA MBBS MD FRCPCH FMedSci
Brough Professor of Paediatric Medicine, Head of School of
Reproductive and Developmental Medicine, University of
Liverpool, Chair Paediatric Medicines Expert Advisory Group

Professor Simon Thomas BSc MB MD FRCP
Professor of Clinical Pharmacology and Therapeutics,
Newcastle University and Consultant Physician, Newcastle
Hospitals NHS Foundation Trust

17. The Commission wishes to extend its thanks to Professors Henry Dargie, Peter Helms, Anthony Nunn and Maggie Pearson, who retired from the Commission in 2009.
18. Details of appointment and re-appointment dates can be found at **Appendix I**.
19. The Commission conducted a review of its Expert Advisory Groups and concluded that the:
- i. Anti-Infectives, HIV/AIDS should be merged with Hepatology to form Anti-Infectives, HIV/AIDS and Hepatology

- ii. Cardiovascular, Diabetes and Renal Medicines and Respiratory and Allergy should be merged to form Cardiovascular, Diabetes, Renal, Respiratory and Allergy
- iii. Dermatology, Rheumatology and Gastrointestinal and Immunology should be merged to form Dermatology, Rheumatology and Gastroenterology and Immunology
- iv. Neurology and Pain Management and Psychiatry and Old Age Psychiatry should be merged to form Neurology, Pain and Psychiatry

CONSIDERATION OF OTHER MATTERS

20. In addition to the consideration of applications and appeals, the Commission also considered and advised on matters of medical and pharmaceutical relevance as follows:

SAFETY OF MARKETED MEDICINES

Efalizumab (Raptiva) – benefit:risk review

21. The Commission and its Pharmacovigilance EAG considered an assessment of the risks and benefits of efalizumab (Raptiva), a centrally authorised monoclonal antibody used in the treatment of moderate to severe psoriasis. This review had been stimulated by reports of Progressive Multifocal Leukoencephalopathy (PML), a serious central nervous system infection. The Commission was concerned about the balance of risks and benefits of the product. The Committee for Medicinal Products for Human Use (CHMP) was not reassured that the risks associated with Raptiva treatment could be adequately managed and voted to suspend the MA for efalizumab. The usage of efalizumab was very limited in the UK and the MA holder sent a letter to health professionals to inform them of the suspension. Information was placed on the MHRA website and was sent to relevant professional bodies and patient groups. An article on this issue was also published in the MHRA's drug safety bulletin, Drug Safety Update.

Long Acting Beta-Agonists (LABA) – benefit:risk review

22. The Commission along with its Respiratory and Allergy and Pharmacovigilance EAGs considered a review of long-acting beta agonists (LABAs) in the treatment of chronic obstructive pulmonary disease (COPD). The Commission advised that the balance of benefits and risks was positive when LABAs were used both as monotherapy and in combination with inhaled corticosteroids (ICS), but reiterated that the key safety issue was the increased risk of pneumonia with the ICS component of combination products. An article on this issue was also published in the MHRA's drug safety bulletin, Drug Safety Update.

Human Papillomavirus (HPV) vaccine – safety monitoring

23. The national immunisation programme with HPV vaccine (Cervarix) started in September 2008. In March 2009 the Commission and its Pharmacovigilance EAG considered a paper outlining progress with the proactive pharmacovigilance strategy to assess the safety of the vaccine in clinical use and considered a detailed analysis of suspected adverse reactions that had been received in association with its use through the Yellow Card Scheme. At that time at least 500,000 doses of vaccine had been administered to girls since the programme started. The Commission advised that no new safety issues had been identified. The Commission and its Pharmacovigilance EAG also considered an assessment of reports of Chronic Fatigue

Syndrome (CFS) and post viral fatigue syndrome which had been received through the Yellow Card Scheme in association with HPV vaccine. The Commission advised that the available evidence did not support a causal association between HPV vaccine and CFS. However as with all possible safety issues, it was recommended that this be kept under close review.

Finasteride (Proscar, Propecia) – risk of breast cancer

24. The Commission and its Pharmacovigilance EAG considered an assessment of the risk of breast cancer with finasteride, which is marketed as Proscar (5mg) for treatment of benign prostatic hyperplasia and as Propecia (1mg) for the treatment of male pattern baldness. The Commission advised that there was sufficient evidence to suggest a small increased risk of breast cancer in males treated with both Proscar and Propecia, although the evidence for an increased risk at the dose of finasteride contained in Propecia was less strong. The Commission advised that warnings should be added to the product information for prescribers and patients for both products. This issue was considered within Europe by the CHMP's Pharmacovigilance Working Party which also agreed that the possibility of an increased risk of breast cancer in males in association with finasteride could not be excluded and that updates should be made to the product information. An article on this issue was also published in the MHRA's drug safety bulletin, Drug Safety Update.

Swine flu pandemic

25. Throughout the swine flu pandemic the Commission and its Pharmacovigilance Expert Advisory Group has received monthly updates on the reports of suspected adverse reactions in association with the flu antivirals oseltamivir (Tamiflu) and zanamivir (Relenza) and also the swine flu pandemic vaccines, (Celvapan and Pandemrix) that have been received through the dedicated swine flu portal. The Commission has noted that the number and nature of the suspected adverse effects are very much in line with what would be expected and that no unexpected new safety issues have been identified from reports received to date. The balance of benefits and risks for the flu antivirals oseltamivir (Tamiflu) and zanamivir (Relenza) and also the swine influenza pandemic vaccines remains positive.

Sibutramine (Reductil) – benefit:risk review

26. In December 2009 the Commission and its Pharmacovigilance EAG considered preliminary data from the Sibutramine Cardiovascular Outcome Trial (SCOUT), which showed an increased risk of serious, non-fatal cardiovascular events such as stroke or heart attack with sibutramine compared with placebo. The concerns from the UK and other Member States led to a Europe wide review in the form of a referral to the CHMP under Article 107 of Directive 2001/83/EC as amended. The Commission advised that the balance of risks and benefits for sibutramine was no longer favourable given the robust evidence of risk, the biological plausibility and the modest weight loss observed. The Commission acknowledged that undiagnosed underlying cardiovascular morbidity is common in the obese population and could not identify a sub-population for which the benefit risk would be positive. The Commission considered that it was not apparent how any risk minimisation measures proposed could change the negative benefit risk of sibutramine. The Commission advised that sibutramine should be withdrawn from the market.

Cough and cold medicines available over the counter for children – risk:benefit review

27. The advice of the Commission informed the UK position during the European discussions at CHMP. In January 2010, the CHMP concluded that risks of sibutramine containing medicinal products outweigh their benefits and recommended the suspension of the marketing authorisations for these medicines across the European Union. MHRA informed UK health professionals through the Central Alerting System and posted information on the MHRA website.
28. In December 2008, the Commission and its Paediatric Medicines and Respiratory EAGs, considered risk:benefit assessments for each of the four classes of ingredients in children's cough and cold medicines available over the counter (OTC), antihistamines, decongestants, expectorants, and cough suppressants, following concerns raised by paediatricians about inadvertent overdose and associated toxicity.

The Commission concluded that the risk:benefit balance of the medicines was unfavourable in children under 6 years. The Commission considered that, given the lower incidence of ADRs in children over 6 years, reduced risk of toxicity by weight, and ability to judge symptomatic relief, the risk:benefit in children over 6 years could be viewed differently. The Commission remained concerned, however, about the lack of data on efficacy and recommended that MA holders be given a time-limited opportunity to provide data demonstrating efficacy in older children.

29. This advice was communicated to health professionals and the public at the beginning of March 2009. The Marketing Authorisation holders submitted updates to the product information in line with the advice. These changes have been approved, and products with the updated information began to enter the supply chain in Autumn 2009. More research on the use of these medicines in children under 12 years is being taken forward by industry.

Codeine: risk of misuse of OTC medicines

30. The Commission considered the risks of inadvertent overuse or misuse of, and addiction to, codeine and dihydrocodeine (DHC) containing solid dose over the counter (OTC) medicines. This followed publication of a report in January 2009 of the All-Party Parliamentary Drug Misuse Group (APPDMG) on physical dependence and addiction to prescription and OTC medicines.
31. In 2005 the Commission's predecessor, the Committee on Safety of Medicines (CSM), had considered the benefits and risks of these medicines and advised action to strengthen warnings, including duration of use, risk of addiction and overuse headache, and voluntary limitation of pack size to 32, with larger packs for dispensing use only. Companies were asked to take a responsible approach to promotional activities. This is backed up by a Code of Practice issued by the Proprietary Association of Great Britain (PAGB).
32. On the basis of the information from the APPDMG report, additional sales data and data from Self Help Groups, the Commission recommended the removal from the product information of all indications relating to colds, influenza, coughs and sore throats, and references to minor painful conditions, with the remaining list of indications being for the short-term

treatment of acute, moderate pain which is not relieved by paracetamol, ibuprofen or aspirin alone. The Commission advised that the warnings 'Can cause addiction' and 'For three days use only' should be added to the patient information leaflet (PIL) and also prominently and clearly displayed on the front of the pack (together with the addition in the PIL of the warning signs of addiction). The Commission advised that all OTC packs of codeine and DHC containing medicines, including effervescent forms, greater than 32 should be reclassified to Prescription Only. The Commission recommended further amendment to the advertising guidelines to reflect the new indications and warnings and encourage responsible promotion of codeine and DHC containing OTC medicines to minimise the risk of addiction and medicines overuse headache.

THE COMMISSION'S EXPERT ADVISORY GROUPS (EAGS) AND AD HOC GROUPS

Anti-Infectives, HIV and AIDS EAG

33. The remit and membership of the Expert Advisory Groups and Ad Hoc Groups are listed in **Appendix 1**.
34. The Anti-Infectives, HIV and AIDS EAG did not meet during 2009 but members were consulted on issues, European and national, by written procedures where timelines precluded a meeting.
35. Following a review by the Commission this Anti-Infectives, HIV and AIDS EAG was merged to form Anti-Infectives, HIV/ AIDS and Hepatology EAG.

Biologicals and Vaccines (BVEAG)

36. The BVEAG met in January and October in 2009 and advised on applications for new medicines and vaccines submitted through the European and National procedures, together with variation applications. The EAG also considered applications via written communication on seven occasions.
37. The BVEAG considered and advised on a product for the prevention of hepatitis B virus re-infection after liver transplantation for hepatitis B induced liver failure. It also considered and advised on a fibrin sealant derived from animal blood products to help control bleeding in surgery when conventional surgical techniques including suture, ligature and cauterization are ineffective or impractical.
38. The BVEAG provided written comments on a vaccine for the prophylaxis of influenza in an officially declared pandemic situation in individuals from 18 years of age; on a medicine indicated for maintenance treatment of ulcerative colitis to prevent relapse and treatment of chronic constipation; and on a monoclonal antibody for the treatment of osteoporosis in post-menopausal women or treatment of bone loss during hormone-ablating oncology treatments. The EAG also provided written comments on a blood product derived specific immunoglobulin; a human plasma fraction for treatment of deficiencies of coagulation factors, reversal of effects of oral anticoagulants or therapeutic plasma exchange procedures; a medicinal product indicated for female infertility; and the Human Papillomavirus (HPV) vaccine.
39. The BVEAG considered and advised on a product for active immunisation against tetanus, diphtheria and pertussis in

persons aged 4 years and over, as a booster. It also considered papers relating to a medicine indicated for imaging in the treatment of breast cancer and an update on the HPV vaccine. An issue regarding importation of a vaccine was discussed. The EAG provided written comments on a medicine indicated for the treatment of acute angioedema attacks in patients with hereditary angioedema.

40. The BVEAG was advised of the impact on the UK supply of plasma-derived medicinal products if only plasma collected from countries with no or low risk/incidence of BSE and/or no cases of vCJD acquired from within that country was used in their manufacture.
41. The BVEAG was advised of an adverse event regarding a gene therapy product in a clinical trial in France.
42. The procedure for assessment of pandemic influenza vaccines (rolling submissions) was explained to the BVEAG. This included use of cloned licenses and strain change variations, for example from H5N1 to H1N1.
43. The membership and function of a new multi-disciplinary committee, the Committee for Advanced Therapies (CAT), which works alongside the CHMP at EMEA was explained. The role of CAT in assessment and the certification procedure was described.
44. The CDREAG met on one occasion, in July, and provided advice by written correspondence in June, September and November, for four other products.
45. At the July meeting, the CDREAG discussed and advised on a centralised application (European procedure) with UK as the Rapporteur for a new chemical entity, intended as an adjunct to radionuclide myocardial perfusion imaging for evaluation of ischaemic heart disease. At the same meeting the EAG also discussed the response from the company to questions on a new 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase inhibitor (HMGR) or "statin," involved in a decentralised procedure with UK as the reference member state (RMS). The product was indicated to correct lipid abnormalities in patients with primary hypercholesterolaemia and combined (mixed) dyslipidaemia, who have not responded adequately to dietary control.
46. In June, the CDREAG advised on the Risk Management Plan for a bicarbonate-based solution, indicated for haemofiltration, haemodialysis and haemodiafiltration, where the UK was the Reference Member State for the product.
47. In September, the CDREAG also advised on a Type II Mutual Recognition Procedure Variation, for an HMGR, to include the indication to reduce the risk of major cardiovascular events in adult patients with an increased risk of atherosclerotic cardiovascular disease based on the presence of cardiovascular risk markers such as age, hypertension, low high-density lipoprotein cholesterol (HDL-C), elevated high-sensitivity C-reactive protein (hsCRP), smoking or a family history of premature coronary heart disease.

Cardiovascular, Diabetes and Renal (CDREAG)

Chemistry, Pharmacy and Standards (CPSEAG)

48. In November, the CDREAG provided advice on two products relating to hypertension. One was for an existing agent, Renin inhibitor combined with Angiotensin II Antagonist, where UK was the co-rapporteur in a European procedure, and the advice was carried forward to the European level discussions on this product at the first cycle of assessment. The EAG advised regarding acceptability of the proposed indications. The second concerned a Decentralised generic application for a combination of Angiotensin II Antagonist with Hydrochlorothiazide. The EAG advised on whether or not the proposed indications were supported by the data from add-on studies in patients on monotherapy.
49. Following a review by the Commission this CDREAG merged with the Respiratory and Allergy EAG to form the Cardiovascular, Diabetes, Renal, Respiratory and Allergy EAG.
50. The CPSEAG met eight times and considered and advised on applications for new drugs, abridged applications, variations and pre-hearing applications for medicines.
51. In February the CPSEAG considered medicines for the treatment of:
 - benign prostatic hyperplasia
 - breast cancer, a special form of lung cancer, gastric cancer or head and neck cancer
 - bacterial infections affecting the chest, urinary tract (kidney, bladder) abdomen and skin. Also for the treatment of children with a reduced resistance to infection.
52. The CPSEAG also considered the following products:
 - a medicine used for relief from nausea and/or vomiting in palliative care patients who have not responded to other drug therapies. This drug blocks some of the brains receptors responsible for the sensation of nausea and process of vomiting
 - a medicine which lowers the amount of uric acid in the body. Too much uric acid in the body causes gout, kidney stones and other types of kidney disease
 - an inhaled steroid hormone delivered from a novel dry powder device indicated for the treatment of asthma.
53. The CPSEAG considered and advised on a request to relax controls regulating the manufacturing process of a product. The controls had been imposed following incidents of aseptic peritonitis. The EAG considered that insufficient process improvements have occurred to allow this.
54. In March the CPSEAG considered medicines for the treatment of:
 - previously treated patients with chronic idiopathic thrombocytopenic purpura (ITP) to increase platelet counts and reduce or prevent bleeding
 - sudden, short-lived attacks of diarrhoea in adults and children aged 12 years and over and for diarrhoea associated

with Irritable Bowel Syndrome in adults

- angina.

55. The CPSEAG also considered the following products:

- three orally inhaled medicines indicated for the treatment of asthma
- a solution to be used for raised pressure within the eye including patients suffering from glaucoma
- a product used for skin disinfection prior to invasive treatments such as blood tests
- an antibiotic indicated for the treatment of acute sinusitis, acute exacerbations of chronic bronchitis, community acquired pneumonia, uncomplicated urinary tract infections, complicated urinary tract infections including pyelonephritis, chronic bacterial prostatitis and skin and soft tissue infections.

56. In April the CPSEAG considered medicines for the treatment of various forms of cancer including breast, lung and head and neck cancers. The EAG discussed orally inhaled medicines indicated for the treatment of asthma.

57. The CPSEAG also considered and advised on a number of European and other regulatory papers.

58. The CPSEAG received a presentation on the background of the current European situation regarding data requirements for biowaivers for generic micelle products. The EAG considered and advised on the background documents.

59. In May the CPSEAG considered medicines for the treatment of:

- moderate to severe symptoms of benign prostatic hyperplasia (BPH)
- macular oedema due to branch or central retinal vein occlusion
- asthma.

60. In July the CPSEAG considered medicines for the treatment of:

- breast cancer; non-small cell lung cancer; prostate cancer; gastric adenocarcinoma; head and neck cancer
- schizophrenia and manic episodes associated with bipolar I disorder
- adult patients with traveller's diarrhoea
- hypertension and angina pectoris
- high blood pressure, heart failure in addition to water tablets, and for the reduction of risk of heart attack, stroke and cardiovascular deaths in patients with or at high risk of cardiovascular disease.

61. The CPSEAG also considered a dry powder inhaler indicated for the treatment of asthma. The EAG also discussed the draft CHMP Guideline on the Investigation of Bioequivalence. The outcome of these discussions was taken forward to the Quality

Working Party. The CPSEAG was presented with a paper concerning parametric release submissions.

62. In September the CPSEAG considered medicines for the treatment of:
- the prophylaxis of acute transplant rejection in patients receiving allogenic renal, cardiac or hepatic transplants
 - asthma.
63. The CPSEAG also considered:
- a medicine for the prevention of skeletal events in patients with breast cancer and bone metastases and for the treatment of osteoporosis in postmenopausal women at increased risk of fracture
 - an antiseptic solution to reduce dental caries in permanent teeth of adolescents and adults
 - a medicine indicated for the initiation of hormonal castration in advanced or metastasising hormone-dependent prostate carcinoma when androgen suppression is necessary
 - a paper concerning parametric release submissions.
64. In October the CPSEAG considered medicines for the treatment of:
- malaria
 - staphylococcal enterocolitis and pseudomembranous colitis due to *Clostridium difficile*
 - asthma.

The CPSEAG also considered an atypical antipsychotic medicine indicated for the treatment of acute and chronic schizophrenic disorders.

65. In December the CPSEAG considered medicines indicated for:
- use in the treatment of opioid addiction
 - the treatment of patients with locally advanced, non-metastatic prostate cancer and for the treatment of metastatic prostate cancer
 - weight loss in adults
 - contraception.
66. In addition, and because of European deadlines Members were consulted and provided written comments. In August the CPSEAG considered a medicine indicated for patients unable to undergo adequate exercise stress. In November the EAG considered:
- A medicine to control blood pressure in patients with hypertension
 - A medicine for the treatment of allergic rhinoconjunctivitis and urticaria
 - A thyroid hormone medicine intended for replacement therapy in patients with hypothyroidism.

- Clinical Trials (CTEAG)**
67. The CTEAG met twice, in April and June, and provided advice by correspondence in September.
68. In April, they considered and advised on a lentiviral vector to be used in the treatment of Wiskott-Aldrich syndrome, and a gammaretroviral vector to be used in the treatment of X-linked severe combined immunodeficiency.
69. In June, they considered and advised on an application related to the development of a therapy in which haploidentical donor T cells are genetically modified with a suicide gene mechanism. They also met representatives of the applicants in respect of the lentiviral vector and the gammaretroviral vector discussed in April.
70. In September, they considered and advised on responses to questions on the T cell suicide gene therapy that had been considered at the June meeting, and a CD80 antagonist indicated for rheumatoid arthritis that had been considered in 2008.
- Dermatology (DEAG)**
71. The DEAG did not meet during 2009 but members were consulted on issues, European and national, by written procedures where timelines precluded a meeting.
72. Following a review by the Commission the DEAG merged to form the Dermatology, Rheumatology, Gastroenterology and Immunology EAG.
- Gastrointestinal and Hepatology (GHEAG)**
73. The GHEAG did not meet during 2009 but members were consulted on issues, European and national, by written procedures where timelines precluded a meeting.
74. Following a review by the Commission the GHEAG merged to form Dermatology, Rheumatology, Gastroenterology and Immunology EAG and also, Anti-Infectives, HIV/ AIDS and Hepatology EAG.
- Medicines for Women's Health (MWHEAG)**
75. The MWHEAG met three times during 2009. At its meeting in January, the EAG considered the risks and benefits of Danazol and Gestrinone and concluded that the overall benefit: risk for these products was positive for their licensed indications.
76. The MWHEAG considered the risk of breast cancer with depot medroxyprogesterone acetate. The EAG concluded that the view on the small risk of breast cancer with this product had not changed since this was last reviewed by Committee on Safety of Medicines in 1996, but that the information provided in the product information could be presented in a more concise manner.
77. The MWHEAG also considered and advised on an application to extend the indications of a medicine licensed for combined hormonal oral contraception to include Treatment of Premenstrual Dysphoric Disorder (PMDD).
78. At its meeting in April, the MWHEAG considered and advised on an application for a low strength locally applied oestrogen product for the treatment of vaginal atrophy in post-menopausal women. It also considered and advised on an application for a product for the treatment of endometriosis. The EAG received an up-date on the status of the revisions to the Core SPC for

HRT products and was informed that a new product had been approved for emergency contraception.

79. At its meeting in July, the MWHEAG considered and advised on an application for a monoclonal antibody for the treatment of osteoporosis in post-menopausal women and in association with hormone-ablating oncology treatments.
80. The MWHEAG additionally considered the risk of fractures with depot medroxyprogesterone acetate. The EAG concluded that the view on the small increased risk of fractures with this product had not changed since this was last reviewed by the Committee on Safety of Medicines in 2004 but that the information provided in the product information should be updated to reflect the latest data.
81. The MWHEAG also received an update on the status of an application to extend the indications of a product licensed for combined hormonal oral contraception to include Treatment of Premenstrual Dysphoric Disorder (PMDD) and was informed of a review of the risk of venous thromboembolism (VTE) in women who switch hormonal contraception.
- Neurology and Pain Management (NPMEAG)**
82. The NPMEAG met twice in 2009. In June, the EAG considered and advised on a new medicine indicated for the symptomatic relief of spasticity in patients with multiple sclerosis.
83. In December, former members of the NPMEAG met again in an ad-hoc capacity. They considered and advised on the same drug from the June meeting.
84. Following a review by the Commission, the NPMEAG merged with the Psychiatry and Old Age Psychiatry EAG to form the Neurology, Pain and Psychiatry EAG (NPPEAG).
- Oncology and Haematology (OHEAG)**
85. The OHEAG met once in 2009 and considered a variation application via teleconference once during 2009.
86. At its meeting in September, the OHEAG considered and advised on a medicine indicated for the initiation of hormonal castration in advanced or metastasising hormone-dependent prostate carcinoma when androgen suppression is necessary. The EAG also considered and advised on a medicine indicated for the treatment of Multiple Myeloma, non-Hodgkin's lymphoma and Chronic Lymphocytic leukaemia.
87. At its teleconference in October, the OHEAG advised on a variation procedure to extend the indication of a medicine currently indicated for the treatment of breast cancer to treat cancers of the stomach.
- Paediatric Medicines (PMEAG)**
88. The PMEAG has continued to play a key role in advising the Commission for Human Medicines (CHM) and the Licensing Authority on the safety, quality and efficacy of medicines for paediatric use and other aspects of UK strategy to improve the number of authorised medicines available for children.
89. Since the implementation of the EU Paediatric Regulation (1901/2006/EC) when the PMEAG membership was strengthened, it

has met on an almost monthly basis with the following mandate:

To advise the Commission on Human Medicines on the safety, quality and efficacy of medicines for paediatric use, including all matters relating to the implementation of the EU Paediatric Regulation.

90. This is the second annual report for the PMEAG under its new remit and highlights its contribution to improving the availability and standard of medicines for children within the context of the European Paediatric Regulation and UK initiatives to ensure the health of children in the UK. The report covers the period January to December 2009. During this time, the EAG met on ten occasions and one meeting was replaced by a written procedure.
91. The PMEAG was reappointed in November 2009. PMEAG expressed its thanks for the contribution of those members who had stepped down and was pleased to welcome a number of new members to the EAG.

Background: Progress with the European Paediatric Regulation

92. It is now three years since the Paediatric Regulation came into force (January 2007). Many of the new procedures introduced to encourage development of medicines for use in children have become established, although there remain challenges as we strive for a common understanding between all stakeholders on appropriate research and development of medicines in children. The expertise provided by the PMEAG has made a significant contribution to developing the UK position and hence influencing European thinking in this area.
93. The most significant aspect of the Regulation has been the introduction of the obligation to comply with an agreed paediatric investigation plans (PIPs) for new medicinal products and those in patent undergoing certain types of further development. Up to December 2009, the European Medicines Agency (EMA) had received over 470 valid applications for PIPs and a further 150 or so applications for full waiver. The number of submissions has been similar for 2008 and 2009 (about 270 in total each year) and covers 20 therapeutic areas with endocrinology (including gynaecology, fertility and metabolism), cardiovascular disease and oncology being the top three therapeutic categories. Overall, 61% of applications are for new medicinal products, 31% for extensions to indication, pharmaceutical form or route of administration and only 3% for off-patent drug substances intended for a paediatric use marketing authorisation (PUMA). UK representatives have acted as Rapporteur or Peer Reviewer for about 10% of PIP submissions.
94. The number of opinions on initial PIP applications and waivers delivered by the European Paediatric Committee (PDCO) has increased this year to over 200 compared to about 130 in 2008. This rise is to be expected as procedures initiated when the Regulation was implemented come through to completion. It is also worth noting the increase in the number of requests for modification of a PIP from 8 last year to 59 in 2009. Analysis of the reasons that PIPs need to be modified will provide useful

information for industry and regulators alike for improving the quality of submissions and their assessment.

95. The rewards offered by the Regulation are critical to its success, as they provide incentives to the pharmaceutical industry which balance the obligations for paediatric development. It is therefore worth noting that this year, the first two products to receive benefits for conducting paediatric studies have been awarded 6 month extension of supplementary patent protection: Cozaar (losartan, an angiotensin II receptor antagonist) and the anti-fungal Cancidas (caspofungin). Furthermore, PDCO has given 14 opinions in 2009 on whether the studies conducted have complied with a PIP compared to 5 last year indicating that the number PIPs being completed is on the increase with the promise of more applications for marketing authorisations being supported by paediatric studies in the future.
96. The Regulation provides for assessment both of older paediatric studies not previously submitted to regulatory authorities (Article 45) and newer studies as they are completed (Article 46). These procedures are being coordinated at European level through CMDh and are taking place in quarterly waves each with about 20 active substances. Responsibility for assessment is being distributed throughout the different member states on a work-sharing basis. Licences for all products (brand-leader and generic) containing the active substances are being updated to comply with the recommendations of these work-sharing procedures. UK has played a significant part by acting as Rapporteur for one-sixth of the assessments so far.
97. PMEAG continues to advise on Marketing Authorisation applications and other regulatory submissions accompanied by paediatric data in addition to its work to support the Paediatric Regulation.

Review of the PMEAG contribution in 2009

Paediatric Investigation Plans

98. PMEAG has advised on all the PIPs where UK is Rapporteur or Peer Reviewer and on selected cases where the UK comments on the PIP summary report only. The table below summarises the number of applications discussed by the EAG.

| PIPs | Sep-Dec 2007 | Jan-Dec 2008 | Jan-Dec 2009 |
|------------------|--------------|--------------|--------------|
| UK rapporteur | 7 | 11 | 13 |
| UK peer reviewer | 4 | 9 | 3 |
| UK comments only | 13 | 28 | 5 |
| Total | 24 | 48 | 21 |

99. The therapeutic areas encompassed by these PIPs include medicines in the areas of psychiatry, urinary disorders and kidney disease, and bone conditions amongst others.

100. The number of PIPs where UK submits comments only has decreased this year due to the re-allocation of resource within the secretariat to the assessment of paediatric work-sharing procedures (see below). However, in a number of these cases expert advice has been sought either from individual members of the EAG or other external experts where it has been known that there would be a particular interest in the paediatric development of the product in the UK.
101. The UK makes a strong contribution to decisions on the development of paediatric medicines at European level. It provides delegates to the PDCO and its sub-groups and UK has been able to put forward names of experts to assist PDCO in its decision-making in clinical, non-clinical and quality areas. The contribution of the PM EAG has been recognised and a number of staff from the paediatric unit at the EMA has been welcomed as observers at EAG meetings in 2009.

Advice on work-sharing procedures

102. The first report where UK was Rapporteur for the assessment of studies submitted under Article 45 of the Paediatric Regulation was considered by the EAG at its second January meeting. During the course of 2009, the EAG was presented with 12 papers for products containing 10 active substances being assessed under work-sharing procedures. One concerned studies submitted under Article 46 while the rest were Article 45 procedures. The UK was Rapporteur for all procedures except one where UK was acting as co-rapporteur for a parallel indication. The products covered a range of therapeutic areas including pain control, psychiatry and musculoskeletal disorders.

Advice related to marketing authorisation applications supported by paediatric data

New medicinal products

103. In 2009, the PMEAG considered applications for new strengths of a combination product containing a steroid and beta₂-agonist suitable for treating asthma in children aged 6 years and over. Higher strength products for the treatment of adolescents are already available. It further advised on the dose of a combination product intended for the symptomatic relief of symptoms associated with the common cold. PMEAG also provided further advice on a new strength of an inhaled corticosteroid for the treatment of persistent asthma, and new solution formulations of an ACE inhibitor and a beta-blocker for the treatment of cardiovascular diseases.

Extensions to use

104. PMEAG also advised on five applications to extend the use of existing products into new paediatric populations. One concerned the addition of children aged 4 and above to the authorisation for an inhaled steroid already used for the treatment of asthma in adolescents. Four applications were for extension from adults to children: a histamine antagonist for the treatment of gastro-oesophageal reflux disease, a paramagnetic imaging agent and an aromatase inhibitor to treat short stature. The last was supported by studies completed according to a PIP and had been submitted under Article 29 of the Paediatric Regulation, whereby approval is obtained in all European member states through a CHMP opinion. UK was acting as Rapporteur.

Other advice related to the use of medicines in the paediatric population

- Therapeutic reviews** 105. The PMEAG provided advice on communication of the risk:benefit of cough and cold remedies in children and a product for the treatment of pain associated with infant teething, mouth ulcers or orthodontic devices. It also considered paediatric use of a medicine for the short-term relief of insomnia and long-acting beta-agonists for the treatment of asthma in children under 12 years of age.
- Drug safety** 106. The PMEAG advised on a medicine for the treatment of post operative nausea and vomiting and on follow-up measures for a product for the treatment of children and adolescents aged 8 years and above suffering from moderate to severe major depressive episodes.
- Regulatory guidance** 107. The PMEAG commented on the value of a European guideline on the investigation of medicinal products in the term and pre-term neonate and received a presentation on new requirements to improve the readability of patient information leaflets.

Renewed UK strategy

108. The PMEAG discussed proposals to renew the UK strategy to provide better medicines for children in the context of the Paediatric Regulation. The successes of the 2004 strategy were also reviewed. A number of areas were identified where further initiatives could improve availability and confidence in the use of medicines in the paediatric population. These will be taken forward for public consultation as the next step.

Conclusion

109. As in previous years, the PMEAG has considered and advised on a wide range of matters relating to the development of paediatric medicines throughout their lifecycle and their clinical use. It continues to support the aims and objectives of the new European Paediatric Regulation by advising on paediatric investigation plans and assessment of paediatric studies submitted through European work-sharing procedures. The EAG has supported the overall UK strategy to provide more medicines properly authorised for children and has looked forward at activities which could build on this progress in the future.
- Patient Information (PIEAG)** 110. The PIEAG met twice in 2009 to advise the Agency on improving the quality of patient information leaflets (PILs) and implementation of recommendations set out in the CSM Patient Information Working Group report, *Always read the leaflet*. The EAG continued to advise on the implementation of European legislation concerning information to patients.
111. The PIEAG welcomed the legal proposal to permit the pharmaceutical industry to provide information on prescription-only medicines to patients which was broadly in line with the UK position.
112. The PIEAG advised on improving comprehensibility of medicines information including the development of lay summaries of risk management plans, signposting to other sources of information

in PILs, and work to review patient information for medicines that may be the subject of misuse or abuse.

113. In relation to risk:benefit, PIEAG members advised on wording of PILs in lay terms for methylphenidate and fentanyl patches where there were particular issues relating to risk benefit. Some members also attended a company meeting on methylphenidate.
114. The PIEAG began work on the development of design guidance for marketing authorisation holders to use when preparing PILs. This ongoing work is led by a working group that includes outside communication and design experts and met twice during the year.
115. The PIEAG endorsed the key elements of a future promotional campaign on recommendations in *Always read the leaflet* which will:
- raise awareness that PILs have changed
 - increase the profile of PILs as a key tool in the safe and effective use of medicines
 - increase use of the PIL as a reference document
 - increase use of the PIL to facilitate dialogue between medicines takers and healthcare professionals.
116. The PIEAG advised on recommendations for future activities to strengthen patient reporting of suspected adverse drug reactions (ADRs) via the Yellow Card Scheme. These focussed around the four key areas of education, promotion, facilitation and motivation. The need for continued and sustained promotional activities to maintain ADR reporting levels was recognised.

Pharmacovigilance (PEAG)

117. The PEAG met on ten occasions during 2009 and considered papers on drug safety issues including:
- gadolinium containing contrast agents and the risk of nephrogenic systemic fibrosis (NSF)
 - the Sibutramine Cardiovascular OUTcome (SCOUT) study and the implications of the results for the balance of risks and benefits of sibutramine in the treatment of obesity
 - drug interaction between clopidogrel and proton pump inhibitors resulting in reduced efficacy of clopidogrel
 - the balance of risks and benefits of modafinil in the treatment of excessive sleepiness associated with certain medical conditions including narcolepsy
 - varenicline (a medicine used to help people stop smoking) and the risk of fatal and non-fatal self-harm, and the results from a study conducted by the University of Bristol and MHRA using the General Practice Research Database (GPRD)¹
 - a review of the risks and benefits of orciprenaline, a drug used in the treatment of asthma
 - finasteride (for the treatment of prostate gland enlargement and for the prevention of hair loss) and the risk of breast cancer in men

¹ Study was subsequently published in the British Medical Journal (BMJ) Reference **BMJ 2009;339:b4360**

- natalizumab (a treatment for multiple sclerosis) and the risk of progressive multifocal leukoencephalopathy (PML)
- risk of PML and implications for the balance of risks and benefits of efalizumab, a treatment for moderate to severe plaque psoriasis
- SSRI antidepressants and safety in pregnancy, risk of bone fractures, persistent sexual dysfunction, and effects on male fertility
- HPV vaccine (cervical cancer vaccine) and chronic fatigue syndrome
- Warfarin and a review of the product information for healthcare professionals and patients.

118. The PEAG's advice on many of these issues was subsequently communicated to healthcare professionals via the MHRA monthly bulletin, Drug Safety Update. Where major regulatory action or restrictions on use were proposed, advice was also sought from the Commission on Human Medicines.

119. The PEAG also gave its advice on four Risk Management Plans for new medicines and a pregnancy risk management plan for mycophenolate mofetil. The EAG also considered regular updates on the safety of the antiviral medicines used to manage the swine 'flu outbreak – oseltamivir (Tamiflu), zanamivir (Relenza), and the new H1N1 swine 'flu vaccines.

120. The PEAG considered a paper describing prescription trends for analgesics between 2003 and 2008, before, during and after the withdrawal of co-proxamol from the UK market.

121. Experts met as an Ad Hoc Group on Pharmacovigilance in November 2009 while the PEAG membership was in the process of appointment.

Psychiatry and Old Age Psychiatry (POAPEAG)

122. The POAPEAG met three times in 2009.

123. In March, the POAPEAG considered and made recommendations to the Commission on Human Medicines (CHM) on a variation application for a medicine used in the treatment and relapse prevention of Major Depressive Disorder. It also considered and advised on a variation application for a medicine used in the treatment and relapse prevention of General Anxiety Disorder (GAD).

124. In June, the POAPEAG considered and advised on a medicine for the treatment of major depressive disorder in bipolar disorder. It also discussed a paper relating to a medicine indicated for the treatment of Major Depressive Disorder in the framework of bipolar disorder.

125. In September, the POAPEAG considered and advised on a medicine indicated for the treatment of schizophrenia and for the treatment of manic episodes associated with bipolar I disorder. It also considered and advised on variation applications for a medicine indicated for the treatment of Generalised Anxiety Disorder and a medicine indicated for the prevention of recurrence in bipolar disorder.

**Respiratory and Allergy
(RAEAG)**

126. Following a review by the Commission, this POAPEAG merged with the Neurology and Pain Management EAG to form the Neurology, Pain and Psychiatry EAG (NPPEAG).
127. The RAEAG met three times during 2009 and considered one assessment via correspondence during 2009.
128. In January, the RAEAG met to discuss a therapeutic review of long-acting β_2 agonists in chronic obstructive pulmonary disease (COPD) and received oral updates on the safety of over-the-counter cough and cold medicines for children, a stimulant drug used for the symptomatic relief of excessive daytime sleepiness associated with narcolepsy and its relevance to obstructive sleep apnoea, and an adverse event possibly associated with a glucocorticosteroid.
129. The April meeting was conducted via teleconference. The RAEAG discussed a therapeutic review of long-acting β_2 agonist use in children with asthma less than 12 years of age.
130. In July, the RAEAG discussed a safety review of a product indicated for reversible airway obstruction and a closely related derivative indicated for the treatment of acute severe asthma or acute exacerbation of severe asthma, applications for Marketing Authorisations for an inhaled glucocorticosteroid in two strengths to be used in the prophylactic management of asthma, an application for a Marketing Authorisation for a long-acting β_2 agonist indicated for use in the treatment of asthma in adults and children and adolescents aged 12 years and above, the reformulation of a product indicated for the treatment of Influenza A and B, and information on an NHS Direct study of a product indicated for the treatment of asthma.
131. In addition, and because of European deadlines Members were consulted and provided written comments. In October, the RAEAG provided written advice on an assessment concerning fatal adverse events that occurred during clinical trials of a long-acting muscarinic receptor antagonist indicated for the relief of symptoms in patients with COPD.
132. Following a review by the Commission, this RAEAG merged with the Cardiovascular, Diabetes & Renal EAG to form the Cardiovascular, Diabetes, Renal, Respiratory and Allergy EAG (CDRRAEAG).

**Rheumatology and
Immunology (RIEAG)**

133. The RIEAG did not meet during 2009 but members were consulted on issues, European and national, by the written procedures where timelines precluded a meeting.
134. Following a review by the Commission the RIEAG merged to form the Dermatology, Rheumatology, Gastroenterology and Immunology EAG.

AD HOC AND WORKING GROUPS**Pharmacy supply of
pseudoephedrine/ ephedrine
Ad Hoc Group**

135. The Commissions' Working Group on pseudoephedrine (PSE)/ ephedrine (EPH) was set up in September 2007 to advise the Commission on the implementation of measures that should be put in place to minimise misuse of OTC medicines containing PSE or EPH in the illicit manufacture of the Class A drug

methylamphetamine, a highly addictive, potent stimulant which affects the central nervous system and can cause serious physical and psychological harm. The Commission advice in July 2007 was that products containing pseudoephedrine and EPH should be reclassified to prescription only in 24 months' time (July 2009) (subject to the legal criteria for POM control being met) unless the risk of misuse of these OTC medicines in the illicit manufacture of methylamphetamine is contained; or at any time before then should evidence emerge that misuse has not been contained.

136. The Working Group met once during the year. From 1 April 2008, the legislation to restrict the sale of pseudoephedrine to maximum of 720mg and ephedrine to no more than 180mg per transaction had been implemented. The Working Group reviewed the effectiveness and impact of the tighter pharmacy controls and other measures put in place to minimise the misuse of OTC medicines containing PSE or EPH in the manufacture of methylamphetamine and presented its report to the Commission in July 2009.
137. From the available evidence, the Commission considered that the measures implemented were helping to contain the potential problem of misuse and that there had been a reduction in sales.
138. In light of this evidence, the Commission agreed with the Group's recommendation that medicines containing PSE or EPH may continue to be sold as pharmacy medicines, provided the measures put in place to contain their misuse continue to be adequate. The Commission also recommended that the present levels of monitoring, education and awareness by pharmacists should be maintained and that liaison with stakeholders such as the Home Office, the Association of Chief Police Officers (ACPO) and the Serious Organised Crime Agency (SOCA) should continue. The Working Group should be reconstituted to review the situation as necessary and in any case on a yearly basis.

Bioequivalence Ad Hoc Group

139. The Bioequivalence Ad Hoc Group met twice during 2009.
140. In July, the Group considered the current European situation regarding data requirements for biowaivers for generic micelle products, and advised on an ACE inhibitor, in oral solution form, for use in children and the elderly who may have difficulty in swallowing tablets, and a Beta blocker, in oral solution form, for use in children. Both products had been referred from the Commission on Human Medicines.
141. In September, the Group considered and advised on: two strengths of a bisphosphonate product, one indicated for the prevention of skeletal events, and the other for the treatment of osteoporosis in postmenopausal women; an immunosuppressive agent indicated, in combination with ciclosporin and corticosteroids, for the prophylaxis of acute transplant rejection in patients receiving allogenic renal, cardiac or hepatic transplants; an Alph-1-adrenoceptor antagonist indicated in the treatment of functional symptoms of benign prostatic hyperplasia. The Group also considered and advised on variations to the licences on a group of products containing a combination of thiazides and potassium.

Mixing of Medicines Working Group

142. In 2008 the MHRA issued a statement saying that in certain circumstances the mixing of medicines prior to administration did not comply with medicines legislation and that this had the potential to impact adversely on palliative care services. The Agency recognised that palliative care required special consideration and that they intended to seek provisional advice from the Commission on Human Medicines on possible options for changes to medicines legislation in advance of the usual public consultation procedures required under the Medicines Act 1968.
143. In the meantime the MHRA stated that any cases would be considered individually. It would not consider taking enforcement action for breaches of medicines legislation by a Nurse or Pharmacist Independent Prescriber engaging in the long standing accepted practice of prescribing and administering (and providing directions to others to administer) a mixture of licensed medication via a single injection or a syringe driver unless it would be in the public interest to do so. That statement also applied to those mixing and administering medicines in accordance with the directions of the prescriber.
144. The proposed consultation, issued formally in December 2008, suggested four possible options, namely: "Do nothing", amend the definition of "manufacture" in the Medicines Act, develop a statutory formulary for "mixing" in palliative care or enable Nurse and Pharmacist Independent Prescribers to specially prepare products for their individual patients and enabling nurses/pharmacists who were not prescribers to mix those medicines prior to administration. The Commission's preliminary view had been that the last of these options was most favourable. However, they wished to consider the matter in more detail in parallel with the public consultation and set up a Working Group to receive advice from external experts and to review the replies to the consultation.
145. The Mixing of Medicines Working Group completed its work in April 2009. Although the Group began by considering the mixing of medicines for the purpose of administration in palliative care, it soon became obvious that there were many other clinical areas where such mixing also took place. The Working Group therefore recommended to the CHM that their preliminary view be expanded, for the purpose of mixing medicines for the purpose of administration to an individual patient, to enable:
- doctors and dentists to direct others (in addition to a pharmacist under existing legislative provisions or a person holding a manufacturer's licence) to mix medicines
 - nurse and pharmacist independent prescribers and supplementary prescribers (the last subject to the Clinical Management Plan) to mix medicines themselves and to also be able to direct others to mix (in addition to a pharmacist under existing legislative provisions or a person holding a manufacturer's licence).
146. The Working Group was aware that a number of the medicines used in palliative care and, for example, critical care were controlled drugs and subject to additional regulatory requirement by the Home Office. The Group therefore sought the Commission's recommendation that the MHRA should

approach the Advisory Council on the Misuse of Drugs to support corresponding amendments to the Misuse of Drugs Regulations. The Working Group also recommended, as a logical consequence of their considerations, that Nurse and Pharmacist Independent Prescribers should be able to prescribe unlicensed medicines for their patients on the same basis as doctors, dentists and supplementary prescribers.

147. The Commission accepted in full the recommendations of the Working Group and also supported the development of guidance on the prescribing and administration of those medicines intended to be mixed. The Commission also supported the availability of objective evidence to guide practitioners on issues such as compatibility and stability of combinations of medicines.

148. Following Ministerial support for the Commission on Human Medicines' recommendations, the relevant changes were made to medicines legislation and came into force in December 2009. In the same month, the Technical Committee of the Advisory Council on the Misuse of Drugs accepted the recommendations of the Commission in respect of controlled drugs.

Working Group on Harm Reduction and Nicotine Replacement Therapy (NRT)

149. The Working Group on Harm Reduction and Nicotine Replacement Therapy met once, in October, during 2009. The Group considered an application for a harm reduction indication for a nicotine based inhalator product, including use in pregnancy, and examining the evidence of safety and efficacy. They also considered:

- the health benefits of cutting down, as opposed to the complete cessation, of smoking
- whether indications including harm reduction are appropriate for other forms of NRT
- changes in product information that would maximize the benefits and minimise the risks of NRT in relation to active and passive smoking
- communication of relevant information to health care professionals and the general public
- innovative NRT products with new formulations and delivery systems.

Working Group on Pharmacy supply Usage Modelling and Antibiotic Resistance (PUMAR)

150. The Group met twice during 2009. In January, the Group discussed: Usage modelling of products containing either, of both of, two bacteriostatic antibiotics mainly used in the prophylaxis and treatment of urinary tract infections; piloting pharmacy supply of the same products for acute uncomplicated cystitis; the surveillance requirements for such a study.

151. In March, the Group discussed: Updated Terms of Reference for the group; the usage of a bacteriostatic antimicrobial for use in the treatment of eye infections; the advertising of Pharmacy products to the public; the potential misuse of a bacteriostatic antibiotic in veterinary medicine. Finally, the Group reviewed the provisional report on its work, to go to the Commission on Human Medicines, and provided comments for incorporation into the final report.

RECLASSIFICATION OF MEDICINES

152. The Commission considered a number of applications for change of legal status including the results of consultation on the POM to P reclassification of tamsulosin. The CHM advised in favour of reclassification of tamsulosin from POM to P, the first pharmacy product aimed specifically at men for the symptoms of benign prostatic hyperplasia. The Commission also considered an application for the proposed reclassification from POM to P of a Non-Steroidal Anti-Inflammatory Drug, for the treatment of non-serious arthritic conditions.
153. The Commission considered the report of the Working Group on Pharmacy supply Usage Modelling and Antibiotic Resistance (PUMAR). This Working Group had been established to advise on the modelling of the likely usage of two antibiotics if they were to be reclassified as Pharmacy medicines, and on the possibility of an increase in antibiotic resistance as a consequence. This followed the wide range of responses to the proposed reclassification of these antibiotics.

Table 1: Summary of products in new therapeutic areas considered for reclassification by CHM during 2009

POM to P

| Product | Substance | Indication |
|---------------|----------------|--|
| Flomax Relief | Tamsulosin | Benign prostatic hyperplasia (BPH) |
| Cystobid | Nitrofurantoin | Acute uncomplicated cystitis in women aged 16-70 years |
| Cysticlear | Trimethoprim | Acute uncomplicated cystitis in women aged 16-70 years |

Orciprenaline

154. The Commission, its Respiratory and Allergy Expert Advisory Group, and its Pharmacovigilance Expert Advisory Group advised on the benefit-risk of orciprenaline, a non-selective beta-agonist approved for the treatment of reversible airways disease. An analysis of the available literature demonstrated that orciprenaline was significantly less efficacious than salbutamol in terms of both the extent and duration of bronchodilation. Yellow Card reports and clinical trial data showed a significantly increased incidence of cardiac side effects, mainly palpitations and tachycardia. Importantly, clinical trial data showed that cardiac side effects occur before maximum bronchodilation is achieved because of its non-selective action. Accordingly, the Commission advised that the balance of benefits and risks for orciprenaline was no longer favourable and concluded that there should be a planned withdrawal of orciprenaline from the UK market. There were no patient groups for whom transfer to a more-selective β_2 -agonist would be inappropriate. This advice was communicated to healthcare professionals in the November 2009 edition of Drug Safety Update. The Marketing Authorisation holder for orciprenaline has agreed to a voluntary withdrawal from the UK market, which should be complete by the end of September 2010.

- Warfarin**
155. The Pharmacovigilance Expert Advisory Group advised on a review and updates to the core safety information in the warfarin SPC. The warfarin SPC was revised in line with current practice, published literature, and Yellow Card data to give clearer and up-to-date advice to healthcare professionals in relation to timing of warfarin treatment after ischaemic stroke, management of the patient prior to surgical or dental procedures, advice on those patients at particular risk of haemorrhage, interactions with herbal products, foods and food supplements and management of the patient with significantly raised INR and/or haemorrhage. The review was communicated in the December 2009 Drug Safety Update and the updated warfarin core safety information, along with further information on the review, featured in a public assessment report on the MHRA website. In particular, healthcare professionals were advised to focus on the contraindications to warfarin therapy, the relevant warnings, and the clinically significant drug interactions.

REPORTING OF ADVERSE DRUG REACTIONS

156. Suspected adverse drug reactions (ADRs) to medicinal products and vaccines are reported to the Commission and the Medicines and Healthcare products Regulatory Agency (MHRA) on a voluntary basis by healthcare professionals, coroners and, as of January 2005 by patients through the Yellow Card Scheme. Reports are also submitted as a legal requirement by pharmaceutical companies holding MAs. Information collected through the Scheme is a vitally important means of monitoring drug safety in clinical practice, acting as an early warning system for the identification of previously unrecognised adverse reactions and increasing knowledge of known adverse drug reactions.
157. Reporting trends in 2009 remain positive with an increased volume of Yellow Card reports submitted, demonstrated by a rise of 2% on the previous year. Patient reporting is now an established part of the Scheme, with 12% of reports coming from patients. The overall proportion of serious reports remains high at 82%. In 2009, there was an increase in the number of ADR reports received from nurses, hospital nurses, pharmacists (speciality not specified), and patients.
158. Importantly, 2009 has shown a capability to respond rapidly to increased reporting associated with changing use of medicines and vaccines, such as immunisation campaigns with HPV and influenza vaccines and wide scale use of antiviral medicines during the flu pandemic. For the 2009 swine flu pandemic, the MHRA with advice from the Commission put in place a proactive risk management strategy to identify any new risks associated with the antivirals and vaccines. This included a dedicated on-line ADR reporting Portal, a new statistical approach to analyse reporting rates of certain ADRs against expected background rates and a weekly public assessment report of the emerging data. The experience with the antivirals has confirmed their known safety profile and no new risks were identified. For the novel swine flu vaccines, the safety experience has been broadly in line with established seasonal flu vaccines, albeit with the expected higher frequencies of injection-site reactions and rates of fever in young children. No serious new risks have been identified with the vaccines.

159. The Commission and the MHRA continue to monitor intensively products carrying a black triangle ▼. Healthcare professionals are asked to report all suspected adverse drug reactions for these products as opposed to focusing only on serious reactions for established products. In 2009, 353 products were on the list for intensive monitoring, 36 were removed from the list during the course of the period, and 151 products were added. A list of medicines under intensive monitoring is regularly updated on the MHRA's website: (<http://www.mhra.gov.uk/blacktriangle>) and is also available by post on request.
160. In selecting products for intensive monitoring, the following criteria have generally been applied:
- (i) new active substance
 - (ii) new combination of active substances
 - (iii) administration via a new route, which is significantly different from existing routes
 - (iv) novel drug delivery system
 - (v) significant new indication, where this is likely to result in a significantly different population being exposed to the drug, or where there are potential safety concerns associated with the new indication.
161. Signals of new and changing drug safety hazards are detected and generated in a timely manner. Changes in the frequency of ADRs already known to be associated with drugs are also closely monitored through the signal detection process.

Table 1 lists the number of Yellow Card reports received from healthcare professionals and patients in the period 1 January 2004 to 31 December 2009.

Table 2 provides details on the speciality of the reporters for reports received in 2009 with 2008 figures included for comparison.

Table 1: Reports of suspected adverse reactions

| Year | No. of registered Reports during period |
|--------------------|---|
| 2004 | 19,969 |
| 2005 | 21,878 |
| 2006 | 21,955 |
| 2007 | 21,752 |
| 2008 | 25,931 |
| 2009 ^{2*} | 26,549 |

* Of the total number of UK spontaneous suspected ADR reports received in 2009, 41% of reports were received via Industry, 47% directly from healthcare professionals, and 12% from patients.

² We are aware of an issue affecting delivery of Yellow Cards through the Royal Mail service which resulted in up to 2,000 reports being "returned to sender". The reporting figures given are for reports actually received. Yellow Cards that are received late as a result of the Royal Mail issue will be recorded against the period they are received in future reports.

Table 2: Speciality of reporter for reports received in 2009 (2008 figures are given in brackets)

| Type of reporter | No. during period | Percentage of all reports |
|--|------------------------|---------------------------|
| Community pharmacist | 453 (608) | 1.6 (2.2) |
| General practitioner | 3371 (4254) | 12.3 (13.9) |
| Hospital doctor | 2282 (2592) | 8.3 (9.5) |
| Hospital health professional | 772 (1000) | 2.8 (3.7) |
| Hospital Nurse | 792 (705) | 2.9 (2.7) |
| Hospital pharmacist | 1118 (1378) | 4.1 (5.0) |
| Literature | 483 (1153) | 1.8 (4.2) |
| Nurse | 3164 (2566) | 11.5 (9.4) |
| Other health professionals [‡] | 4513 (4608) | 16.4 (16.9) |
| Patients and other non-health professionals [†] | 4872 (3911) | 17.7 (14.3) |
| Pharmacist (speciality not specified) | 1769 (1332) | 6.4 (4.9) |
| Physician | 3882 (3631) | 14.1 (9.9) |
| | 27471 (27314)** | |

‡ Other health professionals include: dentists, optometrists, coroners, other non-specified health professionals.

† Patients and non-health professionals include: patients and lawyers.

** An individual report may have multiple reporter sources therefore total numbers of cases cannot be derived from this table. For this information, please refer to Table 1.

162. The Yellow Card strategy was defined in the Yellow Card review in 2004 and set out the aim to strengthen the Yellow Card Scheme through four areas:

- Education – of reporters about the importance of Yellow Card reporting
- Motivation – to understand the motivation of reporters and of the need to develop and maintain promotion and communication strategies for the scheme
- Facilitation – to increase access to the scheme to meet the needs of reporters e.g. through developing electronic reporting
- Promotion – through approaches to incentivise reporting through acknowledgment and feedback.

163. A review of trends in ADR data was completed to understand where efforts to improve reporting were needed. The Commission

supported the conclusions of this review highlighting where activities would be focused in 2009/10. These include facilitating reporting through further improvements to NHS IT systems to allow electronic reporting, engaging with pharmacists to further strengthen the role of pharmacy in the Yellow Card Scheme, educating reporters about the Scheme through the Agency's Outreach and Professional Education Unit and the YCCs, communicating the findings of this analysis to further promote the Scheme and educate and motivate reporters, bringing further improvements to MHRA's existing query and analysis tools to allow for further trend analysis.

164. One of the key areas for strengthening the scheme is through increasing electronic reporting through increased use of the electronic Yellow Card and facilitating reporting through development of new electronic reporting systems.

Patient reporting

165. Since the launch of the new online Yellow Card reporting system in February 2008 the proportion of electronic ADR reports has risen steadily. In 2009, the MHRA received 3,258 suspected ADR reports from patients showing a 97% percentage increase in the numbers of patient reports received when compared to numbers received in 2007. In 2009, over 80% of patient reports were electronic reports.

166. Significant efforts to increase patient awareness and facilitating involvement through promotion of the scheme have been made through a marketing campaign.

167. This aimed to increase awareness and engage through increasing links from patient groups and charities and made use of a TV advert for display in GP surgeries, poster campaign, and nationwide leaflet distribution. It is also planned for information on the Yellow Card Scheme to be translated into a number of foreign languages to increase accessibility.

Pharmacy reporting

168. Pharmacists are recognised as a key reporter group and a strategy for improving engagement with pharmacy is being developed through work with the Department of Health, the Royal Pharmaceutical Society of Great Britain (RPSGB) and pharmacy networks. The aim is to build on the Department of Health's White Paper on improving pharmacy in the UK which includes a number of areas on supporting pharmacovigilance.

Yellow Card Centres

169. The Yellow Card Scheme covers the entire United Kingdom, however to boost reporting in regional areas, five Yellow Card Centres (YCCs) operate across the UK. The YCCs undertake valuable work relating to a number of areas including academic research, promotion and education of health professionals on ADR reporting through the Yellow Card Scheme and communicating drug safety messages. The YCCs also have a role providing advice to the MHRA on areas such as on obtaining follow-up information from reporters.

170. Expertise in the YCCs in engaging with health professionals and through working with the Outreach and Professional Education Unit, we are directing efforts to getting information on ADR reporting into professional training syllabuses. To promote the importance of the Yellow Card Scheme and again to increase

awareness, information on the Yellow Cards Scheme has been communicated and published through posters and oral presentations given at a range of external meetings.

171. The Commission is grateful for the co-operation of those healthcare professionals and patients who submit reports of suspected ADRs and encourages the reporting of all suspected reactions to newly introduced drugs, as well as serious suspected reactions to established medicines and vaccines.

MEMBERSHIP OF THE COMMISSION ON HUMAN MEDICINES (CHM)

Chair

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Lay representative

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Professor Ian V D Weller² (Co Vice-Chairman) MD FRCP
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Professor of Toxicology, Toxicology Unit, The Medical School and Institute for Research in Environment & Sustainability, University of Newcastle-upon-Tyne

¹ Re-appointed October 2009

² Re-appointed November 2009

³ End of appointment October 2009

⁴ Appointed November 2009

Invited Experts to Commission Meetings

Mrs Alison Bowser

Independent lay representative; Royal College of GPs, Cornwall and Isles of Scilly PCT, NICE medicines concordance guidelines development group; Member of Pseudoephedrine Working Group, Dermatology EAG, Paediatric Medicines EAG, Patient Information EAG, Pharmacovigilance EAG, Lay Members Forum, PUMAR, Mixing Group (Attended January, February, March, April, May, June, July)

Professor David Gawkrödger MB ChB MRCP MD FRCP

Professor of Dermatology, University of Sheffield; Member of the Dermatology Expert Advisory Group (Attended February)

Professor Chris O'Callaghan MD FRCP FRCPCH

Consultant Respiratory Paediatrician, University of Leicester and Leicester Royal Infirmary & Children's Hospital, Leicester (Attended March)

Professor Robert I Lechler MB ChB PhD FRCP FRCPATH FMedSci
Vice Principal (Health), King's College London; Member of Clinical Trials EAG (Attended April, June)

Mr Asif Muneer BSc MD FRCS (Urol)
Consultant Urological Surgeon, University College London Hospital; Senior Fellow in Urology, University College London Hospital (Attended May)

Mr Andy Murdock
Pharmacy Relations and Governance Director, Lloyds Pharmacy Ltd (Attended May)

Professor Ian Rennie MB ChB FRCS(Ed) FRCOphth
Head of Academic Ophthalmology & Orthotics Unit, University of Sheffield; Honorary Consultant Ophthalmic Surgeon, Royal Hallamshire Hospital (Attended May)

Professor Rosalind Smyth MA MBBS MD FRCPCH FMedSci
Brough Professor of Paediatric Medicine; Head of School of Reproductive and Developmental Medicine, University of Liverpool; Chair, Paediatric Medicines Expert Advisory Group (Attended June)

Emeritus Professor Edward Gordon Smith MSc FRCPATH FRCP FRCPE FMedSci
Professor of Haematology, St George's Hospital, University of London; Member of Oncology & Haematology EAG (Attended June)

EXPERT ADVISORY GROUPS**MEMBERSHIP OF THE ANTI-INFECTIVE/ HIV & AIDS EXPERT ADVISORY GROUP
(1 January - 31 October 2009)****Remit**

To advise the Commission on the safety and efficacy of medicines for use in anti-infectives, HIV and AIDs.

Chair**Dr Barbara Bannister** MSc FRCP

Consultant in Infectious and Tropical Diseases, Royal Free Hospital, London

Members**Professor George Kinghorn** MB ChB MD FRCP

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Consultant and Lead Clinician in the Clinical Infectious Diseases Unit, Great Ormond Street Hospital

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Dr Ross Taylor MB ChB MD FRCP (Edin) FRCGP DCH

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Professor Ian V D Weller MD FRCP

Professor of Sexually Transmitted Diseases, University College London Medical School

MEMBERSHIP OF THE BIOLOGICALS AND VACCINES EXPERT ADVISORY GROUP

Remit

To advise the Commission established under Section 2 of the Medicines Act on the quality, safety and efficacy of medicinal products of biological or biotechnological origin including vaccines which are the subject of marketing authorisation applications; and to advise on such other matters as are referred to it.

Chair

Dr Angela E Thomas¹ MB BS PhD FRCPE FRCPATH FRCPCH
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Members

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Professor of Biotechnology, Westminster University

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Professor Andrew Hall¹ MBBS MSc PhD FRCP FFFPHM
Professor of Epidemiology, London School of Hygiene and Tropical Medicine; Chairman of the Joint Committee on Immunisation and Vaccinations

Dr Stephen C Inglis BSc PhD
Director, National Institute for Biological Standards and Control (NIBSC)

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Deputy Chair of the Human Tissue Authority; member of the ACDP TSE Working Group and the CJD Incidents Panel

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Dr Robin Thorpe¹ BSc PhD FRCPATH
Head, Division of Biotherapeutics, National Institute for Biological Standards and Control (NIBSC)

¹ Re-appointed 1 November 2009

² End of appointment 31 October 2009

MEMBERSHIP OF THE CARDIOVASCULAR, DIABETES AND RENAL MEDICINES EXPERT ADVISORY GROUP (1 January - 31 October 2009)

Remit

To advise the Commission on the safety and efficacy of medicines used for the treatment and prevention on cardiovascular, diabetic and renal diseases.

Chair

Professor Henry Dargie MB ChB FRCP FESC

Consultant Cardiologist and Co-Director of CRI in Heart Failure, Glasgow University

Members

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Consultant Physician and Diabetologist, Royal Hallamshire Hospital, Sheffield

Dr Caroline L Vaughan BSc PhD

Lay Member of Hammersmith Hospitals Research Ethics Committee

MEMBERSHIP OF THE CARDIOVASCULAR, DIABETES, RENAL, RESPIRATORY AND ALLERGY MEDICINES EXPERT ADVISORY GROUP (1 November - 31 December 2009)

Remit

To advise the Commission on the safety and efficacy of medicines used for the treatment and prevention of cardiovascular, diabetic and renal diseases.

Chair

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Dr Caroline L Vaughan BSc PhD

Lay Member of Hammersmith Hospitals Research Ethics Committee

MEMBERSHIP OF THE CHEMISTRY, PHARMACY AND STANDARDS EXPERT ADVISORY GROUP

Remit

To advise the Commission established under Section 2 of the Medicines Act on the quality in relation to safety and efficacy of medicinal products which are the subject of marketing authorisation applications and to advise on such other matters as are referred to it.

Chair

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Professor Roger J Griffin² MRPharmS
Professor of Anticancer Drug Discovery and Development, University of Newcastle

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Academic Community Pharmacist; Visiting Professor of Pharmacy at Huddersfield University; Past President of the RPSGB

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Practising Hospital Pharmacist, NHS Eastern Region

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Professor of Physical Pharmaceutics, Bradford University

¹ Re-appointed 12 November 2009

² End of appointment 31st October 2009

³ Appointed on 12 November 2009

Invited Experts to the Chemistry, Pharmacy and Standards Expert Advisory Group

Mr V'lain G Fenton-May B Pharm M I Pharm FRPharmS
Pharmaceutical Microbiology (attended February)

Professor Faith M Williams MA PhD
Professor of Toxicology, Toxicology Unit, The Medical School and Institute for Research in Environment & Sustainability and Medical Toxicology Centre, University of Newcastle-upon-Tyne (attended April)

MEMBERSHIP OF THE CLINICAL TRIALS EXPERT ADVISORY GROUP

Remit

To advise the Commission on:

- First Time in Man (FTIM) studies with new compounds acting (directly or indirectly) via the immune system with a novel target or a novel mechanism of action or having a secondary potential effect on the immune system via a mechanism of action which currently is not well characterised.
- FTIM studies with novel compounds acting via a possible or likely species specific mechanism
- Any FTIM studies which are otherwise seen as requiring expert advice.
- Other clinical trials involving classes of compound where MHRA may wish to seek external expert advice or Commission may wish to have oversight.
- Provide expert advice on whether a product's mechanism of action is novel and comes within the scope of the EAG.
- Provide MHRA with expert advice on pre-meeting scientific advice documentation for within scope compounds.
- Other clinical trials where MHRA may wish to seek advice or where there is a difficult risk benefit balance.
- Other clinical trials involving products where a new class safety issue has been identified

Chair

Professor Robert Lechler¹ MB ChB PhD FRCP FRCPATH FMedSci
Vice-Principal (Health), King's College, London

Members

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Mrs Madeleine Wang³
Lay Representative – Patient Advocate

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¹ Re-appointed from 1 November 2009

² End of appointment 31 October 2009

³ Appointed from 1 November 2009

MEMBERSHIP OF THE DERMATOLOGY EXPERT ADVISORY GROUP (1 January - 31 October 2009)

Remit

To advise the Commission on the safety and efficacy of medicines for use in dermatological conditions/diseases.

Chair

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Members

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Independent lay representative, Royal College of GPs, Cornwall and Isles of Scilly PCT, NICE medicines concordance guidelines development group

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Consultant Dermatologist, St John's Institute of Dermatology, Guy's and St Thomas' Hospital

Professor Martin J Kendall MBChB MD FRCP
Professor of Clinical Pharmacology, Birmingham University Medical School

Dr Celia Moss BA MB BS MA MRCP DM FRCP MRCPC
Consultant Dermatologist, Birmingham Children's Hospital

Dr Ross Taylor MB ChB MD FRCPE FRCGP DCH
Senior Lecturer in General Practice, University of Aberdeen; General Medical Practitioner Principal, Grampian Health Board

MEMBERSHIP OF THE GASTROINTESTINAL AND HEPATOLOGY MEDICINES EXPERT ADVISORY GROUP (1 January - 31 October 2009)

Remit

To advise the Commission on the safety, quality and efficacy of medicines for use in gastrointestinal and hepatic diseases.

Chair

Professor Michael J G Farthing MD FRCP
Vice Chancellor, University of Sussex

Members

Dr Alison L Jones MB ChB MD FRCP FRCPE
Clinical Toxicologist & General (internal) Medicine and Director of the Medical Toxicological Unit and National Poisons Information Service, Guy's & St Thomas NHS Trust

Professor Roger H Jones FRCGP FRCP(Ed) FMed Sci (founder fellow) FRCP FFPHM
Head of Department of General Practice and Primary Care, School of Medicine at Guy's, King's College and St Thomas' Hospitals

Dr John C Mansfield MA MBBS MD FRCP
Consultant Physician and Senior Lecturer in Gastroenterology, Royal Victoria Infirmary and University of Newcastle Upon Tyne

Professor Kevin Moore BSc MB BS PhD FRCP
Professor of Hepatology, Royal Free Hospital, London

MEMBERSHIP OF THE MEDICINES FOR WOMEN'S HEALTH EXPERT ADVISORY GROUP

Remit

To advise the Commission on the safety and efficacy of medicines related to endocrinology and women's reproductive health from menarche to menopause and conditions related to the menopause, such as osteoporosis. The medicines covered will include medicines for contraception, emergency contraception and termination of pregnancy; medicines for infertility and assisted conception; HRT and non-hormonal treatments for osteoporosis.

Chair

Dr Mary Armitage¹ BSc MB ChB(Hons) FRCPE FRCP DM

Consultant Physician and Endocrinologist, Royal Bournemouth Hospital; Clinical Director of Medicine and Honorary Clinical Senior Lecturer, Southampton University

Members

Dr Sarah R Atkinson¹ MB BS

Associate in General Practice, Parkstone Health centre, Poole, Dorset; Medical Officer Bournemouth and Poole Contraceptive Health Services

Professor Dame Valerie Beral² MB BS MD FRCP FRCOG FFPHM FMedSci FRS

Professor of Epidemiology, Cancer Epidemiology Unit, University of Oxford

Professor Juliet Compston¹ MD FRCP FRCPATH

Professor of Bone Medicine & Honorary Consultant Physician, School of Clinical Medicine, Cambridge University

Dr Ailsa Gebbie¹ (Vice-Chair) MB CHB FRCOG

Consultant in Community Gynaecology, Family Planning & Well Woman Services, NHS Lothian, Edinburgh

Dr Annabelle Glasier² MB ChB MD FRCOG

Consultant in Sexual and Reproductive Health, Family Planning and Well Woman Services, NHS Lothian, Edinburgh

Dr Sally L Hope¹ MA BM BCh FRCGP DRCOG

Principal in General Practice, The Surgery, Woodstock, Oxford

Professor Mary Lumsden¹ BSc MB BS MD FRCOG

Professor of Medical Education & Gynaecology, University of Glasgow

Professor Klim McPherson² PhD FFPHM FMedSci

Visiting Professor of Public Health Epidemiology, Nuffield Dept of Obstetrics & Gynaecology, John Radcliffe Hospital, Oxford

Mrs Julietta Patnick¹ CBE BA(Hons)

Director, NHS Cancer Screening Programmes Sheffield – Lay Representative

Dr Siobhan Quenby¹ BSc MD MBSC FRCOG CCST

Professor of Obstetrics, Warwick University

Professor Stuart Ralston¹ MD FRCP FMedSci FRSE

Head of the School of Molecular and Clinical Medicine & ARC Professor of Rheumatology, Molecular Medicine Centre, Western General Hospital, Edinburgh

Carolyn, Lady Roberts¹ RGN RHV MSc

Chair, The Ethox Foundation, Oxford Centre for Ethics and Communication in Healthcare Practice; Lay Representative

Dr P C Connie Smith¹ MB BS MFSRH
Consultant in Sexual and Reproductive Health Care, Westminster PCT

Professor Martin Vessey¹ CBE MD FRCP FFPH FMedSci FRS
Emeritus Professor of Public Health, Oxford University

¹ Re-appointed from 1 November 2009

² End of appointment 31 October 2009

MEMBERSHIP OF THE NEUROLOGY AND PAIN MANAGEMENT EXPERT ADVISORY GROUP (1 January - 31 October 2009)

Remit

To advise the Commission on the safety and efficacy of medicines for use in neurological conditions and pain management.

Chair

Dr Michael J Donaghy DPhil(Oxon) FRCP

Reader in Clinical Neurology, Oxford University; Consultant Neurologist, Radcliffe Infirmary, Oxford

Members

Dr Richard J Coleman BSc MB MS MRCP (Edin) MD FRCP (Lon)

Consultant Neurologist, Aberdeen Royal Infirmary

Dr Beverley Jane Collett MB BS FRCA

Consultant in Pain Management & Anaesthesia; Assistant Medical Director, Leicester Royal Infirmary

Professor Alastair Compston MBBS(Hons) PhD FRCP (Lon) FRSA FMedSci FIBiol

Professor of Neurology and Head of the Department of Clinical Neurosciences, University of Cambridge

Dr Helen J Cross MB ChB PhD FRCP FRCPCH

Reader/ Consultant in Paediatric Neurology, Institute for Child Health

Professor John Duncan BA BMBS MA (Ox) DM (Ox) FRCP (Lon) FMedSci

Professor of Clinical Neurology, Head of Department of Clinical and Experimental Epilepsy, Institute of Neurology, UCL

Dr Nicholas A Fletcher BSc MBBS MD FRCP

Consultant Neurologist Walton Centre for Neurology & Neurosurgery, Liverpool

Professor Karen Forbes MB ChB FRCP Dip Pall Med Cert Med Ed MILT

Consultant and Macmillan Professorial Teaching Fellow in Palliative Medicine, United Bristol Healthcare Trust

Professor Ralph P Gregory BM FRCP

Consultant Neurologist, Royal Berkshire and Battle NHS Trust and Oxford Radcliffe Hospitals NHS Trust

Mr Michael J Harnor MSc MEd

National Chairman, British Epilepsy Association (Epilepsy Action); Chair, The Greater Manchester Neurological Alliance; Lay representative

Ms Susan V Haydon BA(Hons)

Lay Representative, Helpline and Support Services Development Officer for Migraine Trust

Dr Anthony L Johnson BSc PhD FIS FSS CStat

Medical Statistician, Institute of Public Health, Cambridge

Dr Russell J M Lane BSc(Hons) MB BS(Hons) MD FRCP

Consultant Neurologist, Charing Cross Hospital

Professor Peter M Rothwell MD PhD FRCP

Professor of Clinical Neurology, Radcliffe Infirmary

Dr Christopher M Verity MA FRCP FRCPCH DCH DRCOG

Consultant Paediatric Neurologist, Addenbrooke's Hospital, Cambridge

**MEMBERSHIP OF THE NEUROLOGY, PAIN AND PSYCHIATRY EXPERT ADVISORY GROUP
(1 November - 31 December 2009)**

Remit

To advise the Commission on the safety and efficacy of medicines for use in neurological conditions and pain management.

Chair

Dr Michael J Donaghy DPhil(Oxon) FRCP
Reader in Clinical Neurology, Oxford University; Consultant Neurologist, Radcliffe Infirmary, Oxford

Members

Professor Ian M Anderson BA MA MBBS MRCP MD FRCPsych
Professor of Psychiatry, University of Manchester

Dr Beverley Jane Collett MB BS FRCA
Consultant in Pain Management & Anaesthesia; Assistant Medical Director, Leicester Royal Infirmary

Professor John Duncan BA BMBCh MA (Ox) DM (Ox) FRCP (Lon) FMedSci
Professor of Clinical Neurology, Head of Department of Clinical and Experimental Epilepsy, Institute of Neurology, UCL

Mr Michael J Harnor MSc MEd
National Chairman, British Epilepsy Association (Epilepsy Action); Chair, The Greater Manchester Neurological Alliance; Lay representative

Dr Russell J M Lane BSc(Hons) MB BS(Hons) MD FRCP
Consultant Neurologist, Charing Cross Hospital

Professor John T O'Brien BA MA BMBCh DM FRCPsych
Professor of Old Age Psychiatry, University of Newcastle-Upon-Tyne

Mrs Meredith H Robson BSc MSc
Clinical psychologist

Mrs Kay F Sheldon MSc (mental health research)
Lay Representative and Mental Health Act Commissioner

Professor Eric A Taylor BA MA MB BChir MRCP MRCPsych FRCP FMedSci
Professor of Child & Adolescent Psychiatry, Institute of Psychiatry, London

Professor Ken Woodhouse MD FRCP FHEA
Pro Vice-Chancellor for Engagement and Professor of Geriatric Medicine, Cardiff University

MEMBERSHIP OF THE ONCOLOGY AND HAEMATOLOGY EXPERT ADVISORY GROUP

Remit

To advise the Commission on the safety, quality and efficacy of medicines of use in the treatment of malignant disease or blood disorders.

Chair

Professor John F Smyth¹ MD FRCP FRCS FRCR FRSE

Professor of Medical Oncology and Director of the CR UK Cancer Research Centre, University of Edinburgh

Members

Mrs Eileen J Barrett¹ BSc PGCE

Group Legal and HR Manager Medical Solutions plc, Nottingham – Lay member

Professor J Cassidy¹ MBChB MD MSc FRCP (G&E)

Professor of Oncology & Head of Dept of Cancer Research UK, Dept of Medical Oncology, University of Glasgow

Professor Jack Cuzick² MSc PhD

Professor of Epidemiology, Wolfson Institute of Preventive Medicine, London

Professor Barry W Hancock¹ OBE DCH MD FRCP FRCR

Professor of Clinical Oncology, University of Sheffield

Dr Alison Jones¹ MB ChB JCHMT MD FRCP

Consultant Oncologist, Medical Oncology, Department of Oncology, Royal Free Hospital,

Professor Jonathan A Ledermann¹ BSc MB BS MD FRCP

Director and Professor of Medical Oncology, Cancer Research UK and UCL Cancer Trials Centre

Professor David C Linch¹ MA BChir FRCP FRCPath FMedSci

Professor of Haematology, Royal Free and University College Medical School

Emeritus Professor E C Gordon Smith¹ MA MSc FRCPath FRCP FRCPE FMedSci

Professor of Haematology, St George's Hospital, University of London

Professor Michael C G Stevens¹ MD FRCP FRCPCH FRCR

CLIC Professor of Paediatric Oncology, University of Bristol

¹ End of appointment 31 October 2009

² Resigned August 2009

MEMBERSHIP OF THE PAEDIATRIC MEDICINES EXPERT ADVISORY GROUP**Remit**

To advise the Commission on the safety, quality and efficacy of medicines for paediatric use, including all matters relating to the implementation of the EU Paediatric Regulation.

Chair

Professor Rosalind Smyth¹ MA MBBS MD FRCPCH FMedSci
Brough Professor of Paediatric Medicine; Head of Division of Child Health, School of Reproductive and Developmental Medicine, University of Liverpool; Chair, Paediatric Medicines Expert Advisory Group

Members

Dr Eileen Baildam⁴ MB ChB DRCOG DCH RCP FRCP FRCPCH
Consultant Paediatric Rheumatologist, Alder Hey Children's NHS Foundation Trust

Mrs Alison Bowser²
Independent lay representative, Royal College of GPs, Cornwall and Isles of Scilly PCT, NICE medicines concordance guidelines development group; Member of Pharmacovigilance, Patient Information, and Dermatology EAGs

Professor Richard Cooke² MD FRCP DCH
Professor of Neonatal Medicine, Liverpool Women's Hospital

Dr Steven Cunningham⁴ PhD FRCPCH FRCP
Consultant Respiratory Paediatrician, Royal Hospital for Sick Children, Edinburgh

Dr Paul Ewings² BSc MSc PhD CStat FRSS
Head of Research & Development and Director of Peninsula and Taunton & Somerset R&D Units

Professor Diana Gibb³ MBChB MD MRCP MSc
Professor in Epidemiology, Medical Research Council Clinical Trials Unit, London; Honorary Consultant Paediatrician, Great Ormond Street Hospital for Children NHS Trust; Honorary Senior Lecturer, Institute of Child Health, London

Professor Ruth Gilbert¹ MB ChB MSc MD FRCPCH
Professor of Epidemiology, Institute of Child Health and UCL

Professor Peter Hindmarsh⁴ BSc MD FRCP FRCPCH
Consultant Paediatric Endocrinologist, Royal Free and University College Medical School

Mrs Jane Houghton² RGN RSCN MSc
Networks and Policy Implementation Officer, ACT the association for children's palliative care

Dr Rebecca Mann¹ BMBS FRCPCH
Consultant Paediatrician, Taunton and Somerset Hospital

Dr Vas Novelli² FRACP FRCP FRCPCH
Consultant in Paediatric Infectious Diseases Unit, Great Ormond Street Hospital

Dr Shirley Price¹ MSc PhD FBTS ERT FHEA
Director of Postgraduate Taught Studies, Division of Biochemical Sciences, Faculty of Health and Medical Sciences, University of Surrey

Dr George Rylance² MB CHB FRCPCH
Consultant Paediatrician and Paediatric Clinical Pharmacology, School of Clinical Medical Sciences (Child Health), University of Newcastle upon Tyne

Professor Michael Stevens¹ (Vice-Chair) MD FRCP FRCPCH FRCR
CLIC Professor of Paediatric Oncology, University of Bristol

Dr Jane Tizard¹ MBBS FRCP FRCPCH
Consultant Paediatric Nephrologist, Bristol Royal Hospital for Children

Dr Heather Wallace¹ PhD FRCPATH FBTS ERT
Senior Lecturer, Department of Medicines and Therapeutics, University of Aberdeen

Mrs Madeleine Wang¹ BA(Hons)
Patient Advocate

Dr William Whitehouse⁴ BSc MB BS DCH FRCP FRCPCH
Clinical Senior Lecturer in Pediatric Neurology, Department of Child Health, Queen's Medical Centre, Nottingham

Professor Andrew R Wolf¹ MB BChir FFA RCS(Eng)
Paediatric Anaesthesiology, Intensive Care and Pain Management, Bristol Royal Infirmary

Dr Geoffrey Wong¹ MA MD(Res) MBBS MRCGP FHEA
GP Principal and Walport Clinical Lecturer in Primary Care, UCL

Dr Edward Wozniak¹ BSc MB BS FRCP FRCPCH
Consultant Paediatrician and Trust Associate Medical Director, Portsmouth Hospitals NHS Trust, (CMO representative)

Dr Morris Zwi¹ MB BCh FRCPsych
Consultant Child and Adolescent Psychiatrist, Richmond Royal Hospital

Observer

Professor Anthony Nunn BPharm FRPharmS(Hon) FRCPCH
Clinical Director of Pharmacy, Royal Liverpool Children's NHS Trust; Associate Director Medicines for Children Research Network, University of Liverpool; Industrial Professor, School of Pharmacy and Chemistry, Liverpool John Moores University

¹ Re-appointed from 1 November 2009

² End of appointment 31 October 2009

³ Appointed 16 April 2009

⁴ Appointed 12 November 2009

MEMBERSHIP OF THE PATIENT INFORMATION EXPERT ADVISORY GROUP (1 January - 31 October 2009)

Remit

- To advise on communication with patients and the public about risk: benefit of medicines, in particular via patient information leaflets (PILS) and when risk:benefit changes.
- To advise on the delivery and monitoring of the strategy to improve the quality of the patient information set out in the Committee on Safety of Medicines Patient Information Working Group report. *Always read the leaflet.*
- To advise on the implementation of new European legislation concerning improvements to patient information, and to advise on European initiatives in the area of patient information including the European Commission's commitment to report on patient information practice.
- To advise the MHRA on ways to facilitate and promote patient reporting and secure further patient engagement in the patient reporting process.

Chair

Ms Joanne C Rule BA

Patient Information and Engagement Adviser

Members

Dr Keith Beard BSc MB ChB FRCP(E&G) FFPM

Consultant Physician, Medicine for the Elderly, Victoria Infirmary, Glasgow

Professor Dianne Berry DPhil C Psychol ACSS

Pro-Vice Chancellor; Research and Professor of Psychology, Reading University

Mr Andrew Boag BA ISTD

Independent Design Consultant, Boag Associates (nominated by the Design Council)

Mrs Alison Bowser

Independent lay representative, Royal College of GPs, Cornwall and Isles of Scilly PCT, NICE medicines concordance guidelines development group

Dr Katherine Darton BA BSc PhD LGSM

Information Officer, MIND

Dr Nicola Gray BSc PhD MRPharmS

Lecturer in Pharmacy Practice, The School of Pharmacy, University of Nottingham

Professor Jennifer Hunt BA MPhil RGN FRCN(Hon) DSc

Research Consultant and Visiting Professor, Institute of Health Research, University of Bedfordshire

Mr Ian Pearson

Disability Awareness Advisor; Magistrate

Dr Ross Taylor MB ChB MD FRCPE FRCGP DCH

Senior Lecturer in General Practice, University of Aberdeen; General Medical Practitioner Principal, Grampian Health Board

Mrs Madeleine Wang BA(Hons)

Patient Advocate

Dr Bruce Warner BSc MSc DPharm MRPharmS

Senior Pharmacist, National Patient Safety Agency

CHM Observer

Carolyn, Lady Roberts RGN RHV MSc

Chair, The Ethox Foundation, Oxford Centre for Ethics and Communication in Healthcare Practice;
Health visitor

Industry observers

Dr Richard Tiner

ABPI Medical Director, Association of the British Pharmaceutical Industry

Mrs Helen Darracott LLB BPharm MRPharmS

PAGB Representative; Director of Legal & Regulatory Affairs, Proprietary Association of Great Britain

Mrs Janet Lewis

Head of Regulatory Affairs, Winthrop Pharmaceuticals, British Generic Manufacturers Association
(BGMA)

MEMBERSHIP OF THE PHARMACOVIGILANCE EXPERT ADVISORY GROUP

Remit

To advise the Commission on Human Medicines on the following in relation to human medicines including herbal products:

- The public health importance of potential new safety signals
- The confirmation and quantification of risks identified
- Appropriate risk minimisation measures including communications
- Design and progress of pharmacovigilance plans
- Methodologies for pharmacovigilance

Chair

Professor Munir Pirmohamed PhD FRCP

Professor of Clinical Pharmacology, Liverpool University; NHS Chair of Pharmacogenetics; Deputy Director, MRC Centre for Drug Safety Science

Members

Professor D Nick Bateman³ BSc MD FRCP FRCP(E) FBPharmacolS FBTS

National Poisons Information Service Edinburgh

Dr Keith Beard (Vice Chair)³ FRCP(Ed) FRCP(Glas)

Consultant Physician in Geriatric Medicine, Victoria Infirmary, Glasgow

Mrs Alison Bowser²

Independent lay representative Royal College of GPs, Cornwall and Isles of Scilly PCT, NICE medicines concordance guidelines development group & Member of Pharmacovigilance, Patient Information and Dermatology EAGs

Dr Robert Bracchi¹ FRCGP

General Practitioner and Honorary Lecturer, University of Wales

Miss Alison B Ewing¹ BSc MSc MIPharmM FRPharmS

Clinical Director of Pharmacy Royal Liverpool and Broadgreen University Hospital NHS Trust

Professor Robin E Ferner¹ MSc MD FRCP

Consultant Physician and Consultant Pharmacologist, City Hospital Birmingham

Professor David Gunnell¹ MB ChB MRCP PhD MSc FFPHM

Professor of Epidemiology, University of Bristol

Ms Jane Harris¹ MSc BN RN RM RHV DN

Teaching Dean, School of Nursing and Midwifery, University of Dundee

Professor Simon R J Maxwell⁴ MD FRCP FRCPE FB PharmacolS FHEA

Professor of Student Learning/ Clinical Pharmacology, Western General Hospital, Edinburgh and University of Edinburgh

Dr Nicholas J Plant⁴ BSc PhD

Senior Lecturer in Molecular Toxicology, University of Surrey

Professor Alan Silman¹ MSc MD FRCP FFPHM FMedSci

Medical Director of the Arthritis Research Campaign

Professor Simon Thomas² BSc MB MD FRCP

Professor of Clinical Pharmacology and Therapeutics, Newcastle University; Consultant Physician, Newcastle Hospitals NHS Foundation Trust

Dr Caroline Vaughan³ BSc PhD

Lay Member of Hammersmith Hospitals Medical Research Ethics Committee; Director, Contact a Family and Trustee, Family Line Surrey

Professor Ken Woodhouse¹ MD FRCP FHEA

Pro Vice-Chancellor for Engagement; Professor of Geriatric Medicine, Cardiff University

¹ Re-appointed from 12 November 2009

² End of appointment 31 October 2009

³ Appointed on 12 November 2009

⁴ Appointed on 10 December 2009

Invited Experts to the Pharmacovigilance Expert Advisory Group

Professor J Horne PhD DSc MSc BSc FBPsS FIBiol CPsych CBiol

Director of the Sleep Research Centre, Loughborough University, Leicestershire (attended December)

Dr T Mackay

Sleep Centre, Royal Infirmary of Edinburgh, Edinburgh (attended December)

Dr A Williams MBBS FRCP

The Sleep Disorders Centre, St Thomas' Hospital, Lambeth, London (attended December)

Dr C Vaughan BSc PhD³

Lay Member of Hammersmith Hospitals Medical Research Ethics Committee; Director, Contact a Family and Trustee, Family Line Surrey (attended March, April, July, September, October)

Professor E Szabadi MD PhD DSc

Psychopharmacology, University of Nottingham, Queen's Medical Centre, Nottingham (attended March)

**MEMBERSHIP OF THE PSYCHIATRY AND OLD AGE PSYCHIATRY EXPERT ADVISORY GROUP
(1 January - 31 October 2009)**

Remit

To advise the Commission on the safety and efficacy of medicines for use in psychiatric conditions.

Chair

Professor Ken W Woodhouse MD FRCP ILTM

Pro Vice-Chancellor, External Affairs, Cardiff University; Professor of Geriatric Medicine

Members

Professor Ian M Anderson BA MA MBBS MRCP MD FRCPsych

Professor of Psychiatry, University of Manchester

Professor Paul E Bebbington BA MA MB BChir MPhil FRCPsych FRCP

Head of Department of Mental Health Sciences; Professor of Social & Community Psychiatry, Royal Free and University College Medical School

Dr Simon Fleming BA MA MB BChir FRCPsych FRCP PhD

Consultant Neuropsychiatrist, South London and Maudsley NHS Trust

Professor Ian Goodyer¹ MA MD FRCPCH FRCPsych FMedSci FRCP PhD

Professor of Child & Adolescent Psychiatry, University of Cambridge

Dr Paul Kinnersley MB ChB

Reader, Department of General Practice, Cardiff University

Dr Anne R Lingford-Hughes BA PhD BM BCh BA MRCPsych

Reader in Biological Psychiatry and Addiction, University of Bristol

Professor Ian G McKeith MD FRCPsych FMedSci

Professor of Old Age Psychiatry, University of Newcastle Upon Tyne

Professor John T O'Brien BA MA BMBCh DM FRCPsych

Professor of Old Age Psychiatry, University of Newcastle Upon Tyne

Professor David G C Owens MD FRCP FRCPsych

Professor of Clinical Psychiatry, Edinburgh University

Mrs Meredith H Robson BSc MSc

Clinical psychologist

Mrs Pauline (Polly) A Robson BA

Lay Member, General Social Care Council, Nursing and Midwifery Council, General Dental Council (Ethics committee)

Mrs Kay F Sheldon MSc (mental health research)

Mental Health Act Commissioner

Professor Eric A Taylor BA MA MB BChir MRCP MRCPsych FRCP FMedSci

Professor of Child & Adolescent Psychiatry, Institute of Psychiatry, London

¹ Resigned April 2009

MEMBERSHIP OF THE RESPIRATORY AND ALLERGY MEDICINES EXPERT ADVISORY GROUP (1 January - 31 October 2009)

Remit

To advise the Commission on the safety and efficacy of medicines for use in respiratory and allergic diseases.

Chair

Professor Peter J Helms MB BS PhD FRCP FRCPCH FFSEM

Professor of Child Health, University of Aberdeen; Consultant Paediatrician, Royal Aberdeen Children's Hospital

Members

Dr Iolo Doull MRCP DM FRCPCH

Consultant Respiratory Paediatrician, Respiratory/ Cystic Fibrosis Unit, Children's Hospital for Wales, Cardiff

Ms Monica J Fletcher MSc BSc PCGE RGN HVdip

Chief Executive, Education for Health (formerly the National Respiratory Training Centre)

Professor Anthony J Frew MA MD FRCP

Professor of Allergy & Respiratory Medicine; Consultant Physician (respiratory and general medicine), Department of Respiratory Medicine, Brighton General Hospital

Dr Vanessa A L Graham BA BM BCh FRCP

Consultant Chest Physician, Central Middlesex Hospital and Willesden Chest Clinic

Dr Philip W Ind BA Cantab MB BChir MA Cantab FRCP

Consultant Physician; Honorary Senior Lecturer in Respiratory Medicine, Imperial School of Medicine, Hammersmith Hospital

Dr Ann Millar MBChB MD FRCP

Professor of Respiratory Medicine, Bristol University; Honorary Consultant, North Bristol NHS Trust

Professor Richard J Powell MBBS DM FRCP

Professor of Clinical Immunology and Allergy, Queens Medical Centre, Nottingham

Professor Stephen G Spiro BSc MB ChB FRCP MD

Professor of Thoracic Medicine; Consultant Physician in General/Thoracic Medicine, University College London Hospitals NHS Trust

Emeritus Professor Anne E Tattersfield OBE MD FRCP FMedSci

Professor of Respiratory Medicine, Nottingham City Hospital

Dr Michael Thomas MB BS FRCP

General Practitioner, Minchinhampton, Gloucestershire; Hospital Practitioner, Respiratory Medicine, Stroud Hospital; Asthma Research Fellow, Aberdeen Hospital

Dr Charles Twort MA MD FRCP FRCPE

Consultant Physician in General & Respiratory Medicine; Director of Postgraduate Education, Guys & St Thomas' NHS Foundation Trust

MEMBERSHIP OF THE RHEUMATOLOGY AND IMMUNOLOGY MEDICINES EXPERT ADVISORY GROUP (1 January - 31 October 2009)

Remit

To advise the Commission on the safety and efficacy of medicines for use in rheumatology and immunology diseases.

Chair

Professor Stuart Ralston MD FRCP FMedSci FRSE

Head of School of Molecular and Clinical Medicine; ARC Professor of Rheumatology, Molecular Medicine Centre, Western General Hospital, Edinburgh

Members

Dr Deborah Bax MB ChB MRCP FRCP MD

Consultant Physician in Rheumatology, Hallamshire Hospital, Sheffield

Mrs Caroline J Dore BSc Statistics

Senior Statistician, ARC Clinical Trials Collaboration, MRC Clinical Trials Unit

Dr Michael Ehrenstein PhD FRCP

Professor of Experimental Rheumatology; Consultant Rheumatologist

Professor John S Hill Gatson MA BM BCh MRCP PhD

Professor of Rheumatology, University of Cambridge

Professor Alan Silman MRCP MSc Social Medicine MFCM MD FFPHM FRCP FMedSci

Medical Director of the Arthritis Research Campaign

Dr A G Wilson MB BCH BAO MRCP DCH PhD FRCP

Reading in Molecular Medicine and Rheumatology; Head of Academic Rheumatology, University of Sheffield

Professor Patricia Mang Ming Woo CBE FRCP FRCPCH FMedSci

Professor of Paediatric Rheumatology and Honorary Consultant, UCL

THE COMMISSION'S AD HOC GROUPS

MEMBERSHIP OF THE BIOEQUIVALENCE AD HOC GROUP

Remit

- To establish clear operating principles for the evaluation of bioequivalence.
- To provide policy advice to the Commission, compatible with EU guidance, on the following issues:
 - i. Acceptance criteria for C_{max} and AUC range and criteria for acceptance of a wider/narrower range for these parameters
 - ii. Highly variable drugs
 - iii. Measurement of parent compound/metabolites and their relative merit in determination of bioequivalence
 - iv. Bioequivalence criteria for drugs with long half-life
 - v. Exemptions from need to do bioequivalence studies
 - vi. Consider other bioequivalence issues as they arise.
- To provide advice on individual applications for Marketing Authorisations as required.

Chair

Professor Ian V D Weller MD FRCP

Professor of Sexually Transmitted Diseases, University College London Medical School

Members

Professor Deborah Ashby OBE BSc MSc PhD CStat(Hon) MFPHM(Hon) MRCP

Professor of Medical Statistics and Clinical Trials and Co-Director, Imperial Clinical Trials Unit, School of Public Health, Imperial College London

Professor Andrew P Grieve BSc MSc PhD FRSS

Professor of Medical Statistics, School of Medicine, King's College, London

Professor Martin J Kendall MB ChB MD FRCP

Professor of Clinical Pharmacology, Birmingham University Medical School

Professor B Kevin Park BSc PhD(Hon) FRCP(Hon) FMedSci FBTS

Professor of Pharmacology and Head of Department of Pharmacology and Therapeutics, Liverpool University

Professor Munir Pirmohamed MC ChB PhD FRCP

Professor of Clinical Pharmacology, Liverpool University

Professor James M Ritter DPhil FRCP FMed Sci

Professor of Clinical Pharmacology, St Thomas' Hospital

Dr Glyn Taylor BSc PhD MRPharms MIOd

Senior Lecturer, Welsh School of Pharmacy, Cardiff University

Dr Alison H Thomson BSc MSc PhD

Area Pharmacy Specialist, Western Infirmary and Strathclyde Institute of Pharmacy and Biomedical Sciences, University of Strathclyde

Professor Martin R Wilkins MD FRCP

Director of Experimental Medicine and Toxicology, Imperial College of Medicine, Hammersmith Hospital

MEMBERSHIP OF THE MIXING WORKING GROUP

Chair

Professor Derek H Calam OBE MA DPhil(Hon) DSc CChem FRSC FRSA(Hon) MRPharmS(Hon)
MBIRA
Visiting Professor of Pharmaceutical Sciences at the University of Strathclyde

Members

Mrs Alison Bowser

Independent Lay representative, Royal College of General Practitioners, Cornwall and Isles of Scilly PCT,
NICE medicines concordance guidelines development group

Professor Karen Forbes MB ChB FRCP Dip Pall Med Cert Med Ed MILT

Consultant and Macmillan Professorial Teaching Fellow in Palliative Medicine, United Bristol Healthcare
Trust

Professor Martin J Kendall OBE MD FRCP

Emeritus Professor of Clinical Pharmacology, Birmingham University Medical School

Mr Robert A Lowe BPharmS MRPharmS

Practising Hospital Pharmacist, NHS Eastern Region

Dr Rosalind Ranson MB BS MA MRCP

General Practitioner, London

Carolyn, Lady Roberts RGN RHV MSc

Chair, The Ethox Foundation, Oxford Centre for Ethics and Communication in Healthcare Practice;
Health visitor

Professor Roger Walker BPharm PhD FRPharms Hon FFPH

Consultant in Pharmaceutical Public Health, National Public Health Service for Wales; Professor in
Pharmacy Practice, Cardiff University

Department of Health

Mr Paul Robinson

Department of Health

MEMBERSHIP OF THE PHARMACY SUPPLY USAGE MODELLING AND ANTIBIOTIC RESISTANCE (PUMAR)

Chair

Dr Barbara Bannister MSc FRCP

Consultant in Infectious and Tropical Diseases, Royal Free Hospital, London

Members

Professor Deborah Ashby OBE BSc MSc PhD CStat(Hon) MFPHM(Hon) MRCR

Professor of Medical Statistics and Clinical Trials, Department of Epidemiology and Public Health, Faculty of Medicine, Imperial College, London

Mrs Alison Bowser

Independent lay representative, Royal College of General Practitioners, Cornwall and Isles of Scilly PCT, NICE medicines concordance guidelines development group (Member of Pharmacovigilance, Patient Information & Dermatology EAGs)

Professor Chris Butler BA MB ChB Diploma in Child Health MRCP CCH Doctor of Medicine

Head of Department, Primary Care and Public Health, Cardiff University

Professor Peter G Davey MB BS MD FRCPE

Professor of Pharmacoeconomics, University of Dundee, President of British Society for Antimicrobial Chemotherapy (BSAC); SACAR Professional Education Sub-Group Chair

Professor Brian Duerden BSc (Hons Bacteriology), MB ChB, MD FRCPath FRCP

Professor of Microbiology and Inspector of Microbiology and Infection Control, Head of Department, Medical Microbiology, Cardiff University, Department of Health

Professor Roger Finch MB ChB FRCPath FRCP FFPM RCP FRCPE

Professor of Infectious Diseases at the University of Nottingham; Consultant to the Nottingham University Hospitals NHS Trust; Chair of the Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)

Dr Steve Leach BA (Oxon) PhD

Scientific Programme Head (Microbial Risk Assessment), Health Protection Agency (HPA)

Dr Terence Maguire BSc PhD MCPP

Pharmacy Contractor, Northern Ireland

Dr Christine McCartney

Director, Regional Microbiology Network, Health Protection Agency (HPA)

Dr Rosalind Ranson MB BS MA MRCP

General Practitioner, London

Carolyn, Lady Roberts RGN RHV MSc

Chair, The Ethox Foundation, Oxford Centre for Ethics and Communication in Healthcare Practice; Health visitor

Professor Roger Walker BPharm PhD FRPharms(Hon) FFPH

Consultant in Pharmaceutical Public Health, National Public Health Service for Wales; Professor in Pharmacy Practice, Cardiff University

Invited Experts

Professor Jonathan Cooke MPharm PhD MRPharmS

Director of Research and Development; Clinical Director of Pharmacy and Medicines Management, University Hospital of South Manchester NHS Foundation Trust, Wythenshawe Hospital, Manchester; Member of the Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)

Dr Robin A Howe

Consultant Microbiologist, Microbiology Cardiff (Velindre NHS Trust), University Hospital of Wales

Government Departments

Mrs Cathy Harrison

Principal Pharmaceutical Officer, Pharmaceutical Advice and Services, Northern Ireland

Ms Gul Root

Principal Pharmaceutical Officer, Department of Health

Mr William Malcolm BSc MSc MPH MRPharmS

Specialist in Pharmaceutical Public Health, NHS Ayrshire & Arran, Scotland

Ms Sally Wellsteed

Team Leader Infection Control, Infectious Diseases and Blood Policy Branch, Specialist Advisory Committee on Antimicrobial Resistance (SACAR) Secretariat, Department of Health

Ms Carwen Wynne-Howells

Chief Pharmaceutical Officer, Welsh Assembly

Royal Pharmaceutical Society of Great Britain

Mr David Pruce

Royal Pharmaceutical Society of Great Britain

MEMBERSHIP OF THE PSEUDOEPHEDRINE WORKING GROUP

Chair

Professor Roger Walker BPharm PhD FRPharms FFPH

Consultant in Pharmaceutical Public Health, National Public Health Service for Wales and Professor in Pharmacy Practice, Cardiff University

Members

Mrs Alison Bowser

Independent lay representative, Royal College of General Practitioners, Cornwall and Isles of Scilly PCT, NICE medicines concordance guidelines development group

Dr Michael John Donaghy DPhil(Oxon) FRCP

Reader in Clinical Neurology, Oxford University; Consultant Neurologist, John Radcliffe Infirmary, Oxford

Mr Roy Gillman BSc MSc

Managing Director Gravitar Ltd (t/a Sheffield Pharmacy)

Professor Peter J Helms MB BS PhD FRCP(L&E) FRCPC

Professor of Child Health, University of Aberdeen; Consultant Paediatrician, Royal Aberdeen Children's Hospital

Dr Terence A Maguire BS PhD MCPP

Pharmacy Contractor, Northern Ireland

Professor Anthony J Nunn BPharm FRPharmS(Hon) FRCPC

Clinical Director of Pharmacy, Royal Liverpool Children's NHS Trust, Liverpool University

Professor Munir Pirmohamed MC ChB PhD FRCP

Professor of Clinical Pharmacology, Liverpool University

Dr Kevin Solomons BSc(Hons) PhD

Head of Medicines Mangement, Surrey Primary Care Trust

Dr Ross Jenkins Taylor MB ChB MD FRCP(Edin) FRCGP DCH

Senior Lecturer in General Practice, University of Aberdeen; General Medical Practitioner Principal, Grampian Health Board

Dr Angela Timoney BSc MSc

Director of Pharmacy, NHS Tayside

MEMBERSHIP OF THE WORKING GROUP ON HARM REDUCTION AND NICOTINE REPLACEMENT THERAPY**Chair****Professor Ian V D Weller MD FRCP**

Professor of Sexually Transmitted Diseases, University College London Medical School

Members**Ms Deborah Arnott**

Director of Action, Smoking and Health

Dr Paul Aveyard

NIHR career scientist, UK Centre of Tobacco Control Studies, Primary Care Clinical Sciences, University of Birmingham

Mrs Alison Bowser

Independent lay representative, Royal College of GPs, Cornwall and Isles of Scilly PCT, NICE medicines concordance guidelines development group; Member of the Pharmacovigilance, Patient Information and Dermatology EAGs

Professor John R Britton MB BS MD FRCP FFPHM

Professor of Epidemiology; Director, UK Centre for Tobacco Control Studies; Head of Division of Epidemiology and Public Health, University of Nottingham

Professor Henry J Dargie MB ChB FRCP FESC FRSE

Consultant Cardiologist, Western Infirmary, Glasgow; Director of the Scottish National Advanced Heart Failure Service; Honorary Professor of Cardiology, University of Glasgow

Professor Peter J Helms MB BS PhD FRCP FRCPE FRCPCH

Professor of Child Health, University of Aberdeen; Consultant Paediatrician, Royal Aberdeen Children's Hospital

Dr Richard B Hubbard MB BS FRCP

Reader in Clinical Epidemiology, Department of Respiratory Medicine, Nottingham University

Professor Martin Jarvis

Professor Emeritus of Health Psychology, Department of Epidemiology and Public Health, University College London

Mr Gareth Jones MRPharmS

NHS Liaison Manager, National Pharmacy Association

Dr Michael Knapton MBBChir FRCGP

Associate Medical Director, Prevention and Care, British Heart Foundation

Dr Marcus Munafò PhD

Reader in Biological Psychology, Bristol University

Dr Rosalind Ranson MB BS MA MRCP

General Practitioner, London

Observers**Dr Lesley Owen PhD**

Technical Adviser (Health Economics), National Institute for Health and Clinical Excellence

Department of Health

Mr Andrew Black
Smoking Policy

Mr Oliver Smith
Smoking Policy

Ms Emma Croghan
Smoking Policy

MEMBERSHIP OF THE EXTERNAL COMMISSION/MHRA EXPERT ADVISORY PANEL

Anaesthesia**Dr Thomas H Clutton-Brock** MRCP FRCA

Senior Lecturer in Anaesthesia and Intensive Care, Queen Elizabeth's Hospital, Birmingham

Dr Griselda M Cooper MBChB FRCA

Senior Lecturer in Anaesthesia, Queen Elizabeth Hospital, Birmingham

Dr Gordon B Drummond MB ChB FRCA FRCP

Senior Lecturer, Department of Anaesthetics, Royal Infirmary, Edinburgh

Dr Adrian R Lloyd-Thomas MB BS FFARCS

Consultant Paediatric Anaesthetist, Hospital for Sick Children, Great Ormond Street

Dr Jonathan J Ross FRCA

Clinical Senior Lecturer, Cardiac Anaesthesia, University of Sheffield

Dr Lindsey T A Rylah MBA FRCA

Consultant Anaesthetist, Basildon Hospital, Essex

Dr Neil Soni MB ChB FRCA FANZCA MD FFICANZCA

Consultant in Anaesthesia and Intensive Care, Chelsea and Westminster Hospital, London

Dr Robert C Tasker MA MBBS FRCP FRCPCH DCH

Consultant and University Lecturer (critical care & anaesthesia), Addenbrooke's Hospital, Cambridge

Cardiology**Professor Stuart M Cobbe** MA MD FRCP FESC

Walton Professor of Medical Cardiology, Glasgow Royal Infirmary

Dentistry**Professor Robin A Seymour** FDS RCS(Edin) PhD

Professor of Restorative Dentistry, The Dental School, Newcastle University.

Mr Paul Kletz BDS

Dental Practitioner

Dr Gordon Watkins MBE BDA

President of the British Dental Association; Member of the Committee on Safety of Devices

Dermatology**Professor Christopher E M Griffiths** BSc MD FRCP

Professor of Dermatology, Dermatology Centre, Hope Hospital, Salford

Diabetology / Endocrinology**Professor D John Betteridge** BSc PhD MD FRCP FAHA

Professor of Endocrinology and Metabolism, University College London, London

Professor Peter Clayton MB ChB FRCPCH

Professor in Paediatric and Endocrinology, Royal Manchester Children's Hospital

Professor Edwin A M Gale MB FRCP

Professor of Diabetic Medicine, Medical School Unit, Southmead Hospital, Bristol

Professor David R Matthews MA Dphil BM BCh FRCP

Professor of Diabetes Medicine (lipids); Director, Oxford Diabetes Centre, Oxford

Professor Paul M Stewart MB ChB MD FRCP FmedSci

Professor of Medicine (endocrinology), Queen Elizabeth Hospital, Birmingham

Epidemiology / Statistics

Professor Richard F A Logan BSc MB MSc MFPHM FRCP FRCPE

Professor of Clinical Epidemiology; Consultant Physician, University of Nottingham Medical School

Gastroenterology

Dr Alan Lobo MD FRCP

Consultant Gastroenterologist, Royal Hallamshire Hospital, Sheffield

Dr Harriet C Mitchison MBBS MA MD FRCP

Consultant Gastroenterologist, District General Hospital, Sunderland

Dr Kelvin Palmer MD FRCPE FRCP

Consultant Gastroenterologist; Clinical Lead, Endoscopy and Diagnostics Collaborative Programme, Gastrointestinal Unit, Western General Hospital

Dr Peter B Sullivan MA MD FRCP FRCPCH

Lecturer/ Consultant Paediatric Gastroenterologist, John Radcliffe Hospital, Oxford

Gynaecology / Family Planning / Well Woman / Obstetrics

Dr Janet Audrey Barter MB ChB Sheff MRCOG

Gynaecologist, Royal Free NHS Trust, London

Miss Sarah Creighton MB BS MD MRCOG

Gynaecologist, University College of London Hospital, London

Professor Hilary Octavia Dawn Critchley BSc(Hons) MB ChB MD FRCOG FRANZCOG

Consultant Gynaecologist, University of Edinburgh, Edinburgh

Professor Ian Jeffrey Jacobs MB BS MA BA MD MRCOG CRC MRC

Consultant Gynaecologist and Oncologist UCLH, Director UCL Institute for Women's Health, Head of the Research Department of Gynaecological Oncology, UCL

Dr Joan Pitkin BSC FRCS FRCOG

Consultant Obstetrician and Gynaecologist, Northwick Park Hospital, Harrow, UK

Mr Anthony Charles Silverstone MB ChB FRCS

Gynaecologist and Obstetrician, University College London Hospitals NHS Foundation Trust, King Edward VII Hospital and The Portland Hospital for Women and Children, London

Professor Stephen K Smith MD FRCOG FIBiol FMedSci

Principal of the Faculty of Medicine and Chief Executive of Imperial College Healthcare NHS Trust

Dr Alistair R W Williams MD Ed MB ChB Ed. MRCP FRCP

Honorary Consultant, Reader, Pathology, The University of Edinburgh, Simpson Centre for Reproductive Health

Haematology / Transfusions**Professor Dame Marcela Contreras** DBE MD FRCPath FRCPEdin FRCP

Professor of Transfusion Medicine, Royal Free and University College Medical School, London

Infectious Diseases / Tropical Medicine**Professor David A Warrell** MA DM DSc FRCP FRCPE FMedSci

Professor of Tropical Medicine and Infectious Disease, John Radcliffe Hospital, Oxford; Founding Director Emeritus, Tropical Medicine; Group Head/ PI and Grant Holding Senior Scientist

Liver / Lipidology**Professor Gilbert R Thompson** MD FRCP

Emeritus Professor of Clinical Lipidology, Division of Investigative Science, Imperial College School of Medicine, London

Professor Elwyn Elias MD BSc FRCP

Consultant Physician and Honorary Professor of Hepatology, The Liver Unit, Queen Elizabeth Hospital, Edgbaston, Birmingham

Medicine (general)**Professor James H McKillop** MB ChB PhD FRCP FRCR

Muirhead Professor of Medicine and Deputy Executive Dean at the University of Glasgow, member of the General Medical Council

Professor Jayne A Franklyn MD PhD FRCP

Professor of Medicine and Head of School of Clinical and Experimental Medicine, College of Medical and Dental Sciences, University of Birmingham

Professor Paul M Stewart MB ChB MD FRCP FmedSci

Professor of Medicine in the Department of Medicine, joint director of The Wellcome Trust Clinical Research Facility and Director of Research in the College of Medical & Dental Sciences

Neurology**Mr Michael Denham** MD FRCP FRSA

Consultant Physician in Geriatric Medicine, Northwick Park, Harrow, UK

Dr Colin R Kennedy MD FRCP FRCPCH

Consultant Paediatric Neurologist and Senior Lecturer, Southampton General Hospital

Professor Pamela J Shaw MBBS MD FRCP

Professor and Head of Academic Neurology Unit, University of Sheffield; Consultant Neurologist, Royal Hallamshire Hospital; Wellcome Senior Research Fellow in Clinical Science; Professor of Neurological Medicine, University of Newcastle upon Tyne

Dr Robin Grant MBChB MD FRCP(Glasg) FRCP(Edin)

Consultant NHS Neurologist; Part-Time Senior Lecturer, Centre for Neuro-Oncology, Western General Hospital, Edinburgh

Professor Ian R Whittle MD PhD FRACS FRCSE(SN) FRCPE

Forbes Professor of Surgical Neurology, Department of Clinical Neurosciences, University of Edinburgh and Honorary Consultant Neurosurgeon, Western General Hospital

Nurse

Ms Carol A Dealey BSc(Hons) RGN RCNT PgDIP

Research Fellow, Department of Nursing, Queen Elizabeth Hospital. Birmingham

Professor Karen A Luker BNurs PhD FMedSci

Professor of Community Nursing and Dean of the School of Nursing, Midwifery and Social Work, Manchester University

Oncology

Professor R Hugh MacDougall MBChb DMRT FRCS FRCR FRCPE

Professor and Dean of Medicine, The Bute Medical School, University of St Andrews, Scotland

Ophthalmologists

Professor Roger J Buckley MA FRCS FRCOphth(Hon) FCOptom

Chair, Ocular Medicine, Anglia Ruskin University; Honorary Visiting Specialist at Addenbrooke's Hospital, Cambridge

Ms Cecilia H Fenerty MD FRCOphth

Consultant Ophthalmologist, Royal Eye Hospital, Manchester

Professor John Forrester MD FRCSE FRCSG FRCOphth FRSE

Cockburn Professor and Head of Department of Ophthalmology at University of Aberdeen; Chairman of the RCOphth Medical Ophthalmology Training Sub-Committee and the RCOphth Diabetic Retinopathy Guidelines Committee

Professor Ian G Rennie MBChB FRCS FRCOPath

Professor and Head of Department of Ophthalmology and Orthoptics Unit, Royal Hallamshire Hospital, University of Sheffield

Professor Peng T Khaw FMedSci

Director, National Institute for Health Research Biomedical Research Centre, Professor, Moorfields Eye Hospital and UCL Institute of Ophthalmology

Orthopaedics

Professor Ian D Learmonth MBChB FRCS FRCS(Ed) FCS(SA) Orth

Head of the Department of Orthopaedic Surgery; Director of Bristol Implant Research Centre; Consultant Orthopaedic Surgeon, Bristol Royal Infirmary

Professor David Marsh MA MB Chir MD FRCS

Professor of Orthopaedics and Musculoskeletal Science, University College, London

Professor David I Rowley BMed Biol MD FRCS

Professor of Orthopaedics and Trauma Surgery; Deputy Dean of the Medical Faculty, University of Dundee

Mr J Keith Tucker MB BS FRCS

Consultant Orthopaedic Surgeon, Norfolk and Norwich Hospital

Palliative Medicine / Pain Management

Professor the Baroness Finlay of Llandaff FRCP FRCGP

Professor of Palliative Medicine, Velindre Cancer Centre, Cardiff

Professor Karen Forbes MB ChB FRCP Dip Pall Med Cert Med Ed MILT

Consultant and Macmillan Professorial Teaching Fellow in Palliative Medicine, Bristol Haematology and Oncology Centre

Paediatricians**Dr Andrew J Cant** BSc MBBS MD FRCP FRCPCH

Consultant in Paediatric Immunology and Infectious Diseases, Newcastle General Hospital

Professor Imti Choonara MD MRCP FRCPCH

Professor in Child Health, (University of Nottingham) Derbyshire Children's Hospital, Derby

Professor Peter Clayton MB ChB MD MRCP FRCPCH

Professor of Child Health and Paediatric Endocrinology, Royal Manchester Children's Hospital

Dr David Heaf MB BS FRCP FRCPCH

Consultant Paediatrician in Respiratory Medicine, Alder Hey Children's Hospital, Liverpool

Dr Colin R Kennedy MD FRCP FRCPCH

Senior Lecturer in Paediatric Neurology; Honorary Consultant, Southampton University Hospitals NHS Trust

Dr Denise Kitchiner MB BCh MD FRCP FRCPCH

Consultant Paediatric Cardiologist, Royal Liverpool Children's NHS Trust, Alder Hay, Liverpool

Dr Philip J Lee MD FRCP

Consultant and Honorary Reader in Inherited Metabolic Disease (hyperlipidaemia), The National Hospital for Neurology and Neurosurgery

Dr Adrian R Lloyd-Thomas MB BS FFARCS FRCA FFPMRCA

Consultant in paediatric anaesthesia and pain management, Hospital for Sick Children, Great Ormond Street, London

Dr Ian Peart

Consultant Paediatric Cardiologist, Royal Liverpool Children's Hospital, Liverpool

Dr Shakeel Qureshi MB ChB FRCP

Consultant Paediatric Cardiologist, Guy's Hospital, London

Dr Alan Smyth MA MBBS MRCP MD FRCPCH

Associate Professor and Reader in Child Health; Honorary Consultant in Paediatric Respiratory Medicine, Nottingham University Hospitals NHS Trust

Dr Peter B Sullivan MA MD FRCP FRCPCH

University Lecturer in Paediatrics; Honorary Consultant Paediatric Gastroenterologist John Radcliffe Hospital, Oxford

Dr Robert C Tasker MA MBBS FRCP FRCPCH DCH

Senior Lecturer (critical care and anaesthesia), Addenbrooke's Hospital, Cambridge

Dr Mark A Turner BSc(Hons) MB ChB PhD MRCP MRCPCH DRCOG CCST

Senior Lecturer in Neonatology, University of Liverpool; Honorary Consultant in Neonatology, Liverpool Women's NHS Foundation Trust

Dr John H Walter MD FRCP FRCPCH

Consultant Paediatrician, Royal Manchester Children's Hospital

Dr Christopher Wren MB ChB

Consultant Paediatric Cardiologist, Department of Paediatric Cardiology, Freeman Hospital

Pathologists / Histopathology /Biology / Immunobiology**Professor Peter G Isaacson** DSc DM FRCPATH

Emeritus Professor of Pathology, UCL

Professor James O'D McGee MD PhD FRCPath FRCP FMedSci
Professor of Morbid Anatomy, John Radcliffe Hospital, Oxford

Professor Ian Lauder MBBS FRCPath FMedSci
Professor of Pathology; Honorary Consultant in Histopathology, Leicester Royal Infirmary

Professor Geraint T Williams BSc MD FRCP (Lond) FRCPath
Associate Head of Section (Clinical), Section of Pathology, Cardiff University School of Medicine

Dr Alistair Williams MD Ed MB ChB Ed. MRCP FRCP
Honorary Consultant; Reader, Pathology, University of Edinburgh, Simpson Centre for Reproductive Health

Professor Sir Nicholas Wright MA MD PhD DSc FRCS FRCP FRCPath FMedSci
Professor of Investigative Medicine, Warden, Barts and The London School of Medicine and Dentistry

Pharmacology / Pharmacognosy

Professor Geoffrey Tucker BPharm PhD FRCPE FRCA FFPM FBPharmacolSoc FBToxicolSoc
Emeritus Professor of Clinical Pharmacology, University of Sheffield

Psychology / Psychiatry

Dr Angus V P Mackay OBE MA BSc(Pharm) MB ChB PhD(Cantab) FRCPsych FRCP(Edin) Medical
Director of the Argyll and Bute NHS Trust; McIntosh Lecturer in Psychological Medicine, Glasgow University

Professor Anne Lingford-Hughes BA PhD BmBCh MRCPsych
Professor of Addiction Psychiatry, Neuropsychopharmacology Unit, Imperial College London

Radiology

Professor Paul D Griffiths MBChB FRCS PhD FRCR
Professor of Radiology and Head of Department of Academic Unit of Radiology, University of Sheffield,
Royal Hallamshire Hospital, Sheffield

Professor Sameh K Morcos FRCS DMRD FFRRCSI FRCR
Consultant Radiologist, Northern General Hospital Sheffield

Renal Medicine / Nephrology

Professor Stephen H Powis BSc(Hons) BM BCh PhD FRCP
Professor of Renal Medicine and Medical Director, Centre for Nephrology University College London,
Royal Free Hospital, London

Dr Elizabeth B Lightstone MA PhD FRCP
Senior Lecturer and Honorary Consultant, Renal Medicine, Imperial College London

Dr David C Wheeler MD FRCP
Reader in Nephrology, Royal Free Hospital School of Medicine University College London

Respiratory Medicine

Dr Bartholomew R O'Driscoll MB BCh MD FRCP
Consultant Physician, Respiratory Medicine, Hope Hospital, Salford

Dr Alan Smyth MA MBBS MRCP MD FRCPCH
Associate Professor and Reader in Child Health; Honorary Consultant in Paediatric Respiratory Medicine,
Nottingham University Hospitals NHS Trust

Mr Alan J B Kirk MB ChB FRCS

Consultant Thoracic Surgeon, West of Scotland Heart and Lung Centre, Golden Jubilee National Hospital, Clydebank

Rheumatology

Dr Terence Gibson MD FRCP

Consultant Physician, Guy's Hospital, London

Professor David A Isenberg MD FRCP

Arthritis and Rheumatism Council Professor of Rheumatology, Arc Professor and academic director of Rheumatology, University College London

Professor Roger D Sturrock MD FRCP

McLeod/ Arthritis and Rheumatism Council; Chair of Rheumatology, Centre for Rheumatic Diseases, Glasgow Royal Infirmary

Toxicology

Professor Nicholas Bateman BSc MD FRCP FRCP(E) FBPharmacolS FBTS

Professor in Clinical Toxicology; Consultant Physician and Director, NPIS Edinburgh, Scottish Poisons Information Bureau, Royal Infirmary of Edinburgh

TSE

Mrs Christine F Farquhar BSc(Hons)

Transmissible Spongiform Encephalopathies (TSE) Researcher, Institute for Animal Health BBSRC and MRC Neuropathogenesis Unit, Edinburgh University

Urology

Mr Chris R Chapple BSc MD DHC FRCS(Urol) FEBU

Professor of Urology, Sheffield Hallam University; Consultant Urological Surgeon, The Royal Hallamshire Hospital

Professor Freddie C Hamdy MD FRCSEd(Urol)

Consultant Urological Surgeon at Oxford Radcliffe Hospitals NHS Trust, Nuffield Professor of Surgery and Professor of Urology

Mr David A Tolley MB FRCS FRCS(Ed)

Consultant Urological Surgeon and Honorary Senior Lecturer, Lothian University Hospitals NHS Trust; Director, The Scottish Lithotripter Centre, Western General Hospital, Spire Murrayfield Hospital and Spire Shawfair Park Hospital, Edinburgh

COMMISSION ON HUMAN MEDICINES/EXPERT ADVISORY GROUPS SECRETARIAT

COMMISSION ON HUMAN MEDICINES

Dr S Singh

Principal Assessor, New Drugs/Abridged

Ms S Morgan

Dr J Williams

Principal Assessor, Pharmacovigilance

Mr L R Whitbread

Secretary

Ms S Singh

Assistant Secretary

BIOLOGICALS/VACCINES

Dr A Cook

Principal Assessor

Ms S Singh

Secretary

CHEMISTRY, PHARMACY AND STANDARDS

Dr L A Anderson

Principal Assessor

Ms S Burch

Secretary

PHARMACOVIGILANCE

Dr J Williams

Ms C Davies

Principal Assessor

Ms S Burch

Secretary

ADVISORY BOARD ON THE REGISTRATION OF HOMEOPATHIC PRODUCTS ANNUAL REPORT 2009

INTRODUCTION

1. The Advisory Board on the Registration of Homeopathic Products ('the Board') was established in 1994 by the Medicines (Advisory Board on the Registration of Homeopathic Products) Order 1994 (S.I. 1994/102) which was revoked and replaced by the Medicines (Advisory Board on the Registration of Homeopathic Products) Order 1995 (S.I. 1995/309), as amended by the Medicines (Advisory Board on the Registration of Homeopathic Products) Order 2006 (S.I. 2006/2386), pursuant to the powers contained in section 4 of the Medicines Act 1968.

Its terms of reference are:

- a) To give advice on safety and quality in relation to any homeopathic medicinal product for human use, in respect of which a certificate of registration has been granted or applied for.
 - b) To give advice on safety, quality and efficacy in relation to any homeopathic medicinal product for human use
 - i) in respect of which a marketing authorization has been granted or has been applied for, or
 - ii) in respect of which a licence of right has been granted.
2. The Committee wishes to congratulate its Chair Dr Tim Chambers on the award of his OBE, a well deserved recognition for many years of service to medicine.

CHAIRMAN/MEMBERS

3. A list of the Board's current membership is at **Appendix I**.

SECRETARIAT

4. The Secretariat is based at the Medicines and Healthcare products Regulatory Agency. A list of the Administrative Secretariat is at **Appendix II**.

MEETINGS

5. There were four meetings in 2009. Meetings were held at the Medicines and Healthcare products Regulatory Agency (MHRA), Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

COSTS

6. For each meeting that they attend, Members are entitled to claim an attendance fee of £275 (Chairman's fee £400). Travel and subsistence is also payable within Department of Health guidelines.

SUMMARY

7. Three new applications for homeopathic marketing authorisations submitted under the National Rules Scheme were considered by the Board in 2009. The Board also advised on three company responses for applications made under the National Rules Scheme.

Additionally the Board considered and advised on a pre-hearing for five applications and also a hearing for one application, all of which were submitted under the Simplified Registration Scheme

The Board also received updates on pharmacovigilance issues and statistics for the homeopathic section of the MHRA website.

Tables showing the number of applications made for registration certificates and homeopathic marketing authorisations and the number of those referred to the Board for advice since it was established is at **Appendix III**.

MEMBERSHIP OF THE ADVISORY BOARD ON THE REGISTRATION OF HOMEOPATHIC PRODUCTS

Chair

Dr Timothy L Chambers OBE JP MB BS FRCP FRCPE FRCPI FRCPCH(Hon) FSLCPaed
Consultant Physician and Nephrologist, Bristol Royal Hospital for Children and Senior Clinical Lecturer in Child Health, Bristol University

Members

Dr Steve Bennett Briton MA MB BChir FRCP FRCPCH
Consultant Paediatrician at Good Hope Hospital, Sutton Coldfield

Professor Christopher Castleden MD FRCP
Emeritus Professor of Medicine, Leicester University

Mrs Patricia Donnachie
Nursing Dean/ Specialist Nurse Practitioner Homeopathy

Dr Michel Erlewyn-Lajeunesse BSc DM MRCPCH PGCME LFHom
Consultant Paediatrician, Allergy Immunology and Infectious Diseases, Southampton University Hospitals NHS Trust, Southampton

Dr Michael R Evans MB ChB
Principal in General Practice, St Lukes Medical Centre Stroud, Clinical Teacher in General Practice University of Bristol; Faculty Member, British Postgraduate Training in Anthroposophic Medicine

Professor Andreas J Gescher BSc PhD DSc
Professor of Biochemical Toxicology, Department of Cancer Studies and Molecular Medicine, University of Leicester

Mrs Christine Glover BSc FRPharmS MIPharmS LFHom (Resigned June 2009)
Royal Pharmaceutical Society of Great Britain

Mrs Kiran Kumar BSc MSc (Homeopathy)
Lay Representative

Dr George B Lockwood BPharm(Hons) PhD MRPharmS
Senior Lecturer in Pharmacy, Director of PIAT, School of Pharmacy & Pharmaceutical Sciences, University of Manchester

Dr Frank Mulder
General Practitioner, Helios Medical Centre, Bristol

Professor Julie Stone MMA LLB PGCE
Independent Consultant in Healthcare Law and Ethics; Visiting Professor in Ethics, Peninsula Medical School

Dr Thomas E Whitmarsh MA FRCP FFHom
Consultant Physician, Glasgow Homeopathic Hospital and The Western Infirmary, Glasgow

Invited Experts to ABRHP meetings

Professor Gillian M Eccleston BSc PhD CChem FRSC FRPharmS (Attended June and September)
Professor of Pharmaceutics, Strathclyde University

MEMBERS OF THE ADVISORY BOARD'S SECRETARIAT

Miss Sue Harris
Principal Assessor

Dr Segundo Mariz
Medical Assessor

Dr Elizabeth Griffiths
Scientific Assessor

Mr Jasbinder Sumal
Pharmaceutical Assessor

Mr Leslie Whitbread
Unit Manager

Ms Shelina Burch
Secretary

Homoeopathic Registrations

| Year | Applications Received | Applications Referred to ABRH | | | Total |
|--------------|-----------------------|-------------------------------|---------------|-------------------|-----------|
| | | Provisional Refusal | Grant Advised | Conditional Grant | |
| 1994 | 25 | 0 | 0 | 0 | 0 |
| 1995 | 24 | 10 | 0 | 3 | 13 |
| 1996 | 54 | 2 | 0 | 0 | 2 |
| 1997 | 88 | 2 | 0 | 1 | 3 |
| 1998 | 70 | 0 | 0 | 0 | 0 |
| 1999 | 73 | 3 | 0 | 3 | 6 |
| 2000 | 9 | 0 | 0 | 0 | 0 |
| 2001 | 13 | 0 | 0 | 0 | 0 |
| 2002 | 11 | 0 | 0 | 0 | 0 |
| 2003 | 0 | 0 | 2 | 0 | 2 |
| 2004 | 30 | 0 | 0 | 0 | 0 |
| 2005 | 13 | 0 | 0 | 0 | 0 |
| 2006 | 4 | 1 | 0 | 1 | 2 |
| 2007 | 1 | 0 | 0 | 0 | 0 |
| 2008 | 2 | 4 | 0 | 1 | 5 |
| 2009 | 0 | 0 | 0 | 0 | 0 |
| TOTAL | 413 | 22 | 2 | 10 | 33 |

Homoeopathic Marketing Authorisations

| Year | Applications Received | Refusal | Applications Referred to ABRH | | Total |
|--------------|-----------------------|----------|-------------------------------|---------------|----------|
| | | | Provisional Refusal | Grant Advised | |
| 2007 | 1 | 0 | 0 | 1 | 1 |
| 2008 | 2 | 0 | 0 | 2 | 2 |
| 2009 | 5 | 0 | 0 | 3 | 3 |
| TOTAL | 8 | 0 | 0 | 6 | 6 |

BRITISH PHARMACOPOEIA COMMISSION ANNUAL REPORT 2009

INTRODUCTION

1. The British Pharmacopoeia Commission, appointed under Section 4 of the Medicines Act 1968, is responsible under Sections 99(1) and 99(6) of The Act for preparing new editions of the British Pharmacopoeia and the British Pharmacopoeia (Veterinary), respectively, and for keeping them up to date. It also 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 (European Treaty Series No. 50; UK Treaty Series No. 32 (1974) CMND 5763) as amended by the Protocol to the Convention (European Treaty Series No. 134; UK Treaty Series No. MISC 16 (1990) CMND 1133). Under Section 100 of the Medicines Act the Commission also selects and devises names to be used at the head of monographs, which are subsequently published as British Approved Names.

MEMBERSHIP

2. A list of Commissioners during 2009, showing their terms of appointment, is shown in **Appendix I**. The term of office of three members ended on 31 December 2009. A review of membership was carried out during the year by the Appointments Commission, the body responsible for appointments to all of the Medicines Act Advisory Bodies. Professor David Woolfson was re-appointed as Chairman for a period of four years from 1 January 2010 and ten current members were re-appointed for varying terms of two or four years.
3. A list of members of the supporting Expert Advisory Groups, Panels of Experts and Working Parties for 2009 is given in **Appendix II**.

CODE OF PRACTICE

4. Members of the British Pharmacopoeia Commission are required to comply with a Code of Practice on Declaration of Interests in the Pharmaceutical Industry. This Code of Practice differs from that applicable to the Commission on Human Medicines and other Medicines Act Advisory Bodies in that, with the exception of the Chairman, members may continue to hold personal interests in the pharmaceutical industry.

MEETINGS

5. The British Pharmacopoeia Commission met three times during 2009. Sixteen meetings of the Expert Advisory Groups and Panels of Experts were also held during the year. The Panel of Experts on Radioactive Materials met for the first time during 2009 to discuss UK activity in this field. These meetings were held at the Medicines and Healthcare products Regulatory Agency (MHRA), 1 Nine Elms Lane, London SW8 5NQ.

6. Summary Minutes of the meetings of the British Pharmacopoeia Commission and its Expert Advisory Groups and Panels of Experts can be found on the new British Pharmacopoeia website (www.pharmacopoeia.gov.uk).

SECRETARIAT

7. The British Pharmacopoeia Secretariat is based at 1 Nine Elms Lane, London SW8 5NQ. A list of its members is shown in **Appendix III**.

LABORATORY

8. The British Pharmacopoeia Laboratory is based at the Laboratory of the Government Chemist (LGC), Queen's Road, Teddington, Middlesex, TW11 0LY. The Laboratory is managed under a collaboration agreement with LGC. The Laboratory Management Board is shown in **Appendix III**.

COSTS

9. For each meeting that they attend, members of the British Pharmacopoeia Commission are entitled to claim a combined preparation and attendance fee of £275 (Chairman's fee, £400.) Members of the Expert Advisory Groups and Panels of Experts are entitled to claim a fee of £150 per meeting attended (Chairman's fee, £275). Travel and subsistence is also payable within MHRA guidelines. The costs during 2009 in terms of fees and in terms of travel and subsistence for the British Pharmacopoeia Commission and its supporting Expert Advisory Groups and Panels of Experts were £25,100.00 and £14,008.30 respectively (total, £39,108.30).

PROGRESS AND PUBLICATIONS

British Pharmacopoeia 2010

10. The British Pharmacopoeia 2010 was published in August 2009. This new edition is now available as a package containing the four volumes of the British Pharmacopoeia 2010, the one volume of the British Pharmacopoeia (Veterinary) 2010 and access to the CD-ROM and online versions of both publications. The e-book version of the publication has been welcomed by users and the British Pharmacopoeia 2010 is also available as an e-book.
11. This new edition contains about 3300 monographs for substances and articles used in the practice of medicine and almost 400 infrared reference spectra, together with the customary appendices and supporting material. The effective date of the British Pharmacopoeia 2010 is 1 January 2010.
12. All monographs published within the sixth edition of the European Pharmacopoeia, as amended by Supplements 6.1 to 6.5, are included either in this edition of the British Pharmacopoeia or, where appropriate, in the associated edition of the British Pharmacopoeia (Veterinary). Monographs of the European Pharmacopoeia are clearly distinguished from those of national origin by means of a chaplet of stars that appears alongside the monograph title. Where appropriate, statements of relevance to UK usage, such as Action and use and the list of BP preparations, have been added to the European Pharmacopoeia monographs.

13. The British Pharmacopoeia 2010 contains 40 new monographs of national origin which were not published in previous editions. These include new monographs for unlicensed medicines, Traditional Herbal Medicines and homoeopathic stocks and mother tinctures.
 14. The British Pharmacopoeia General Notice on Crude Drugs; Traditional Herbal and Complementary Medicines was amended to clarify the use of the acronyms 'THM' and 'THMP' (relating to traditional herbal medicines). The General Notice on Homoeopathic Medicines was amended to include an explanation for the term 'Potentisation' when used in reference to homoeopathic medicine.
 15. As a consequence of an on-going review, two monographs were revised to replace the test for Pyrogens by the test for Bacterial endotoxins. A further 41 monographs were revised to remove reference to testing at the maximum valid dilution as the detail concerning the appropriate dilution of test solutions is covered in Appendix XIV C: Test for Bacterial Endotoxins.
 16. Following the introduction of a new editorial style for chromatographic and dissolution methods in the BP 2008, further refinements have been made and applied to over 100 monographs. The new style will be applied to all national monographs in future editions.
 17. The monographs for Herbal and Complementary Medicines were incorporated in a new section entitled 'Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products'. The separate section for 'Materials for use in the Manufacture of Homoeopathic Preparations' has been retained.
 18. The Appendix on Apparent Volume (XVII D) was omitted and a new Appendix entitled Wettability of Porous Solids Including Powders (XVII T) was added to harmonise with the European Pharmacopoeia.
 19. Four new Supplementary Chapters were added to provide additional guidance to the user: Guidelines for Using the Test for Sterility (IV P); Preservative-free Unlicensed Medicines (V A); Bio-equivalence of Oral Suspensions (V B); Traditional Herbal Medicines (VII).
- British Pharmacopoeia (Veterinary) 2010**
20. The British Pharmacopoeia (Veterinary) 2010 was published as a companion volume to the British Pharmacopoeia 2010 in August 2009. The effective date of the British Pharmacopoeia (Veterinary) 2010 is 1st January 2010.
 21. One monograph was revised to replace the test for Pyrogens by that for Bacterial endotoxins.
- British Approved Names**
22. Supplement Number 3 to British Approved Names 2007 was published in August 2009, adding 22 new names not previously published.
- CD-ROM and BP Online**
23. A new version (14.0) of the CD-ROM containing both the British Pharmacopoeia 2010 and the British Pharmacopoeia (Veterinary) 2010 was issued as a component of the British Pharmacopoeia

2010 package, together with access to the online version of the publications (www.pharmacopoeia.co.uk).

24. A new feature was introduced to allow individual monographs to be purchased. A maximum of three BP monographs can now be supplied electronically, on request, together with the necessary supporting information including the Introduction, General Notices, Appendices and Supplementary Chapters.
- Prices and Availability** 25. Details of the prices and availability of the above-mentioned publications are shown in **Appendix IV**.
- Future Publications** 26. By the end of 2009 work was progressing on the preparation of the next editions of the British Pharmacopoeia and British Pharmacopoeia (Veterinary). These will be published during 2010 and will have an effective date of 1 January 2011.
27. Three in-year electronic updates will be issued, providing users with the text of the European Pharmacopoeia Supplements 6.6, 6.7 and 6.8 in advance of the implementation dates of these Supplements on 1 January, 1 April and 1 July 2010, respectively. These updates will only be available via the BP online. The texts will subsequently be included in the BP 2011 publications.

OTHER PHARMACOPOEIAL MATTERS

- BP Website** 28. A number of improvements have been made to the British Pharmacopoeia website (www.pharmacopoeia.gov.uk) since it was launched on 1 September 2008. These include provision for the online payment for British Pharmacopoeia Chemical Reference Substances and the publication of a list detailing all the editorial and technical changes included in the British Pharmacopoeia 2010 and the British Pharmacopoeia (Veterinary) 2010.
29. The new site has increased the amount of information available to both the public and users of the British Pharmacopoeia and has provided greater transparency in the monograph development and revision process. Users of the BP have benefitted from additional information on the interpretation and application of BP monographs, facilitated by a section on frequently asked questions.
- Unlicensed Medicines** 30. Nine new monographs for unlicensed formulations were published in the British Pharmacopoeia 2010. Monographs that only apply to unlicensed medicines are identified as such in the British Pharmacopoeia by inclusion of a statement indicating that the medicines are not licensed in the United Kingdom.
31. Information continues to be collected on widely used preparations for which there are currently no published standards. The BP continues to work with NHS groups and the pharmaceutical industry and receives appropriate advice on medicinal preparations prescribed in the UK for which no licensed formulations are available.
32. The BP are contributing to the review of the regulations relating to unlicensed medicines currently being undertaken by the MHRA and the Department of Health.

33. The inclusion of BP monographs for unlicensed medicines has been widely recognised as a valuable addition to the publication since they provide legally enforceable standards for such products.
- Traditional Herbal Medicines**
34. A new monograph for a widely used traditional herbal medicinal product and a new General Monograph to cover the requirements for processed herbal drugs were included in the British Pharmacopoeia 2010 to support the European Directive on Traditional Herbal Medicines.
35. Information continues to be collected on a number of substances widely used in Traditional Chinese Medicine and in Ayurvedic Medicine in the UK for which there are currently no European standards. National and international collaboration is being sought to identify validated analytical methods and suitable standards.
- Homoeopathic Preparations**
36. Two monographs for homoeopathic stocks and mother tinctures were included in the British Pharmacopoeia 2010 to support the simplified registration scheme for the licensing of homoeopathic preparations.
- BP Reference Materials**
37. The BP Laboratory has continued its programme to establish British Pharmacopoeia Chemical Reference Substances (BPCRS) for use in connection with national monographs. A significant number of formulated preparation monographs were amended in the British Pharmacopoeia 2010 and the British Pharmacopoeia (Veterinary) 2010 to refer to new BPCRS established by the BP Laboratory.
38. Forty one new BP Reference Materials were established to support the British Pharmacopoeia 2010 and British Pharmacopoeia (Veterinary) 2010, 66 were replaced and 90 were re-tested to ascertain their continued stability.
39. The demand for these reference materials remained high throughout the year. 12182 vials were sold within the UK and to countries worldwide.
- Nomenclature**
40. The Commission continued to provide advice and comments to the WHO Committee on International Nonproprietary Names. Recommended INN (rINN) for products licensed in the UK are subsequently adopted as British Approved Names. UK Experts attended two meetings during the year at which a total of 157 applications were evaluated. Two rINN Lists (61 and 62), containing a total of 126 recommended names, were published by the World Health Organization during the year.
41. Following the submission of a UK position paper on vaccine abbreviations during 2008, the WHO Expert Committee on Biological Standardisation undertook to review vaccine abbreviations used in WHO documents in collaboration with industry.
42. The BP Secretariat is also responsible for assessing proposed invented names for medicines in the UK and providing the UK input to the EMEA Naming Review Group. During the year 455 proposed invented names were assessed on behalf of the MHRA and 518 on behalf of the EMEA.

43. The Secretariat provided significant input into a guidance document entitled "MHRA Guideline for the Naming of Medicinal Products and Braille Requirements for Name on Label" which was subsequently published on the MHRA website (www.mhra.gov.uk).
- Review of the Medicines Act**
44. The BP Secretariat is contributing to the consolidation of The Medicines Act 1968, which is part of a wider review of the existing UK legislation relating to medicines for human use being undertaken by the MHRA.
45. The first stage of the project is to consolidate over 80 Statutory Instruments and the original Medicines Act into one text which will then be reviewed to identify any necessary amendments and improvements.
- European Pharmacopoeia**
46. The sixth and seventh Supplements to the sixth edition of the European Pharmacopoeia (Supplements 6.6 and 6.7) were published in July 2009 and October 2009 and came into effect on 1 January 2010 and 1 April 2010 respectively. The eighth Supplement (Supplement 6.8) was published in December 2009 and will come into effect on 1 July 2010. The text of these publications will be included in the next editions of the British Pharmacopoeia or British Pharmacopoeia (Veterinary), as appropriate.
47. The UK continued to play a highly active role in support of the work of the European Pharmacopoeia Commission and its expert groups, providing Chairmen to three Groups of Experts and six Working Parties and experts to all of the principal Expert Groups and Working Parties. Dr Gerard Lee, the Secretary and Scientific Director, continued in his role as the Second Vice-Chair of the European Pharmacopoeia Commission.
48. The BP Laboratory provides technical support for the work of the European Pharmacopoeia Commission. It participates in the voluntary scheme to validate draft monographs published in Pharmedica and provides technical data in support of the elaboration of new monographs and revision of existing monographs.
49. As provided for in Section 65(8) of the Medicines Act 1968, supplementary lists of Approved Synonyms for names at the head of monographs of the European Pharmacopoeia were prepared and published on the recommendation of the Commission on Human Medicines.
50. A list of the current membership of the United Kingdom delegation, and the names of the UK members of Groups of Experts and Working Parties during 2009, is included in **Appendix V**.
- International Liaison and Collaboration**
51. Liaison was maintained on a wide range of topics relating to pharmacopoeial matters and nomenclature with various international organisations and authorities and other non-governmental bodies including the World Health Organization (WHO), the Australian Therapeutic Goods Administration Laboratories, the Canadian Health and Food Protection Branch, the United States Pharmacopoeia (USP) and the United States Adopted Names (USAN) Council.

52. As part of the Memorandum of Understanding with the Chinese State Food and Drug Administration (SFDA), work to establish a collaboration agreement between the British Pharmacopoeia and the Chinese Pharmacopoeia (ChP) continued.
53. Collaboration between the International Pharmacopoeia of the WHO and the British Pharmacopoeia continued, with progress being made towards reaching a formal agreement regarding the elaboration of monographs.
54. The BP was invited to participate in the WHO Consultation on Specifications for Medicines and Quality Control Laboratory Issues. Many of the standards included in the International Pharmacopoeia, and the policies employed, are consistent with those in the British Pharmacopoeia.
55. Methods of working with the Indian Pharmacopoeia were considered further, with a view to establishing collaboration on standards.
56. The United States Pharmacopoeia expressed a wish for collaboration with the British Pharmacopoeia. A meeting was held to discuss possible areas for co-operation between the two pharmacopoeias.

ACKNOWLEDGEMENTS

57. Significant input to the work of the British Pharmacopoeia Commission continued to be received from members of staff from the Licensing, Vigilance and Risk Management of Medicines and Inspection, Enforcement & Standards divisions of the Medicines and Healthcare products Regulatory Agency, from the Department of Health, from the National Institute for Biological Standards and Control and from the Veterinary Medicines Directorate.
58. The Commission wishes to express its heartfelt thanks to those members who retired at the end of 2009: Mrs Margaret Dow, Dr Aileen Lee and Professor Peter York. In particular, the Commission wishes to acknowledge the contribution of Dr Lee, who has served for a total of 16 years.
59. The Commission wishes to express its gratitude to all Expert Advisory Group, Panel and Working Party members for the invaluable contribution they have made towards the continuing improvement of standards in the British Pharmacopoeia and to members of the United Kingdom delegation to the European Pharmacopoeia Commission and to UK members of its Groups of Experts and Working Parties who have unstintingly provided time, attention and expertise to the work of that Commission.
60. The Commission also wishes to acknowledge the advice of the publishing team at The Stationery Office in the production of the British Pharmacopoeia 2010 and the British Pharmacopoeia (Veterinary) 2010.

OBITUARY

61. It was with great sadness and regret that the Commission learnt of the death of Dr Betty Jackson. Dr Jackson had been associated with the work of the British Pharmacopoeia for over 20 years and had been a member of the Expert Advisory Group on Herbal and Complementary Medicines and of its predecessor the former Committee on Crude Drugs and Galenicals.

MEMBERSHIP OF THE BRITISH PHARMACOPOEIA COMMISSION DURING 2009

Chair

Professor David Woolfson¹ BSc PhD CChem FRSC FPSNI
Professor of Pharmaceutics, Queens University of Belfast

Members

Professor Graham Buckton¹ BPharm PhD DSc AKC FRPharmS CChem FRSC
Professor of Pharmaceutics, School of Pharmacy, University of London

Professor Donald Cairns¹ BSc PhD MRPharmS CSci CChem FRSC
Associate Head, School of Pharmacy and Life Sciences, Robert Gordon University, Aberdeen

Mr Barry Capon¹ CBE MA DL (Lay representative)
Non-executive Director, Norfolk and Waveney Mental Health NHS Foundation Trust

Professor Alastair Davidson¹ BSc PhD FRPharmS
Visiting Professor of Pharmaceutical Sciences, University of Strathclyde

Mrs Margaret A Dow¹ MSc PhC
Consultant in the registration of biological and biotechnological products

Dr Thomas D Duffy¹ BSc PhD FRPharmS CChem MRSC FCQI CQP MRQA
Director, Lowden International (providing consultancy and training to pharmaceutical organisations)

Mr V'lain Fenton-May² (Vice-Chair) BPharm MIPharmM FRPharmS
Specialist Quality Controller to the Welsh Hospitals

Mr Christopher Goddard¹ BSc DIS CSci EurChem CChem FRSC
Quality Control Manager, Recipharm Limited

Dr Keith Helliwell³ BPharm PhD MRPharmS
Senior Technical Adviser, William Ransom & Son PLC

Dr Rodney L Horder¹ BPharm PhD MRPharmS
Divisional Vice President, European Quality and Regulatory Strategy, Abbott

Dr Aileen M T Lee¹ BVMS PhD MRCVS
Member of the Veterinary Medicines Directorate; Specialism – Regulation of Veterinary Immunological Products

Dr Lincoln Tsang¹ BPharm LLB PhD FRSC FIBiol FRSA FRPharmS Solicitor
Life Sciences Lawyer; Partner, Arnold & Porter LLP

Mrs Josephine Turnbull¹ LLB (Lay representative)
Chairman of Tees, Esk and Wear Valley NHS Trust

Professor Elizabeth Williamson¹ BPharm PhD MRPharmS
Professor of Pharmacy, University of Reading

Professor Peter York¹ BSc PhD DSc FRPharmS CChem FRSC
Professor of Physical Pharmaceutics, University of Bradford

Dr Gerard Lee BPharm PhD FRPharmS MRSC CChem
Secretary and Scientific Director

¹ 1 January 2006 to 31 December 2009

² 1 January 2008 to 31 December 2010

³ 1 January 2008 to 31 December 2011

**MEMBERSHIP OF EXPERT ADVISORY GROUPS, PANELS OF EXPERTS
AND WORKING PARTIES OF THE BRITISH PHARMACOPOEIA COMMISSION
DURING 2009**

Expert Advisory Groups

| | |
|---|---|
| ABS: Antibiotics | R L Horder (Chairman), P York (Vice-Chairman), A Ambrose, A H Andrews, J F Chissell, P Ellis, S Green ¹ , R Harryman, A Livingstone, W Mann, S Patel, B White, I R Williams |
| HCM: Herbal and Complementary Medicines | E Williamson (Chairman), L A Anderson (Vice-Chairman), M Berry, P Bremner, K Chan ¹ , T Chapman, A Charvill, K Helliwell, C Leon, A C Moffat, J D Phillipson, M Pires, J Sumal (<i>Corresponding member</i> B P Jackson ²) |
| MC1: Medicinal Chemicals | A G Davidson (Chairman), D Cairns (Vice-Chairman), M Ahmed, L Anderson ¹ , J C Berridge, M Broughton, A J Caws, P Fleming, W J Lough, D Malpas, G Marco |
| MC2: Medicinal Chemicals | T D Duffy (Chairman), C T Goddard (Vice-Chairman), M Cole, B M Everett, S Jones, M A Lee, J Lim, P Murray, M Turgoose |
| MC3: Medicinal Chemicals | V Fenton-May (Chairman), E Williamson (Vice-Chairman), S Arkle, J F Chissell, C T Goddard, W K L Pugh, R Tomlinson, R Torano, M Tubby, I R Williams |
| NOM: Nomenclature | J K Aronson (Chairman), L Tsang (Vice-Chairman), M Ahmed, P W Golightly, A D McNaught, G P Moss, C Preston, R Thorpe, B Warner ¹ (<i>Corresponding members</i> R G Balocco Mattavelli, E M Cortés Montejano, J Robertson) |
| PCY: Pharmacy | R L Horder (Chairman), A D Woolfson (Vice-Chairman), M Aulton, E Baker, S Branch, G Buckton, G Davison, G Eccleston, D Elder, R Lowe, B R Matthews, J F McGuire, S C Nichols |
| ULM: Unlicensed Medicines | V Fenton-May (Chairman), T D Duffy (Vice-Chairman), I Beaumont, A Charvill, P Forsey, W Goddard, S Jones, M A Oldcorne, A Pandya, N J Precious, J Rothwell, J Smith |

Panels of Experts

| | |
|---|---|
| BIO: Biological and Biotechnological Products | M A Dow (Chairman), L Tsang (Vice-Chairman), A F Bristow, D H Calam, J Cook, J Lawrence, B Mason ¹ , A Onadipe, A M Pickett, S Poole, D Sesardic, P Sheppard, W J Tarbit, J N A Tettey, A H Thomas, R Thorpe |
| BLP: Blood Products | B Cuthbertson, A R Hubbard, S Jenkins, J Lawrence, P Varley |
| IGC: Inorganic and General Chemicals | C T Goddard (Chairman), A C Cartwright, B M Everett, P Henrys, D Malpas, C Mroz, I D Newton |
| MIC: Microbiology | V Fenton-May (Chairman), S Denyer, D P Hargreaves, B R Matthews, P Newby |

RAD: Radioactive Materials

S R Hesslewood, A M Millar, R D Pickett, S Waters

VIP: Veterinary Immunological Products

A M T Lee (**Chairman**), A H Andrews, A M Brady, K Redhead, J Salt, P W Wells

Working Parties

CX: Excipients

G Buckton (**Chairman**), C Mroz (**Vice-Chairman**), E Anno, R Cawthorne, B R Matthews, M I Robertson

¹ Retired during the year

² Deceased, October 2009

MEMBERS OF THE BRITISH PHARMACOPOEIA COMMISSION STAFF DURING 2009

SECRETARY AND SCIENTIFIC DIRECTOR

Dr M G Lee

SECRETARIAT

Mrs M Vallender (Editor-in-Chief)

Mr S Young (Head of Science)

Mrs M Barrett

Mr A Bentley (until February)

Mr A Evans

Miss J Francomb

Mr A Gibb (from July)

Dr P Holland

Dr R A Pask-Hughes

Mr J Pound

Mrs L Schachar (née Caller)

Dr F J Swanson

Mr R L Turner

Mr M Whaley

LABORATORY MANAGEMENT BOARD

Dr M G Lee (Secretary and Scientific Director, BP)

Mr S Young (Head of Science, BP)

Mrs P Robbins (née Webb) (BP Laboratory Team Leader, LGC)

Dr D Craston (The Government Chemist; Director, Research & Technology, LGC)

Mr S Wood (Head of Regulatory and Legislative Services, LGC)

ADMINISTRATIVE

Mr B Delahunty

Mr W Jeffries

Ms D Myburgh

Miss J Paine

BRITISH PHARMACOPOEIA COMMISSION PUBLICATIONS DURING 2009

Publications may be purchased from TSO Publications Centre, from Government Bookshops or from the Pharmaceutical Press.

British Pharmacopoeia 2010 package

Consisting of:

- British Pharmacopoeia 2010
- British Pharmacopoeia (Veterinary) 2010
- CD-ROM/ Online Access (single-user licence, allowing access to three in-year electronic updates)
(Subscription price, £830.00)

British Pharmacopoeia 2010 (Electronic)

- The e-book
(Price £398, available to registered purchasers of the British Pharmacopoeia 2010 only)

Individual BP Monograph (only supplied electronically)

- (Price £200 for the first text, £150 each for the second and third texts)

British Approved Names

- British Approved Names 2007: Supplement No. 3
(Price £14.00)

EUROPEAN PHARMACOPOEIA COMMISSION

UNITED KINGDOM DELEGATION: A D Woolfson (**Head of Delegation**),
V Fenton-May, M G Lee

Alternates: A G Davidson, A M T Lee, M Vallender

MEMBERS OF GROUPS OF EXPERTS FROM THE UNITED KINGDOM DURING 2009:

| | | |
|--------------|---|--|
| Group 1 | Microbiology | V Fenton-May |
| Group 6 | Biological Substances | A F Bristow |
| Group 6B | Human Blood and Blood Products | A R Hubbard |
| Group 7 | Antibiotics | B White |
| Group 9G | Medicinal Gases | M G Lee (Chairman), P Henrys I Beaumont (Specialist) |
| Group 10A | Organic Chemistry (Synthetic Products) | M Broughton |
| Group 10B | Organic Chemistry (Synthetic Products) | S Arkle |
| Group 10C | Organic Chemistry (Synthetic Products) | A J Caws |
| Group 10D | Organic Chemistry (Synthetic Products) | C T Goddard |
| Group 11 | Organic Chemistry (Natural Products) | A G Davidson (Chairman), M Tubby |
| Group 12 | Dosage Forms and Methods | A D Woolfson (until July), R Horder (from July) |
| Group 13A | Phytochemistry A | K Helliwell |
| Group 13B | Phytochemistry B | K Helliwell (Chairman), P Bremner |
| Group 13H | Fatty Oils and Derivatives | R Cawthorne, M Evans (Specialist) |
| Group 14 | Radioactive Compounds | R D Pickett |
| Group 15 | Sera and Vaccines | D Sesardic, S Schepelmann (Specialist) |
| Group 15V | Veterinary Sera and Vaccines | A M Brady |
| Group 16 | Plastic Containers for Pharmaceutical Use | T Hewins |
| Group P4 | Procedure 4 | S Young |
| Group P4 BIO | Procedure 4 for Biologicals | K Chidwick |

MEMBERS OF WORKING PARTIES FROM THE UNITED KINGDOM DURING 2009:

| | |
|---------------------------------------|-------------------------------|
| Alkyl Mesilates | J Midgley (Chairman) |
| Allergens | A Cook |
| Bacterial Endotoxins Test | S Poole |
| Botulinum Toxin | D Sesardic |
| Cell Therapy Products | M O'Kane |
| Bovine Serum | A M T Lee |
| Chromatographic Separation Techniques | S Young |

| | |
|---|---|
| Dialysis Solutions | M G Lee (Chairman) |
| Functionality-related Characteristics | C Mroz |
| Gene Transfer Medicinal Products | S Longhurst |
| Glycan Mapping | C T Yuen |
| Heavy Metals | A Evans |
| Homoeopathic Manufacturing Methods | R A Pask-Hughes |
| Homoeopathic Raw Materials and Stocks | R A Pask-Hughes |
| Inhalanda | S C Nichols, K Truman |
| Inorganic Chemistry | C T Goddard |
| Microbiological Quality of Herbal Drugs | K Helliwell (Chairman) |
| Modern Microbiological Methods | S Denyer |
| Monoclonal Antibodies | R Thorpe (Chairman), P Varley |
| Monocyte Activation Test | L Finlay, S Poole |
| Mycoplasmas | R A J Nicholas |
| Near-Infrared Spectrometry | A C Moffat |
| Nuclear Magnetic Resonance | C Jones |
| Pharmaceutical Preparations | V Fenton-May (Chairman), G Buckton |
| Powder Characterisation Techniques | P York |
| Precursors for Radiopharmaceutical Preparations | J Brain |
| Process Analytical Technology | N Broad |
| Propellants | S C Nichols |
| Rules of Procedure | M G Lee |
| Special Revision Programme | M G Lee |
| Standard Terms | M Ahmed |
| Statistics | R Gaines Das |
| Traditional Chinese Medicines | K Chan |
| Water for Pharmaceutical Use | M G Lee (Chairman) |
| Water for Preparation of Extracts | K Helliwell |

HERBAL MEDICINES ADVISORY COMMITTEE ANNUAL REPORT 2009

INTRODUCTION/BACKGROUND

1. The Herbal Medicines Advisory Committee (“the Committee”) was established under the powers contained in section 4 of the Medicines Act 1968 and the Committee was formally created on 30 October 2005. The functions of the Committee are set out in the Herbal Medicines Advisory Committee Order 2005.

The Herbal Medicines Advisory Committee advises on the safety, quality and efficacy, in relation to human use, of:

- (a) herbal medicinal products eligible for registration under the simplified traditional use registration procedure established under European Directive 2004/24/EC and
 - (b) unlicensed herbal medicinal products (unless it is subject to an application for a marketing authorisation, product licence or a homeopathic certificate of registration).
2. The Committee may also advise on the safety, quality and efficacy, in relation to human use, of herbal medicinal products which have a marketing authorisation, product licence or certificate of registration, or which are the subject of an application for such authorisation, licence or certificate, if Health Ministers or the licensing authority request such advice, or provide the Committee with information relating to that product.
 3. The role of the Committee will concern primarily issues relating to safety and quality, since there is not a requirement for efficacy to be separately demonstrated in relation to registered traditional herbal medicines or unlicensed products sold under section 12 of the Medicines Act. However, efficacy is still relevant – under the traditional herbal registration scheme, the pharmacological effects or efficacy of the medicinal product must be plausible on the basis of long-standing use and experience.

CHAIRMAN/MEMBERS

4. A list of the Committee’s current membership is at **Appendix I**.

SECRETARIAT

5. The Secretariat is based at the Medicines and Healthcare products Regulatory Agency. A list of the Administrative Secretariat is at **Appendix II**.

MEETINGS

6. There were four meetings in 2009. Meetings were held at the Medicines and Healthcare products Regulatory Agency (MHRA), Market Towers, 1 Nine Elms Lane, London SW8 5NQ.
7. Summary minutes of the meetings of the Committee can be found on the MHRA website (www.mhra.gov.uk >Committees >Medicines advisory bodies).

COSTS

8. For each meeting that they attend, Members are entitled to claim an attendance fee of £275 (Chairman's fee £400). Travel and subsistence is also payable within Department of Health guidelines.

TRADITIONAL HERBAL REGISTRATIONS**Applications considered**

9. During the year the Committee considered and advised on six applications for traditional herbal medicinal products.

In May, the Committee considered an application for a traditional and herbal medicinal product for the symptomatic relief of migraine and tension headache. The Committee was also given an oral report on the progress of the review of herbal marketing authorisations.

In July, the Committee considered a traditional herbal medicinal product used to relieve symptoms of minor urinary tract complaints.

In September, the Committee considered a traditional herbal medicinal product used to relieve symptoms of blocked-up sinuses and sinusitis based on traditional use only. The Committee also discussed a traditional herbal medicinal product used to relieve of coughs, such as chesty coughs and dry, tickly, irritating coughs, hoarseness, catarrh and other congestive symptoms, based on traditional use only.

In November, the Committee considered a traditional herbal medicinal product used to relieve cough based on traditional use only. The Committee also discussed a traditional herbal medicinal product used to support kidney function based on traditional use only.

Table 1 lists the number of applications received which are referred to HMAc.

Table 1 Number of Traditional Herbal Registrations

| Year | Number of applications received | Number of applications referred to HMAc | Number of applications approved |
|------|---------------------------------|---|---------------------------------|
| 2006 | 14 | 2 | 1 |
| 2007 | 17 | 4 | 6 |
| 2008 | 20 | 2 | 18 |
| 2009 | 47 | 6 | 22 |

SAFETY ISSUES**Reporting of suspected adverse drug reactions**

10. Suspected adverse reactions to medicinal products including herbal medicines are reported to the Medicines and Healthcare products Regulatory Agency (MHRA) on a voluntary basis by

healthcare professionals, HM Coroners and patients through the Yellow Card Scheme. Reports are also submitted as a legal requirement by companies holding Marketing Authorisations or Traditional Herbal Registrations.

Information collected through the scheme is an important means of monitoring safety, acting as an early warning system for the identification of previously unrecognised adverse reactions and increasing knowledge of known adverse reactions.

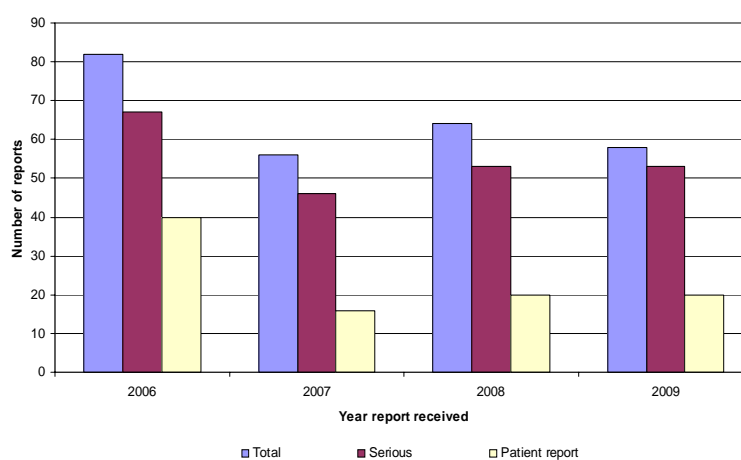
During 2009 the presentation of herbal reports of suspected adverse reactions was revised. All new reports received since the previous meeting were presented but the figures were adjusted to remove reports associated with food products, medical devices, cosmetics and products containing non-herbal ingredients.

Table 2 details the number of Yellow Card reports received in the period 1 January 2006 to 31 December 2009 taking the amendments indicated above into account. This data is also presented in figure 1 below.

Table 2 Reports of suspected adverse reactions

| Year | Total number of reports received | Number of serious reports received | Number of reports received from patients |
|------|----------------------------------|------------------------------------|--|
| 2006 | 82 | 67 | 40 |
| 2007 | 56 | 46 | 16 |
| 2008 | 64 | 53 | 20 |
| 2009 | 58 | 53 | 20 |

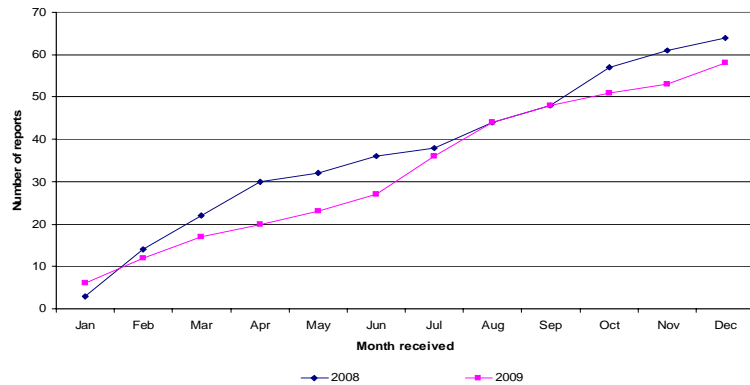
Figure 1 Breakdown of reports received between 2006 and 31 December 2009



The Committee is grateful for the co-operation of those healthcare professionals and patients who submit reports of suspected adverse reactions and encourages the reporting of all suspected reactions to herbal medicines.

A direct comparison of reporting rates for 2008 and 2009 is provided in figure 2 below.

Figure 2 Number of reports received by month for 2008 and 2009



The Committee continues to be concerned about the low level of reporting of herbal adverse reactions. The Agency has launched a multi-media awareness campaign in GP surgeries across the UK, a digital poster is being shown in some GP surgeries, as well as the distribution of over 140,000 Yellow Cards to pharmacies to encourage use of the Yellow Card scheme, particularly by patients.

Safety of marketed products

11. *Aristolochia*

The MHRA instigated work on the scope of the current prohibition on *Aristolochia* species in unlicensed medicines. The Committee gave advice on this work, which is ongoing.

POLICY ISSUES

The traditional herbal registration (THR) identifier

12. During the year the MHRA introduced a certification mark for industry to use with products registered under the THR scheme. The aim was to enable consumers wishing to use herbal medicines to distinguish products which meet the required regulatory standards. The Committee advised MHRA on the introduction of the identifier, and in particular on the inclusion of a prominent explanation of the traditional use basis of the scheme.

Review of Section 12 (1) of the Medicines Act 1968

13. The Department of Health issued a public consultation, on behalf of the four Health Departments, on the issue of whether, and if so how, herbal practitioners, acupuncturists and traditional Chinese practitioners should be regulated. The Committee submitted comments in response. The Committee, since its formation, has been concerned about the limited protection offered to patients by the current regulatory regime under which herbal practitioners operate (section 12(1) of the Medicines Act 1968). The response reflected the Committee's view that it is not realistically possible to deliver substantive improvements in protection through reformed medicines legislation unless and until practitioners are subject to systematic professional regulation and accountability; and that the option of statutory regulation would most effectively deliver the objective of improved public health protection.

MEMBERSHIP OF THE HERBAL MEDICINES ADVISORY COMMITTEE

Chair

Professor Philip A Routledge¹ OBE MB BS MD FRCP FRCPE FBTS

Professor of Clinical Pharmacology, Wales College of Medicine, Cardiff University; Honorary Consultant Physician, Cardiff and Vale NHS Trust

Members

Professor Peter J Aggett² OBE MSc FRCPCH FRCP

Emeritus Professor of Child Health and Nutrition, University of Central Lancashire; Honorary Consultant Paediatrician, Lancashire Teaching Hospitals NHS Foundation Trust

Mr Anthony J Booker³ MRSC MRCHM MBAC

Practitioner of Oriental Medicine, Kent

Dr Robert C G Bracchi³ BSc MB Bch FRCGP

General Practitioner, Abergavenny, Monmouthshire

Ms Alison M Denham³ BA(Soc) FNIMH

Herbal Practitioner and Senior Lecturer in Herbal Medicine, University of Central Lancashire, Preston

Dr Michael R Evans³ MB ChB

Principal in General Practice, St Lukes Medical Centre Stroud; Clinical Teacher in General Practice University of Bristol; Faculty Member, British Postgraduate Training in Anthroposophic Medicine

Dr Shantha B W Godagama³ DAMS MBAC MF(Hom) MAcF FAMA(UK)

Practitioner, Ayurvedic Medicine/Acupuncture; London President, Ayurvedic Medical Association (UK); Director, Ayurvedic Medical Centre, Hale Clinic, London; Board of Directors EHPAAMA (UK)

Mrs Christine A Gratus³ BA MBA

Lay representative

Mrs Agnes Grunwald-Spier⁴ JP BSc(Econ) MA

Lay Representative

Professor Paul Harrison⁵ BSc PhD CBiol FSB FRSA FBTS

Visiting Professor at Cranfield University and Director of PTCH Consultancy Ltd

Professor Gabrielle Hawksworth (Vice-Chair) PhD

Professor of Molecular Toxicology, College of Life Sciences & Medicine, University of Aberdeen

Professor Michael Heinrich³ MA MSc PhD

Professor and Head of Centre for Pharmacognosy & Phytotherapy, The School of Pharmacy, University of London

Mrs Vivienne J Hinks³ BSc(Hons)

Senior Lecturer, School of Health and Wellbeing, University of Wolverhampton; Aromatherapy Practitioner

Dr Steven B Kayne³ BSc PhD MBA LLM MSc DAgVetPharm FRPharmS FCPP MPS(NZ) FNZCP FFHom

Community Pharmacist and Honorary Consultant Pharmacist, Glasgow Homeopathic Hospital

Mr Simon Y Mills⁴ MA MCPP FNIMH

Teaching Fellow, Peninsula College of Medicine and Dentistry/ Herbal Practitioner, Exeter Devon

Dr Barbara A Pendry⁵ PhD BSc(Hons) PG CE MNIMH

Senior lecturer and programme leader for herbal medicine at the University of East London; Mental Health Act Associate Manager at Barnet, Enfield and Haringey Mental Health NHS Trust; Medical Herbalist Consultant Practitioner to Cheryrlodge Cancer Care Ltd

Professor J David Phillipson DSc PhD MSc FRPharms FLS

Emeritus Professor of Pharmacognosy, School of Pharmacy, London University

Professor Raymond J Playford³ MB BS PhD FRCP

Professor of Medicine and Consultant Physician, Barts and the London Hospital Queen Mary, University of London

Ms Deborah J Shaw³ BSc (Hons) Phd

Clinical Scientist/ Research Scientist, Herbal Medicines, Medical Toxicology Unit, Guy's and St Thomas' NHS Foundation Trust

Dr Jidong Wu MB MSc MATCM

Senior Lecturer and Programme Advisor in Traditional Chinese Medicine at Middlesex University

¹ Re-appointed 30 October 2009 to 31 December 2013

² Appointed 3 March 2009 to 2 March 2013

³ Re-appointed 15 December 2009 to 31 December 2013

⁴ End of appointment 14 December 2009

⁵ Appointed 15 December 2009 to 31 December 2012

MEMBERS OF THE COMMITTEE'S SECRETARIAT

Dr Linda Anderson

Principal Assessor

Mr Richard Woodfield

Policy

Mrs Leigh Henderson

Safety

Mr Leslie Whitbread

Unit Manager

Ms Shelina Burch

Secretary

THE INDEPENDENT REVIEW PANEL FOR ADVERTISING ANNUAL REPORT 2009

INTRODUCTION

1. The Independent Review Panel for Advertising ('the Panel') was established in 1999 as a result of a consultation in 1997 on the proposed amendments to the Advertising and Monitoring of Advertising Regulations 1994. The amendments were designed to increase the effectiveness of these regulations, a move which some saw as increasing the MHRA's regulatory powers. In response to these concerns the MHRA introduced a procedure allowing companies to make representations to an Independent Review Panel. Where a company has requested a review, the findings of the Panel have to be taken into consideration before a final decision on a company promotion for a product can be made.

CHAIRMAN/MEMBERS

2. A list of the Panel's membership is at **Appendix I**.

SECRETARIAT

3. The Secretariat is based at the Medicines and Healthcare products Regulatory Agency. A list of the Administrative Secretariat is at **Appendix II**.

MEETINGS

4. There were no meetings held in 2009.

COSTS

5. For each meeting that they attend, Members are entitled to claim an attendance fee of £150 (Chairman's fee £275). Travel and subsistence is also payable within Department of Health guidelines.

MEMBERS OF THE INDEPENDENT REVIEW PANEL FOR ADVERTISING

Chair

Mr Kevin Mooney¹ LLB(Hons)

Partner and Head of Intellectual Property, Simmons & Simmons

Members

Mr John Ferguson² OBE FRPharmS FPS(NZ) HonDSc

Former Secretary and Registrar of the RPSGB, Haywards Close, West Sussex

Dr Surendra Kumar² MBBS DCH FRCGP

Principal in General Practice in Widnes, Cheshire; National President, British International Doctors Association

Dr John Mucklow² MD FRCP

Consultant Physician and Clinical Pharmacologist, University Hospital of North Staffordshire NHS Trust

Dr Jane Richards² OBE MB BS FRCGP D(Obst) RCOG DCH

General Practitioner (Retired)

Dr Nuala Sterling² CBE FRCP

Consultant Physician; Emeritus in Geriatric Medicine, Southampton University Hospitals Trust

Dr Sheila Stevens² PhD MRPharmS

Former Head of Scottish Department of the Royal Pharmaceutical Society of Great Britain; Independent Pharmaceutical Consultant

¹ Appointed 1 October 2009 to 18 August 2011

² End of appointment 30 September 2009

MEMBERS OF THE PANEL'S ADMINISTRATIVE SECRETARIAT

Mr Leslie Whitbread
Unit Manager

Ms Shelina Burch
Secretary

Mr Fred Huckle
Assistant Secretary

THE INDEPENDENT REVIEW PANEL FOR BORDERLINE PRODUCTS ANNUAL REPORT 2009

INTRODUCTION

1. The Medicines for Human Use (Marketing Authorisations, etc) Amendment Regulations 2000 introduced a statutory procedure for deciding whether a product is a “relevant medicinal product” when the licensing authority gives notice that it is minded to determine that a product is a “relevant medicinal product”. The statutory procedure provides an option to a company to seek review of a provisional determination by the Independent Review Panel (“the Panel”). Where a company has requested the review of a decision, the findings of the Panel have to be taken in consideration before a final decision can be made.

CHAIRMAN/MEMBERS

2. A list of the Panel's membership is at **Appendix I**.

SECRETARIAT

3. The Secretariat is based at the Medicines and Healthcare products Regulatory Agency. A list of the Administrative Secretariat is at **Appendix II**.

MEETINGS

4. There was one meeting of the Panel during 2009. The meeting was held at the Medicines and Healthcare products Regulatory Agency (MHRA), Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

COSTS

5. For each meeting that they attend, members are entitled to claim an attendance fee of £150 (Chairman's fee £275). Travel and subsistence is also payable within Department of Health guidelines.

SUMMARY

6. A table showing the number of oral hearings and written representations dealt with by the Panel since its inception is at **Appendix III**. Please note that the figures cover the MHRA's statistical year 1 April-31 March rather than the calendar year.

WRITTEN APPEAL

7. At its only meeting in 2009, the Panel reviewed a written appeal. A product called Skinny Mini had been marketed in the United Kingdom as a dietary or food supplement. The Panel advised that the product was a relevant medicinal product and subject to the provisions of The Medicines for Human Use (Marketing Authorisations, etc) Regulations 1994 (SI 1994/3144) as amended by The Medicines For Human Use (Marketing Authorisations, etc) Amendment Regulations 2000 (SI 2000/292).

MEMBERSHIP OF THE INDEPENDENT REVIEW PANEL FOR BORDERLINE PRODUCTS

Chair

Mr Kevin Mooney LLB(Hons)

Partner and Head of Intellectual Property, Simmons & Simmons

Members

Professor Janet Bainbridge¹ OBE BSc(Hons) PhD MiBiol CBIol FRSA

On secondment to the regional Development Agency, OneNorthEast, as Senior Specialist Advisor Government Europe

Dr Paramjit Gill¹ DM BM DCH MRCP ILTM

General Practitioner; Clinical Senior Lecturer, Department of Primary Care and General Practice, University of Birmingham

Dr Shantha Godagama¹ DAMS MBACC MF(HOM) MACF FAMA (UK)

President Ayurvedic Medical Association UK; President, General Council for Ayurveda; Founder Dean, College of Ayurveda UK, Director, Ayurvedic Medical Centre at the Hale Clinic, London

Mr Christopher Hedley¹ AHG

Private Practice as Medical Herbalist in London; Lecturer and Clinic Tutor at Westminster University; Lecturer at the Scottish School of Herbal Medicine; Advisor to London Community Herbalists; Member of THEN; Member of the Herb Society

Professor Peter Houghton¹ BPharm PhD FRPharmS FRSC Cchem

Professor of Pharmacognosy, Department of Pharmacy, Kings College London

Mrs Kiran Kumar¹ BSc MSc

Lay representative

Dr Surendra Kumar¹ SB St J MBBS DCH FRCGP

Principal in General Practice in Widnes, Cheshire; National President, British International Doctors Association (ex CSM member)

Dr Pamela Mason¹ BSc(Hons) MSc PhD MRPharmS

Journalist and Freelance Pharmaceutical and Nutritional Writer and Consultant

Mr Michael McIntyre¹ MA FINIMH FRTCHM MBAC

Chairman of the European Herbal Practitioners Association; Trustee of the Prince of Wales Foundation for Integrated Health; External Examiner for the University of Westminster

Dr Namasivayam Sathiyamoorthy¹ DAMS DAc PhD FAMA(UK)

Consultant at several Ayurvedic Medical Clinics; Director of the Eastern Clinic, Natural Medicine Centre, Tooting; Consultant at Kankus Clinic, Harley Street; Founder General Secretary of the Ayurvedic Medical Association UK

Mr Ian Smith¹ BSc MSc MIFPA

Aromatherapist and Former Chairman of the International Federation of Professional Aromatherapists

Dr Jidong Wu¹ MB MSc MATCM

Senior Lecturer and Programme Advisor in Traditional Chinese Medicine at Middlesex University

Mr Brian D Yates¹ MA MSc FRSA

Chairman, Consumers' Association and Which?; Member, General Medical Council Fitness to Practise Panels; Member Immigration Appeal Tribunal

¹ **End of appointment 31 March 2009**

MEMBERS OF THE PANEL'S ADMINISTRATIVE SECRETARIAT

Mr Leslie Whitbread

Unit Manager

Ms Shelina Burch

Secretary

Mr Fred Huckle

Assistant Secretary

Number of Hearings

| Year | Cases Heard | Oral Hearings | Written Hearings |
|--------------|-------------|---------------|------------------|
| 2009/10 | 0 | 0 | 0 |
| 2008/9 | 1 | 0 | 1 |
| 2007/8 | 4 | 3 | 1 |
| 2006/7 | 2 | 1 | 1 |
| 2005/6 | 3 | 0 | 3 |
| 2004/5 | 3 | 1 | 2 |
| 2003/4 | 3 | 3 | 0 |
| 2002/3 | 15 | 10 | 5 |
| 2001/2 | 16 | 0 | 16 |
| Total | 47 | 18 | 29 |

Results of Hearings

| Year | Cases Heard with MHRA | Panel Concurred with MHRA | Panel Disagreed | Cases Adjourned |
|--------------|-----------------------|---------------------------|-----------------|-----------------|
| 2009/10 | 0 | 0 | 0 | 0 |
| 2008/9 | 1 | 1 | 0 | 0 |
| 2007/8 | 4 | 4 | 0 | 0 |
| 2006/7 | 2 | 1 | 1 | 0 |
| 2005/6 | 3 | 3 | 0 | 0 |
| 2004/5 | 3 | 3 | 0 | 0 |
| 2003/4 | 3 | 3 | 0 | 0 |
| 2002/3 | 15 | 15 | 0 | 0 |
| 2001/2 | 16 | 15 | 1 | 0 |
| Total | 47 | 45 | 2 | 0 |

CODE OF PRACTICE FOR CHAIRMEN AND MEMBERS OF THE COMMISSION ON HUMAN MEDICINES, CERTAIN SECTION 4 COMMITTEES AND EXPERT ADVISORY GROUPS

1. INTRODUCTION

- | | |
|-----------------------------------|---|
| Purpose of the Code | 1.1 This Code of Practice sets out the rules to be followed by chairmen and members of advisory committees holding and declaring interests in the pharmaceutical industry. The Code of Practice also provides guidance on holding and declaring other relevant interests, and on how interests that have been declared will be managed. The Code applies to chairmen and members of all the statutory committees and Expert Advisory Groups (EAGs) established to contribute advice to the Licensing Authority on the regulation of medicines available on the UK market. Separate rules apply to the British Pharmacopoeia Commission (BPC) because of their different role and remit. |
| Importance of impartiality | 1.2 Ministers expect the advice they receive on matters relating to the regulation of medicines to be impartial. Ministers also expect to be able to seek such advice from a wide range of highly skilled professionals who are senior and well regarded in their respective fields. Many experts in the field of medicines have, or have had, connections with the pharmaceutical industry and other commercial organisations whose business may be considered relevant to their work on the advisory bodies but may have an impact on their impartiality. For example, the University department for which an individual is responsible may have received a research grant from industry, or the individual may have shareholdings from previous industry employment. |
| | 1.3 To reassure Ministers and the public that the advice on which decisions about medicines is based is impartial, it is important to have in place a robust policy governing the declaration and management of relevant interests. In the interests of transparency and accountability, this Code of Practice, the declarations made by chairmen and members of the various committees, and the actions taken to manage potential conflicts of interest are made public. In addition, where an individual has declared in advance of a meeting an interest that would exclude him or her from the relevant discussions, this information will be used by the secretariat to ensure that, wherever possible, the relevant committee papers are not sent to that individual. |

2. SCOPE

- | | |
|---|---|
| Committees and groups to which this Code applies | 2.1 The Code of Practice applies to the chairmen and members of the following committees and groups: <ul style="list-style-type: none"> • Commission on Human Medicines (CHM) • The following Section 4 committees: <ul style="list-style-type: none"> - Herbal Medicinal Products Committee (HMPC) |
|---|---|

- The Advisory Board on the Registration of Homoeopathic Products (ABRH)
- The Expert Advisory Groups (EAGs) established by the CHM and/or the Section 4 committees

2.2 This Code of Practice does not apply to the British Pharmacopoeia Commission (BPC), which is also a section 4 committee but does not advise Ministers directly. A separate Code has been developed for the BPC to take account of their different role and remit.

3. DEFINITIONS

3.1 For the purposes of this Code of Practice, the following definitions apply:

Pharmaceutical Industry

3.2 "Pharmaceutical industry" means:

- Companies, partnerships or individuals who are involved with the manufacture, sale or supply of medicinal products, including herbal medicinal products and homeopathic products
- Trade associations representing companies involved with such products
- Companies, partnerships or individuals who are directly concerned with research, development or marketing of a medicinal product, including herbal medicinal products and homeopathic products which is being considered by the CHM or by one of the Section 4 committees or Expert Advisory Groups.

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

Immediate family

3.3 "Immediate family" means:

Spouse or partner and members of the family living in the same household. Members of the family include dependent children, any adult children or other relative (such as parent) living in the same household.

4. INTERESTS WHICH NEED TO BE DECLARED

Summary of interests that need to be declared

4.1 It is the responsibility of each individual to identify and to declare all relevant interests. The following types of interest must be declared by chairmen and members of all committees and groups:

- Their own financial interests in the pharmaceutical industry; (financial interests are either personal or non-personal, and either specific to the product being discussed, or non-specific);
- Financial interests in the pharmaceutical industry held by members of their immediate family;

- Any other matter that could affect their impartiality, or that could reasonably be perceived as affecting their impartiality. Some examples of interests that are relevant in the context of this Code of Practice, not all associated with the pharmaceutical industry, are set out in section 4.7 below.

4.2 The following paragraphs describe in more detail the types of interests that must be declared. The procedures for handling interests that have been declared are described in Section 7.

Personal interests

4.3 A personal interest in the context of this Code, involves the payment, in any form, to an individual personally, by a pharmaceutical company whose business may be directly affected by the advice of the advisory body. At a meeting, personal interests must be declared as **specific** (that is, payment relates to a particular product under consideration), or as **non-specific** (that is, not related to the particular product under discussion). The following main examples of interests to be declared should not be regarded as a definitive list, and the Medicines and Healthcare products Regulatory Agency (MHRA) secretariat to each committee will advise if a chairman or member is in any doubt.

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

Fee-paid work: any work commissioned by the pharmaceutical industry for which the individual is paid in cash or kind;

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

Expenses/ hospitality provided by a pharmaceutical company: special rules apply to attendance at conferences or similar events. These are covered in paragraphs 4.8 et seq. below;

Unit trusts and similar: Assets over which chairmen and members and/or their immediate family have no financial control (such as holdings in a wide share portfolio -Unit Trust or similar – where the Fund Manager has full discretion over the composition of the portfolio) do not need to be declared. However, funds held in a portfolio in which chairmen and members and/or their immediate family have the ability to instruct the Fund Manager as to the composition of the fund must be declared.

Pension entitlement: Accrued pension rights from earlier employment in the pharmaceutical industry do not need to be declared.

Personal interests – special rules applicable to the CHM and certain Section 4 committees

4.4 The chairman and members of the CHM, HMAc and ABRH serve on the committees that provide advice direct to the Licensing Authority. For this reason, they are not permitted to hold any current personal interests in the pharmaceutical

industry. This policy also applies to the chairmen of the Pharmacy and Standards EAG, the Pharmacovigilance EAG and the Biologicals and Vaccines EAG by virtue of their membership of the CHM. The chairmen and members of the CHM and the chairmen and members of the HMA and ABRH, and the chairmen of the three EAGs specified are required to make a declaration on appointment that they are disposing / have disposed of any such current personal interests.

- 4.5 The chairmen and members of these committees have three months from the date of appointment to dispose of any current personal interests in the pharmaceutical industry. During this period, they are required to declare any relevant current personal interests at meetings and to exclude themselves from discussion on the relevant product(s) and abstain from any vote.

Non-personal interests

- 4.6 A non-personal interest in the context of this Code, involves payment that benefits a department for which an individual is responsible, but is not received by the member personally. As with personal interests, non-personal interests at a meeting must be **specific** or **non-specific**. The main examples that follow should not be regarded as a definitive list, and the advice of the committee secretariat provided by the MHRA should be sought if a chairman or member is in any doubt.

Fellowships: the holding of a fellowship endowed by the pharmaceutical industry or any other relevant industry;

Support by the pharmaceutical industry or any other relevant industry: any payment, other support or sponsorship by the pharmaceutical or other industry that does not convey any pecuniary or material benefit to the individual personally but that benefits his/her position or department;

Grants from a company: for example, for the running of a unit or department for which an individual is responsible;

Grants or fellowships to sponsor a post or staff member in the unit for which the individual is responsible: this does not include financial assistance given to individual students;

Commissioning of research or other work or advice from staff who work in a unit for which the individual is responsible.

Other relevant interests

- 4.7 It is not only financial interests in the pharmaceutical industry that are relevant. A wide range of other matters may also be considered to be relevant, depending on the circumstances and matters under consideration by a committee on which an individual serves, and could include non-financial interests. There are no hard and fast rules concerning "other" interests that need to be declared. In considering whether an interest is relevant and therefore should be declared, the guiding principle must be whether the matter might reasonably be perceived as affecting a member's impartiality. Some examples of matters that might fall under this heading are set out below. These are not exhaustive and individuals should always seek advice from

the MHRA Secretariat if they are in any doubt about whether or not a matter is relevant:

- An individual, or his department, has done research work relating to a particular product, or class of products. Although the research has not been funded by any particular pharmaceutical company, the research has taken a particular line e.g. in relation to the safety of the products, or their efficacy;
- An individual has made public statements (either favourable or unfavourable) about a particular company, or product, or class of products or about a competitor's product or class of product;
- The relevant committee is considering whether a product should be reclassified e.g. from prescription only, to a pharmacy medicine, and the individual has a particular interest in the reclassification being made e.g. because he is a retail pharmacist and he will benefit financially;
- An individual participates in, or is connected with, a charity or pressure group that would have an interest in the outcome of the advice being given;
- An individual has a family member who suffers from an illness who would benefit from treatment if a product under discussion were to be authorised;
- An individual has a family member who has suffered a severe reaction or other problem as a result of treatment with a product under discussion;
- Matters relating to persons who are not immediately family members, but are closely connected with the committee expert e.g. adult child no longer living in the same household, or non-family member whose work or other interests are closely associated with the pharmaceutical industry and which could reasonably be perceived as affecting the individual's impartiality. An example might be where a committee is giving advice in relation to a product and a close family member or friend has had a major development responsibility for that product;
- Interests in a company manufacturing the delivery system (e.g. syringes or other medical equipment) for a particular medicinal product;

**Attendance at conferences,
scientific meetings and
similar**

- 4.8 Government recognises that it is usual for conferences, scientific meetings and other events associated with healthcare, medicines or related matters to receive some form of sponsorship either directly, or indirectly via a special fund, from the pharmaceutical industry. Government also recognises the importance of being able to receive advice from leading experts who are able to keep themselves up to date with developments at the cutting edge of science, and that this is mainly done through attendance at educational and scientific events and meetings. It is therefore essential to set out rules for attendance at these and similar events as questions may be legitimately

raised as to whether participation in the event, or even mere attendance, will compromise their impartiality in any way. This is particularly important in respect of chairmen and members of the CHM and Section 4 committees, (including the chairmen of the Pharmacy and Standards EAG, the Pharmacovigilance EAG and the Biologicals and Vaccines EAG) who, as set out above, are not permitted to hold personal interests in the pharmaceutical industry.

- 4.9 The nature of the events that fall within the scope of this Code of Practice and the industry sponsorship received can vary widely from, at one extreme, a conference sponsored by a single company to launch a product to, at the other extreme, a scientific meeting organised by a learned society that has received some financial support from a number of companies paid into a dedicated meeting fund. Between these extremes there are many variations in events and funding that may occur.
- 4.10 In order that the chairmen and members of CHM, HMAc, ABRH and the three EAG chairmen specified in paragraph 4.8 above, should be able to attend appropriate scientific events to keep their knowledge up to date, the MHRA has established a discretionary fund to meet the reasonable expenses (e.g. travel and accommodation costs) incurred in their attendance. The relevant MHRA committee secretariat will administer the fund, and chairmen and members wishing to claim the costs of attendance at such events must make an application in good time to enable appropriate travel and other arrangements to be made. The fund will cover educational events that are relevant to maintaining the expertise of individuals serving on the CHM, HMAc, ABRH and the three specified EAGs, where acceptance of financial support from industry (for example a single pharmaceutical company) would not be appropriate. Separate guidance on the allocation of resources from the fund has been developed for use by the MHRA secretariat.
- 4.11 In some cases it will be permissible for members of CHM, HMAc, ABRH and these three EAG chairmen to attend events sponsored by the pharmaceutical industry (and accept the payment of their expenses) without recourse to the MHRA discretionary fund. For example, where a learned society holds an international conference that is sponsored by a number of different pharmaceutical companies, it will generally be acceptable for the member to accept such an invitation and to receive payment of expenses, although in such instances declaration of attendance and receipt of funding must be declared in the normal way.
- 4.12 If funding and/or expenses are paid specifically for an individual's attendance but nevertheless paid to his department rather than the individual himself, it will not normally be acceptable for the individual to attend.
- 4.13 Benefits of this nature paid to an immediate family member that also benefit the committee chairman or member (e.g. a company pays his or her flight costs so that he or she can attend a conference with a family member) must be declared as the individual's own interest. However, there is no requirement to declare educational conferences and similar events attended by immediate family members.

- 4.14 If an individual attends an educational conference or similar, he or she should avoid participation in, for example, “satellite” meetings sponsored and arranged by specific companies or focusing on specific products where involvement in discussions might reasonably be perceived as affecting his or her impartiality. If in doubt, this must be raised with the MHRA Secretariat at the earliest possible opportunity, who will be able to provide further guidance.
- 4.15 The rules for holding personal interest in the pharmaceutical industry do not apply to chairmen and members of EAGs, apart from chairmen of the 3 EAGS described at paragraph 4.8 above, and for the reasons set out in paragraph 4.4 above. Therefore, these experts may attend meetings sponsored by the pharmaceutical industry and accept funding of expenses, but these must be declared.
- 4.16 Attendance at conferences, scientific meetings and other events relevant to this Code must be declared at the first meeting of the committee after the event has taken place. This declaration may affect an individual’s participation in discussions over the subsequent months. The declarations will be published annually in the report of the work of the committees.
- 4.17 The situations described are not exhaustive and individuals should always seek advice from the MHRA Secretariat if they are in any doubt about whether or not they should attend, or whether, having attended, they need to declare attendance as an interest.
- 5. SPECIAL POSITION OF EXPERTS ATTENDING FOR THE DAY AND EXPERTS CALLED TO ADVISE THE COMMITTEES ON SPECIFIC ISSUES**
- 5.1 Experts who are invited to attend committees for the day, for example if a regular member cannot be available or cannot participate in discussions because of his or her interests, are known as “Experts for the Day”. They are co-opted as full members of the committee for that day, may participate fully in all discussions and may vote. They are therefore required to make a full declaration of interests in the same way as is required of a full member of that committee. Experts called to advise a committee on particular issues may not hold interests in the issue under discussion.
- 6. DECLARATION OF INTERESTS**
- 6.1 Chairmen and members are required to make a full declaration of interests on appointment and annually. They must also inform the MHRA secretariat promptly of any changes or updates to the terms of their declaration during the year. This includes reporting promptly attendance at events described in paragraphs 4.8 - 4.17. If an individual is uncertain as to whether or not an interest should be declared, he or she must seek guidance from the MHRA secretariat. Chairmen and members are also required to make further declarations of relevant interests at meetings when they will be advised as to the procedure that will apply.

- Annual declaration**
- 6.2 The annual declaration must include all the financial (personal and non-personal) interests in the pharmaceutical industry of the chairmen and members currently held or held in the last 12 months and financial interests in the pharmaceutical industry that they know of that are held by their immediate family. Members and chairmen are also required to include in the annual declaration details of any other matter which could reasonably be regarded as affecting their impartiality.
- 6.3 The declaration of certain interests will not be restricted to the last 12 months. For example, an individual's significant involvement in the development of a particular product will need to be declared each year as well as at relevant meetings, and may restrict that individual's participation in some discussions.
- 6.4 The chairmen and members' declaration of their own interests will identify them with the interests declared, but the interests declared do not need to be quantified. For example, in declaring a grant received by a department for which the individual is responsible, only the company name is required, not the value of the grant.
- 6.5 When the annual declaration includes matters relating to other persons, names are not required, nor do the interests declared need to be quantified. For example, in declaring shareholdings only the company name is required, not the numbers or values of shares held. Family members should be referred to simply as: "immediate family member" and closely connected persons as "other person". In nearly all circumstances this will protect the anonymity of those whose interests must be declared by the serving committee member, although we recognise that in very exceptional circumstances it may be possible for that individual to be identified.
- 6.6 The annual declaration made by all chairmen and members of all the CHM, the Section 4 committees and EAGs will be published each year in the Annual Report of the Advisory Bodies.

Declarations at meetings

- 6.7 Chairmen and members are required to declare relevant interests at meetings, whether or not those interests have previously been declared to MHRA. The type of interest must be declared, that is, whether it is personal or non-personal, specific or non-specific or other.
- 6.8 If an issue arises for discussion and an individual is concerned about a matter that could be regarded as affecting his or her impartiality and this matter has not already been declared, he or she must raise this with the MHRA secretariat in advance of the meeting if possible. This will enable the secretariat, wherever possible, to ensure that he or she is not sent any papers concerning issues on which the individual cannot be regarded as impartial. Where it has not been possible to identify such issues in advance, the individual must raise the issue with the MHRA secretariat or the chairman as early as possible before the meeting takes place, and in any event before discussion of the relevant agenda item. The chairman of the committee is responsible for taking the decision on how declared interests should be handled.

7. PARTICIPATION IN DISCUSSIONS WHEN AN INTEREST HAS BEEN DECLARED

7.1 “Taking part in discussions” means speaking at meetings or voting. Where an individual is not to take part in a discussion, he or she should leave the room before the discussion commences, and return only when that agenda item is complete.

7.2 The following paragraphs describe, for each category of interests declared, the actions to be taken.

Personal Interests

7.3 A **personal specific interest** will have been declared if an individual has worked on the product under consideration and is receiving or has received payment for that work. As a general rule, the individual will normally not be allowed to take part in discussions as they relate to that product, except where the Chairman exercises his discretion (which will be rarely exercised) to answer questions from other members. A significant involvement in the development of a product will usually debar an individual from ever participating in discussion on that product. A less significant involvement, or less specific work with or on a product, may not permanently debar an individual, but such decisions will need to be taken on a case by case basis, taking account of the nature of the involvement, its specificity and when the work was undertaken.

7.4 If an individual has declared a **personal non-specific interest** the individual must take no part in discussions on that agenda item, except at the Chairman’s discretion to answer questions from other members. If the personal non-specific interest relates to shares that have been disposed of, the individual will generally be permitted to take part in discussions once three months have elapsed from the date of the disposal of them. If the personal non-specific interest relates to other matters, such as a payment received from a pharmaceutical company, the individual will generally be permitted to take part in discussions once 12 months has elapsed from the date of receipt of payment. However, in some cases it will not be appropriate for the individual to take part even though 12 months have elapsed – for example, where he has an ongoing consultancy or other financial relationship with the pharmaceutical company.

7.5 If the individual has declared a personal interest in relation to a member of his or her immediate family, he or she should similarly take no part in discussions except at the Chairman’s discretion to answer questions from other members. Such interests may range from a family member’s major role in the development of a product under consideration to a family member’s shareholdings.

Non-Personal Interests

7.6 A **non-personal specific interest** will have been declared if the department for which the individual is responsible is currently receiving payment in respect of work done on the product. The individual will generally not be able to take part in proceedings where a department for which he has responsibility has carried out specific work on the product under discussion.

7.7 A **non-personal, non-specific interest** will not normally debar an individual from taking part in discussions, unless exceptional

circumstances arise in which it is not appropriate for them to do so.

7.8 If an individual declares non-personal interests of an immediate family member, this will not generally prevent him or her from taking part in discussions.

Other Interests

7.9 If an individual has declared an interest which does not fall within one of the categories described, but which he or she considers could be perceived as affecting his or her impartiality, whether that individual will be permitted to take part in discussions will depend upon the circumstances. In some cases, it will be sufficient for the individual to declare the interest, so that others taking part in the discussion are aware of his or her interests and can view his or her contribution in that light. An example might be where a member owns retail pharmacies and the discussion addresses the classification of a product from prescription to non-prescription status. In other circumstances it may not be appropriate for an individual to take any part in discussions, except at the chairman's discretion to answer questions from other members. The chairman and/or the MHRA Secretariat will advise on these matters. The chairman of the committee is responsible for taking the decision on how declared interests should be handled.

Rival Products

7.10 It is important to remember that not only the company whose application is being considered will be affected by the advice that is given by advisory bodies – companies who make competitor products may also be affected.

7.11 If a product is being discussed and an individual is aware that he or she has an interest in a company which markets a rival product, the business of which will directly benefit or suffer as a result of the advice that is given, the individual must declare that interest at the meeting. An example might be where an application for a generic product is being considered and the individual holds an interest in the current brand-leader, or where a new active substance is under consideration that will directly affect the market of another company for a similar product in which an individual has an interest. Whether the individual will be permitted to take part in discussions will depend upon the circumstances and the extent to which the business of the competitor is likely to be affected

7.12 There is no requirement to carry out specific research to identify issues such as these – individuals need only to declare interests of which they are aware.

Consideration of Classes of Products

7.13 If an advisory body is considering issues relating to a class of products, the issue of interests remains relevant. Individuals must still declare interests in the usual way. Whether they will be permitted to take part in discussions will depend upon the circumstances, including the class of products being considered, the nature of the advice being given.

8. RECORD OF INTERESTS

8.1 A record is kept in the MHRA of:

- names of chairmen and members who have declared interests on appointment, when an interest first arises or through the annual declaration, and the nature of the interest;
- names of chairmen and members who have declared interests at meetings of the CHM, Section 4 Committees and EAGs, giving dates, names of relevant products and companies, details of the interest declared and whether the individual took part in the proceedings.

9. PUBLICATION

9.1 Interests declared to the MHRA by chairmen and members of all committees, including EAGs, will be published each year in the Annual Reports of the CHM and Section 4 Committees (normally published in July).

9.2 Interests of immediate family and other closely connected people declared by chairmen and members will be included in the Annual Reports. This information will provide only the name of the committee chairman or member, the source of the interest (e.g. the company name), will not provide any financial information nor numbers (e.g. for shares) nor identify the family member or other holding the interest by name.

COMMISSION ON HUMAN MEDICINES: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|----------------------------|--------------------|--------------------|--|--|---|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Sir Gordon Duff (Chair) | None | None | None | None | |
| Professor Deborah Ashby | None | None | GlaxoSmithKline Sanofi-Aventis Pfizer Limited F Hoffmann-La Roche AG Novartis Pharma AG Amgen NV Genzyme Europe BV Merck KGaA Bayer Schering Pharma AG AstraZenca A/S Novo Nordisk A/S | Methodological collaboration Methodological collaboration Methodological collaboration Methodological collaboration Methodological collaboration Methodological collaboration Methodological collaboration Methodological collaboration Methodological collaboration Methodological collaboration Methodological collaboration | Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes |
| Dr Barbara Bannister | None | None | None | None | |
| Mrs Alison Bowser | None | None | Valeant Pharma | Consultancy for public events | No |
| Professor Derek Calam | None | None | None | None | |
| Professor Janet Darbyshire | None | None | Amgen AstraZenca | Neupogen: support for drug GM-CSF: discounted drug direct to sites; educational grant Cediranib: drug and placebo; unrestrictive grant; provision of CRO for distribution and randomization | Yes Yes |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|-----------------------------------|--------------------|--------------------|------------------------|--|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Professor Janet Darbyshire (cont) | | | Bayer | Sorafenib: support for drug; logistical support; educational grant Moxifloxacin: support for drug costs and possibly trial costs | Yes |
| | | | Baxter | Support for reduced price pumps | Yes |
| | | | ITGI (Schering-Plough) | Pegylated Interferon (alpha-2b): support for drug Docoirubicin: support for drug Temozolomide: free drug; educational grant | Yes |
| | | | Lilly | Gemcitabine: support for drug | Yes |
| | | | Merck | Topotecan: support for drug | Yes |
| | | | Merck Serono | Raltegravir: support for drug Cetuximab: support for drug; an educational grant to fund clinical trial and associated translational research | Yes |
| | | | Novartis | Zoledronic Acid: support for drug; educational grant IL-2: support for drug | Yes |
| | | | Pfizer | Celecoxib: support for drug; logistical support; educational grant Colorectal Trials Portfolio: support for clinical trials (£15,000 awarded for 2009/2010) | Yes |
| | | | Pierre Fabre | Navelbine: discounted drug | Yes |
| | | | Roche | Loron 520: support for drug; educational grant | Yes |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|-----------------------------------|--------------------|--------------------|---|--|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Professor Janet Darbyshire (cont) | | | Roche (cont) | Bevacizumab: support for drug; unrestricted grant; provision of CRO for monitoring, database and drug distribution; grant for TR sample collection; educational grant for cardiac monitoring and per patient payments to sites Capecitabine: support for drug Bevacizumab: funding to purchase drug DNase: support for drug and trial costs | |
| | | | Sanofi-Aventis | Docetaxel: discounted drug; educational grant Rifafour: support for drug only Rifampicin: support for drug only Rifapentine: support for drug only | Yes |
| | | | Abbott | Kaletra, Aluvia: financial support for virology work in DART; drug support terminated in September 2009 | Yes |
| | | | Boehringer Ingelheim | Nevirapine: support for drug; financial support (terminated in December 2009) | Yes |
| | | | Boehringer Ingelheim/ Bristol-Myers Squibb | Efavirenz, Atripla: support for drug; financial support and small virology substudy Chapas 1 | Yes |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|-----------------------------------|--------------------|--------------------|---|--|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Professor Janet Darbyshire (cont) | | | Cipla | Lamivir-S, Pedimune: support for drug (terminated in September 2009) | Yes |
| | | | Gilead Sciences | Tenofovir, Emtricitabine, Atripla: support for drug and financial support | Yes |
| | | | Gilead/ Tibotec, a division of Janssen-Cilag Ltd/ Roche | Financial support for resistant database | Yes |
| | | | GlaxoSmithKline | Abacavir, Zidovudine, Lamivudine: support for drug; financial support | Yes |
| | | | | Indevus PRO2000: support for drug | Yes |
| | | | Sanofi Pasteur | NYVAC C: support for vaccine | Yes |
| | | | Tibotec | Darunavir: support for drug | Yes |
| | | | Virco | Resistance-tests: support for assays | Yes |
| Professor Henry Dargie | None | None | Insys Therapeutics Inc | Tetrahydrocannabinol: support for drug; collection and analysis of safety blood samples; salary and associated expenses of a study monitor | Yes |
| | | | Svizera Europe | Isoniazid: support for drug Ethambutol: support for drug Pyrazinamide: support for drug Pyridoxine: support for drug | Yes |
| | | | Cell Gene | Safety Monitoring Committee | Yes |
| | | | Novartis | Safety Monitoring Committee | Yes |
| | | | Cardiokine | Safety Monitoring Committee | Yes |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|---|--------------------|--------------------|---|---|--|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Dr Michael Donaghy | None | None | None | None | |
| Dr Colin Forfar | None | None | None | None | |
| Professor Peter Helms | None | | None | None | |
| Ms Amanda Hoey | None | None | None | None | |
| <p>Additional information: My partner is employed by the BMJ Group as Director of BMJ Learning. BMJ Group (including the BMJ Learning department) receives revenue from a range of sources, including from pharmaceutical companies. Revenue from pharmaceutical companies is received through: Subscriptions to BMJ Group products (eg journals); Display advertising for pharmaceutical (and non-pharmaceutical) products; Sponsorship (eg for journal supplements); Events (eg exhibitor fees, sponsored symposia at BMJ Masterclasses); Sales of article reprints; Syndication and license fees; Unrestricted educational grants (eg to give free access to BMJ Learning modules to other groups of users); Commissioning fees for customised content (eg fees for customised learning modules); Usage fees for hosting BMJ Group content on other websites. The BMJ Learning department is governed by the BMJ Groups advertising and sponsorship policy. The BMJ Group sets high ethical standards in all its activities and above all defends the right to editor.</p> | | | | | |
| Professor Martin Kendall | None | None | None | None | |
| Professor Antony Nunn | None | None | None | None | |
| Professor Kevin Park | None | None | Pfizer AstraZeneca Novartis GSK | Non-specific Non-specific Non-specific Non-specific | Yes Yes Yes Yes |
| Professor Maggie Pearson | None | None | None Xenobiotica Journal AstraZeneca GlaxoSmithKline Pfizer Commission of the EU (FP6) British Toxicology Society | None Associate Editor Research funding Research funding Research funding Research funding Secretary to the Education Subcommittee | Yes Yes Yes No No Yes |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|----------------------------|--------------------|------------------------------------|--------------------------------------|---|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Professor Munir Pirmohamed | None | None | GSK | Attended a meeting but cost met by MHRA | No |
| Dr Rosalind Ranson | None | None | None | None | |
| Carolyn, Lady Roberts | None | None | None | None | |
| Professor Rosalind Smyth | None | None | GlaxoSmithKline Plc | Grant for member in Department | Yes |
| | | | Auralis | As above | Yes |
| | | | CDSS | As above | Yes |
| | | | Pharmaceutical Service Network (PSN) | As above | Yes |
| | | | Pharmalys | As above | Yes |
| | | | Quay Pharmaceuticals | As above | Yes |
| | | | Shire Human Genetic Therapies | As above | Yes |
| | | | Takeda Global R&D Centre (Europe) | As above | Yes |
| | | | Therakind | As above | Yes |
| | | | Walker Graham Pharma Consulting | As above | Yes |
| Dr Angela Thomas | None | None | None | None | |
| Professor Simon Thomas | Lundbeck | Consultancy (ended September 2009) | Boehringer Ingelheim | Non-personal research grant | Yes |
| | | | AstraZenca | Non-personal research grant | Yes |
| | | | PPD | Non-personal research grant | Yes |
| | | | Servier Research and Development | Non-personal research grant | Yes |
| | | | GlaxoSmithKline | Non-personal research grant | Yes |
| | | | Baxter | Non-personal research grant | Yes |
| | | | EUSAPharm | Non-personal research grant | Yes |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|---|--------------------|--------------------|------------------------------|---|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Professor Simon Thomas (cont) | | | Symphogen A/S | DMC chair (charged to Newcastle University) | Yes |
| | | | MDS Pharma Services | As above | Yes |
| | | | Hoffmann-La Roche | Non-personal research grant | Yes |
| | | | Bristol-Myers Squibb Company | Non-personal research grant | Yes |
| Professor Roger Walker | None | None | None | None | |
| Additional information: I do place on record the fact that my wife is a community pharmacist and works for Boots. | | | | | |
| Professor Ian Weller | None | None | Roche | * | Yes |
| | | | GSK | * | Yes |
| | | | Merck | * | Yes |
| | | | Pfizer | * | Yes |
| | | | Boehringer Ingelheim | * | Yes |
| | | | Gilead | * | Yes |
| | | | Abbott | * | Yes |
| | | | BMS | * | Yes |
| *I am co-chair of an Oversight Committee which oversees a large programme of research on the side effects of HIV drugs. This effort was initiated by the EMEA in 1999. This programme is funded by all these companies and funds are handled by a contract research organisation (CRO) from which my honorarium is paid and then paid into a department fund and not kept personally. My travel, hotel accommodation and meals are also covered by the CRO. | | | | | |
| Professor Faith Williams | None | None | AstraZeneca | Research funding | Yes |
| | | | Nycomed | Research funding | No |
| | | | Pfizer | Research funding | No |

ANTI-INFECTIVE, HIV AND AIDS EXPERT ADVISORY GROUP: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|------------------------------|---------------------|--------------------|------------------------|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Dr Barbara Bannister (Chair) | None | None | None | None | |
| Professor George Kinghorn | GSK Pharmaceuticals | Lecture fee | None | None | |
| Dr Vas Novelli | | | | | |
| Professor Robert Read | Novartis Vaccine | Investigator | None | None | |
| Dr Ross Taylor | None | None | None | None | |
| Professor Ian Weller | None | None | Roche | * | Yes |
| | | | GSK | * | Yes |
| | | | Merck | * | Yes |
| | | | Pfizer | * | Yes |
| | | | Boehringer Ingleheim | * | Yes |
| | | | Gilead | * | Yes |
| | | | Abbott | * | Yes |
| | | | BMS | * | Yes |

*I am co-chair of an Oversight Committee which oversees a large programme of research on the side effects of HIV drugs. This effort was initiated by the EMEA in 1999. This programme is funded by all these companies and funds are handled by a contract research organisation (CRO) from which my honorarium is paid and then paid into a department fund and not kept personally. My travel, hotel accommodation and meals are also covered by the CRO.

BIOEQUIVALENCE WORKING GROUP: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|------------------------------|--------------------|--------------------|--------------------------|------------------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Professor Ian Weller (Chair) | None | None | Roche | * | Yes |
| | | | GSK | * | Yes |
| | | | Merck | * | Yes |
| | | | Pfizer | * | Yes |
| | | | Boehringer Ingelheim | * | Yes |
| | | | Gilead | * | Yes |
| | | | Abbott | * | Yes |
| Professor Deborah Ashby | None | None | BMS | * | Yes |
| | | | GlaxoSmithKline | Methodological collaboration | Yes |
| | | | Sanofi-Aventis | Methodological collaboration | Yes |
| | | | Pfizer Limited | Methodological collaboration | Yes |
| | | | F Hoffmann-La Roche AG | Methodological collaboration | Yes |
| | | | Novartis Pharma AG | Methodological collaboration | Yes |
| | | | Amgen NV | Methodological collaboration | Yes |
| | | | Genzyme Europe BV | Methodological collaboration | Yes |
| | | | Merck KGaA | Methodological collaboration | Yes |
| | | | Bayer Schering Pharma AG | Methodological collaboration | Yes |
| | | | AstraZenca A/S | Methodological collaboration | Yes |
| | | | Novo Nordisk A/S | Methodological collaboration | Yes |
| | | | Professor Andrew Grieve | Pfizer Grd | Consultancy |
| Allergan | Consultancy | | | | |
| Bioexcell | Consultancy | | | | |
| GSK | Consultancy | | | | |
| Novexcell | Consultancy | | | | |
| Novartis | Consultancy | | | | |

* Additional information: I am co-chair of an Oversight Committee which oversees a large programme of research on the side effects of HIV drugs. This effort was initiated by the EMEA in 1999. This programme is funded by all these companies and funds are handled by a contract research organisation (CRO) from which my honorarium is paid and then paid into a department fund and not kept personally. My travel, hotel accommodation and meals are also covered by the CRO.

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|-----------------------------------|---|--|------------------------|--|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Professor Andrew Grieve (cont) | Vifor Eli Lilly Helsinn CMED | Consultancy Consultancy Consultancy Consultancy | | | |
| Professor Martin Kendall | None | None | None | None | |
| Professor Kevin Park | None | None | Pfizer | Non-specific | Yes |
| Professor Munir Pirmohamed | None | None | GSK | Attended a meeting but costs met by MHRA | No |
| Professor James Ritter | None | None | None | None | |
| Dr Glyn Taylor | | | | | |
| Dr Alison Thomson | None | None | None | None | |
| Professor Martin Wilkins | Pfizer Bayer-Schering BioMarin GSK | Lecture fees Lecture fees Grant to institution Funding to institution | None | None | |

BIOLOGICALS AND VACCINES EXPERT ADVISORY GROUP: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|-----------------------------|--------------------|--------------------|-------------------------------------|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Dr Angela Thomas (Chair) | None | None | None | None | |
| Professor Christopher Bucke | Vernalis | Shares | None | None | |
| Professor Derek Calam | None | None | None | None | |
| Professor Mary Collins | None | None | None | None | |
| Professor Andrew Hall | None | None | None | None | |
| Dr Stephen Inglis | None | None | Alba Therapeutics | Contract | Yes |
| | | | Amson Vaccines and Pharma (PVT) Ltd | Contract | Yes |
| | | | Anti-Soma | Contract | Yes |
| | | | Artus GMBH | Contract | No |
| | | | Baxter Healthcare SA | Contract | No |
| | | | BBT Biotech | Contract | No |
| | | | Bharat Serums and Vaccines Ltd | Contract | Yes |
| | | | Bio Farma | Contract | No |
| | | | Biocon Ltd | Contract | No |
| | | | Biofact | Contract | Yes |
| | | | CADILA Pharmaceuticals Ltd | Contract | No |
| | | | Celsus Labs | Contract | Yes |
| | | | Chiron Behring | Contract | No |
| | | | CSL Ltd | Contract | Yes |
| | | | DBV Technologie | Contract | Yes |
| | | | Dilafor AB | Contract | Yes |
| | | | Emcure Pharmaceuticals Ltd | Contract | No |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|--------------------------|--------------------|--------------------|--|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Dr Stephen Inglis (cont) | | | Endell Veterinary Group | Contract | No |
| | | | Evans (now part of Novartis) | Contract | Yes |
| | | | GeneMedix | Contract | Yes |
| | | | Glycart Biotechnology AG | Contract | Yes |
| | | | Glycoform Ltd | Contract | No |
| | | | Grifols | Contract | No |
| | | | GSK | Contract | Yes |
| | | | GTC Biotherapeutics | Contract | Yes |
| | | | Immunobiology Ltd | Contract | Yes |
| | | | Insense | Contract | |
| | | | IPH, Belgium | Contract | Yes |
| | | | Ipsen, Biomeasure Inc | Contract | Yes |
| | | | Julphar (Gulf Pharmaceutcial Industries) | Contract | Yes |
| | | | Kamada Ltd | Contract | No |
| | | | Novartis | Contract | No |
| | | | Octapharma | Contract | No |
| | | | Paion Deutschland GMBH | Contract | No |
| | | | Pfizer | Contract | No |
| | | | Pharmaceutical Scientist Inc | Contract | No |
| | | | Philogen | Contract | No |
| | | | Plasso | Contract | No |
| | | | Powdermed | Contract | No |
| | | | Roche | Contract | No |
| | | | Sanofi Pasteur | Contract | Yes |
| | | | Serum Institute of India Ltd | Contract | No |
| | | | Siemens (formerly Bayer) | Contract | No |
| | | | Solstice | Contract | No |
| | | | Sotex Pharma Firm | Contract | Yes |
| | | | Stabilitech Ltd | Contract | Yes |
| | | | Tepnel/MSD | Contract | Yes |
| | | | Vectura Ltd | Contract | Yes |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|---|----------------------|--|------------------------------|---|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| | | | Viranative AB | Contract | No |
| | | | West Pharmaceutical Services | Contract | No |
| | | | Wockhardt Ltd | Contract | No |
| | | | Wyeth | Contract | No |
| <p>Additional information: The National Institute for Biological Standards and Control (NIBSC) is a not-for-profit, public body whose purpose is to safeguard and enhance public health through the standardisation and control of biologicals used in medicine. NIBSC engages with commercial organisations in the course of fulfilling its public health role. The Institute's Corporate Strategy includes the following objectives: To anticipate emerging quality and safety issues associated with existing and future biological medicines; To facilitate the development of novel biological medicines. Both of these strategic objectives require active engagement with industry. In addition, NIBSC interacts with industry to ensure that its inventions are developed to a stage where they can have a tangible public health benefit. In some instances, it is appropriate for NIBSC to charge commercial organisations for its products and services, in line with guidance issued from HM Treasury ('Fees and Charges Guide' and 'Selling into Wider Markets'). NIBSC endeavours to make the same products and services equally available to commercial organisations, without prejudice. Where there is a significant risk of a conflict of interest, this is managed using a transparent, auditable framework. This approach ensures that NIBSC does not undermine its reputation for independence, impede its research programme or otherwise reduce its ability to deliver its core mission.</p> | | | | | |
| Professor James Ironside | Ark Therapeutics Ltd | Consultancy (limited to a single product: Cerepro) | Baxter Healthcare | Financial support for reasearch | Yes |
| Dr Helen Lachmann | Novartis | Fees; consultancy | Novartis | Investigator in Canakinumab trials; investigator in Kiacta trials | Yes |
| | | | Bellus | Investigator in Kiacta trials | No |
| Professor Elizabeth Miller | None | None | None | None | |
| Professor Robert Read | Novartis Vaccine | Investigator | None | None | |
| Carolyn, Lady Roberts | None | None | None | None | |
| Dr Robin Thorpe | None | None | None | None | |

CARDIOVASCULAR, DIABETES, RENAL MEDICINES EXPERT ADVISORY GROUP: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|---------------------------------|---|---|-------------------------------------|---|-------------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Professor Henry Dargie (Chair) | None | None | Cell Gene Novartis Cardiokine | Safety Monitoring Committee Safety Monitoring Committee Safety Monitoring Committee | Yes Yes Yes |
| Professor Richard Donnelly | Janssen-Cilag Eli Lilly MSD Schering-Plough Takeda (UK) | Consultancy administered via University of Nottingham Fee (one Advisory Board meeting) Fee (two Advisory Board meetings) and speaker fees Speaker fees Speaker fees | None | None | |
| Professor Paul Durrington | Pfizer Pfizer | Grant Lecture Fee MSD | None | None | |
| Professor Abdel Meguid El Nahas | Pfizer Novo Nordisk Genzyme Boehringer Ingelheim Napp Novartis | Consultancy; lecture fees Consultancy Funding of a piece of research equipment Lecture fee Lecture fee Lecture fee | None | None | |
| Dr Colin Forfar | None | None | None | None | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|-----------------------|--|---|------------------------|---|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Dr Michael Gamage | Medtronic Inc CRDM Cardiac Rhythm Device Management) | Consultancy; fee paid work; travel expenses (relating to implantable devices and leads only) | None | None | |
| | St Jude Medical (Cardiac Rhythm Management) | Consultancy; fee paid work; travel expenses (relating to implantable devices and leads only) | None | None | |
| Dr David Goldsmith | Roche | Speaker, Advisory Board | None | None | |
| | Amgen | Speaker, Advisory Board | | | |
| | Merck | Speaking | | | |
| | Novartis | Speaker, Advisory Board | | | |
| | Genzyme | Speaker, Advisory Board | | | |
| Shire | Speaker, Advisory Board | | | | |
| Dr Andrew Grace | GlaxoSmithKline Research and Development Ltd | Consultancy | Xention Ltd | BBSRC-CASE PhD | Yes |
| | Sanofi-Aventis | Consultancy | None | None | |
| | Xention Ltd | Consultancy | None | None | |
| Professor Philip Home | Novonordisk | Extra-European affiliates for education activities | Sanofi-Aventis | Continuing intermittent consultation for external commercial healthcare organisations (on behalf of University of Newcastle upon Tyne) | Yes |
| | Novonordisk | Research; project support | | | |
| | BMS/ AstraZeneca | Research; project support | | | |
| | Sanofi-Aventis | Research; project support | | | |
| | | | Sanofi-Aventis | As above | Yes |
| | | | Sanofi-Aventis | As above | Yes |
| | | | GSK | As above | Yes |
| | | | Merk Inc | As above | Yes |
| | | Merck-Nordisk | As above | Yes | |
| | | Novartis | As above | Yes | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|---|--------------------|--|-------------------------|--|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Professor Philip Home (cont) | | | Research Groups Servier | Continuing intermittent consultation for external commercial healthcare organisations (on behalf of University of Newcastle upon Tyne) | Yes |
| | | | Roche Diagnostics | As above | Yes |
| <p>Additional information: The International Diabetes Federation (IDF) received funding from all the above companies (Novo Nordisk, BMS/ AstraZeneca and Sanofi-Aventis) but also Eli Lilly and Company, Takeda, and Merck Santé for recent activities (Clinical Guidelines Task Force – to 2007) in which I was involved but not remunerated for. Nearly all companies support the IDF World Diabetes Congress for which I am Programme Committee Chair 2009. Directorship: North East Diabetes Trust (charity), WorldWIDE Initiative for Diabetes Education (non-profit company). WorldWIDE is supported by GlaxoSmithKline, Merck Inc, Novo Nordisk A/S, Novartis, Pfizer, and Sanofi-Aventis.</p> | | | | | |
| Professor Alan Jardine | None | None | Norvatis | Consultancy; grants; clinical trials | Yes |
| | | | Roche | As above | Yes |
| | | | Pfizer | As above | Yes |
| | | | Astellas | As above | Yes |
| | | | MSD | As above | Yes |
| | | | Astrazenca | As above | Yes |
| Mitsubishi | As above | No | | | |
| Dr Michael Stewart | AstraZeneca | Sponsorship to attend scientific meeting (ESC, Barcelona, Sept 2009) | None | None | |
| Professor Alan Struthers | GSK | Shares | Wyeth | Grant | Yes |
| | AstraZeneca | Shares | Stirling Medical | Grant | Yes |
| | Pfizer | Consultancy; speakers fee | | | |
| | Evotec | Consultancy | | | |
| Professor Solomon Tesfaye | None | None | None | None | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|---------------------|-------------------------|--------------------|------------------------|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Dr Caroline Vaughan | RioTech Pharmaceuticals | Shares | None | None | |

CARDIOVASCULAR, DIABETES, RENAL, RESPIRATORY AND ALLERGY MEDICINES EXPERT ADVISORY GROUP: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|--------------------------------|--------------------------------|---|------------------------|--|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Professor Colin Forfar (Chair) | None | None | None | None | |
| Professor Steven Cunningham | Schering Plough | Lecture Fee | None | None | |
| Professor Richard Donnelly | Janssen-Cilag | Consultancy administered via University of Nottingham Fee (one Advisory Board meeting) Fee (two Advisory Board meetings); speaker fees Speaker fees Speaker fees | None | None | |
| | Eli Lilly | | | | |
| | MSD | | | | |
| | Schering-Plough Takeda (UK) | | | | |
| Dr Iolo Doull | MSD | Advisory | None | None | |
| | GSK | Lecture fee | | | |
| | AstraZeneca | Lecture fee | | | |
| Dr John Firth | None | None | Astellas | Support of renal transplantation service; research and support of renal educational meetings | |
| | | | Novartis Roche | As above Support of renal transplantation and renal anaemia service; research and support of renal educational meetings | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|------------------------|--|--|------------------------|---|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Dr John Firth (cont) | | | Amgen | Support of renal anaemia service; research and renal mineral and bone disease studies and of renal educational meetings | |
| | | | Shire | Support of renal mineral and bone disease studies and of renal educational meetings | |
| | | | Genzyme | As above | |
| Professor Anthony Frew | Allergy Therapeutics | Consultancy; principal investigator; speaker fees; travel expenses | None | None | |
| | ALK-Abello UK | Consultancy; speaker fees | | | |
| | GSK | Consultancy | | | |
| | Merck Sharp & Dohme | Speaker fees | | | |
| | Schering-Plough | Speaker fees | | | |
| | Allergopharma | Consultancy | | | |
| Dr Andrew Grace | Glaxosmithkline Research and Development Ltd | Consultancy | Xention Ltd | BBSRC-CASE PhD | Yes |
| | Sanofi Aventis | Consultancy | | | |
| | Xention Ltd | Consultancy | | | |
| Dr Vanessa Graham | AstraZeneca | Limited shares | None | None | |
| | GlaxoSmithKline | Limited shares | | | |
| | Genus | Sponsorship for TB field trip to Malawi (November 2009) | | | |
| Dr Philip Ind | GSK | Advisory Board (Asthma/ COPD Therapy) | None | None | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|------------------------|--------------------|--|------------------------|--------------------------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Dr Philip Ind (cont) | AstraZeneca | Accommodation; conference travel expenses; father holds some shares | | | |
| | Nykomed | Accommodation; conference travel expenses; Advisory Board (roflumilast) | | | |
| | Aerovance | Expert Advisory Board (pitracinra); lecture fee; clinical trial PI; hospitality (dinner) | | | |
| | Pfizer/ Boehringer | Lecture fees (tiotropium and COPD therapy); hospitality (lunch) | | | |
| | Trinity-Chiesi | Accommodation; conference travel expenses; Advisory Board (Fostair) | | | |
| | Vectura Group Plc | Expert Advisory Board (no fee paid) | | | |
| Professor Alan Jardine | None | None | Norvatis | Consultancy; grants; clinical trials | Yes |
| | | | Roche | Consultancy; clinical trials | Yes |
| | | | Pfizer | Consultancy; clinical trials | Yes |
| | | | Astellas | Consultancy; clinical trials | Yes |
| | | | MSD | Consultancy; clinical trials | Yes |
| | | | AstraZeneca | Consultancy; grants; clinical trials | Yes |
| | | | Mitsubishi | Consultancy; clinical trials | No |
| Professor Ann Millar | Intermune | Clinical trial | None | None | |
| | Astra | Clinical trial | | | |
| | Boehringer | Clinical trial | | | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|---------------------|---------------------------------|---|------------------------|--------------------------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Dr Michael Stewart | AstraZeneca | Sponsorship to attend scientific meeting (ESC, Barcelona, Sept 2009) | None | None | |
| Dr Michael Thomas | GlaxoSmithKline Merck and Co | Advisory panel; consultancy on research study Speaker's honorarium | Asthma UK | Fellowship and chief medical advisor | Yes |
| Dr Charles Twort | None | None | None | None | |
| Dr Caroline Vaughan | RioTech Pharmaceuticals | Shares | None | None | |

CHEMISTRY, PHARMACY AND STANDARDS EXPERT ADVISORY GROUP: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|-------------------------------|--|--|---|---|---|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Professor Derek Calam (Chair) | None | None | None | None | |
| Professor Michael Aulton | Napp Novartis Ratiopharm Sandoz | Patent issues; fees Patent issues; fees Patent issues; fees Patent issues; fees | None | None | |
| Ms Helen Barnett | None | None | None | None | |
| Professor Graham Buckton | Pharmaterials Ltd Eli Lilly Allergan Teva Gideon Richter | Salary; shares Wife employed Consultancy Consultancy Consultancy | None | None | |
| Professor Donald Cairns | None | None | Dow Chemicals Glaxo Smith Kline Lifescan Equazen Pfizer AAH Pharmaceuticals DM Wood Medical | Free samples of Methocel Sponsor lecture Sponsor prize Hospitality for speakers Donated textbooks Sponsor prize Sponsor prize | No Yes Yes Yes No Yes Yes |
| Professor Brian Clark | Lundbeck Pharmaceuticals Canada SmithKline Beechams USA | Consultancy; expert witness Consultancy; expert witness | None | None | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|-----------------------------|--------------------------------|---|--|--|-------------------------------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Professor Gillian Eccleston | None | None | Thornton & Ross Ltd, UK | University consultancy | No |
| Mr V'Iain Fenton-May | Cephalon Ltd | Consultancy (Abelcet Liposomal Amphotericin) | Advisory Committee on Borderline Substances (PASA) | Travel expenses | Yes |
| | Qualacept Ltd | Consultancy | | | |
| | Royal Pharmaceutical Society | Fees | | | |
| | Cardiff and Vale NHS Trust | Fees | | | |
| Professor Roger Griffin | Strathclyde University | Fees | Astex Pharmaceuticals UCB Pharma Sienna Biotech Merck Serono Onyx Scientific | Research collaboration Research collaboration Research collaboration Research collaboration Research collaboration | Yes Yes Yes Yes Yes |
| | British Pharmacopoeia | Fees | | | |
| | KuDOS Pharmaceuticals | Milestone payments; revenue | | | |
| | AstraZeneca Pharmaceuticals | Milestone payments; revenue | | | |
| | Taylor Wessing (legal company) | Consultancy – various pharmaceutical companies | | | |
| | Agouron-Pfizer | Milestone payments; revenue | | | |
| Professor Geoffrey Hanlon | De Novo Pharmaceuticals | Milestone payments; revenue | Denfotex Sauflon Pharmaceuticals Benchmark Oils | Research grant Research grant Research grant | Yes Yes No |
| | GlaxoSmithKline | Personal shares | | | |
| | Reckitt Benckiser | Consultancy (not within last 12 months); interests limited to Gaviscon products | | | |
| Dr Gillian Hawksworth | None | None | None | None | |
| Mr Robert Lowe | Baxter healthcare | Conculty – one-off event (April 2009) | None | None | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|-------------------------------|--|--|--|---|------------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Professor Christopher Marriot | Halation Ltd Vectura Ltd Remedica Ltd MedPharm Ltd British American Tobacco | Shares; fees Shares Directorship; fees Shares Consultancy | None | None | |
| Professor Anthony Smith | Pharmovation Therakind | Director - School of Pharmacy company which manages School of Pharmacy intellectual property Non-executive director - School of Pharmacy spin-out | None | None | |
| Professor Kevin Taylor | None | None | AstraZenca Pfizer | Research grant Education grant | Yes Yes |
| Professor Peter York | Pharmtech Ltd Osat Ltd Biosat Ltd Lena Nanoceutics Crystec Ltd Nektar Therapeutics GSK (via GSK legal advisors Howrey) | Director; shares; dividend Director Director; shares; dividend Director Director; shares Shares Consultancy | Nextar Therapeutics Boehringer Ingelheim BMS | University department grant University department grant University department grant | Yes No Yes |

CLINICAL TRIALS EXPERT ADVISORY GROUP: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|----------------------------------|--------------------|--------------------|------------------------|---|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Professor Robert Lechler (Chair) | None | None | None | None | |
| Dr Susan Bews | Sanofi aventis | Shares; pension | None | None | |
| Professor Derek Calam | None | None | None | None | |
| Professor Janet Darbyshire | None | None | Amgen | Neupogen: support for drug only GM-CSF: discounted drug direct to sites; educational grant | Yes |
| | | | AstraZenca | Cediranib: drug and placebo; unrestricted grant; provision of CRO for distribution and randomization | Yes |
| | | | Bayer | Sorafenib: support for drug; logistical support; educational grant Moxifloxacin: support for drug and possibly trial costs | Yes |
| | | | Baxter | Support for reduced price pumps | Yes |
| | | | ITGI (Schering-Plough) | Pegylated Interferon (alpha-2b): support for drug Docoirubicin: support for drug Temozolomide: free drug; educational grant | Yes |

| MEMBER | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
|-----------------------------------|-----------------|--------------------|-----------------------|--|-----------------|
| Professor Janet Darbyshire (cont) | | | Lilly | Gemcitabine: support for drug | Yes |
| | | | Merck | Topotecan: support for drug | Yes |
| | | | Merck Serono | Raltegravir: support for drug Cetuximab: support for drug; educational grant to fund clinical trial and associated translational research | Yes |
| | | | Novartis | Zoledronic Acid: support for drug; educational grant | |
| | | | Pfizer | IL-2: support for drug Celecoxib: support for drug; logistical support; educational grant | Yes |
| | | | | Colorectal Trials Portfolio: support for clinical trials (£15,000 awarded for 09/10) | Yes |
| | | | Pierre Fabre Roche | Navelbine: discounted drug Loron 520: support for drug; educational grant Bevacizumab: support for drug; unrestricted grant; provision of CRO for monitoring, database and drug distribution; grant for TR sample collection; educational grant for cardiac monitoring and per patient payments to sites Capecitabine: support for drug only Bevacizumab: funding to purchase drug DNase: support for drug; trial costs | Yes |

| MEMBER | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
|-----------------------------------|-----------------|--------------------|--|--|-----------------|
| Professor Janet Darbyshire (cont) | | | Sanofi-Aventis | Docetaxel: discounted drug; educational grant Rifafour: support for drug Rifampicin: support for drug Rifapentine: support for drug | Yes |
| | | | Abbott | Kaletra, Aluvia: financial support for virology work in DART; drug support terminated in September 09 | Yes |
| | | | Boehringer Ingelheim | Nevirapine: support for drug; financial support (terminated in December 09) | Yes |
| | | | Boehringer Ingelheim/ Bristol-Myers Squibb | Efavirenz, Atripla: support for drug; financial support; small virology substudy Chapas 1 | Yes |
| | | | Cipla | Lamivir-S, Pedimune: support for drug only (terminated in September 09) | Yes |
| | | | Gilead Sciences | Tenofovir, Emtricitabine, Atripla: support for drug; financial support | Yes |
| | | | Gilead/ Tibotec, a division of Janssen-Cilag Ltd/ Roche GlaxoSmithKline | Financial support for resistant database Abacavir, Zidovudine, Lamivudine: support for drug; financial support | Yes Yes |
| | | | Indevus Sanofi Pasteur | PRO2000: support for drug NYVAC C: support for vaccine | Yes Yes |
| | | | Tibotec Virco | Darunavir: support for drug Resistance-tests: support for assays only | Yes Yes |

| MEMBER | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
|-----------------------------------|--|--|------------------------|--|-----------------|
| Professor Janet Darbyshire (cont) | | | Insys Therapeutics Inc | Tetrahydrocannabinol: support for drug; collection and analysis of safety blood samples; salary and associated expenses of a study monitor | Yes |
| | | | Svizera Europe | Isoniazid: support for drug Ethambutol: support for drug Pyrazinamide: support for drug Pyridoxine: support for drug | Yes |
| Professor Andrew George | Smart Targeting | Shareholder; on scientific panel (unpaid at present) | None | None | |
| Professor Andrew Grieve | Pfizer Grd Allergan Bioexell GSK Novexell Novartis Vifor Eli Lilly Helsinn CMED | Consultancy Consultancy Consultancy Consultancy Consultancy Consultancy Consultancy Consultancy Consultancy Consultancy | None | None | |
| Professor John Isaacs | Roche | Consultancy; speaker fees; sponsored attendance at international meetings; sponsorship of CPD-approved workshop in Newcastle | None | None | |
| | Genzyme | Consultancy; research grant; sponsorship of CPD-approved workshop in Newcastle | | | |

| MEMBER | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
|------------------------------|-------------------|--|-----------------|--------------------|-----------------|
| Professor John Isaacs (cont) | Abbott | Speaker fees; research grant; attendance at an international meeting; sponsorship of CPD-approved workshop in Newcastle. | | | |
| | BMS | Consultancy; speaker fees; attendance at an international meeting | | | |
| | Eli-Lilly | Consultancy | | | |
| | Apitope | Consultancy | | | |
| | GSK | Consultancy; research grant; patent holder on monoclonal antibody licensed to GSK (otelixizumab) | | | |
| | Biogen-Idec | Speaker fees; consultancy | | | |
| | UCB-Celltech | Research grant; sponsorship of CPD-approved workshop in Newcastle | | | |
| | Centocor | Sponsorship of CPD-approved workshop in Newcastle | | | |
| | Chugai | Sponsorship of CPD-approved workshop in Newcastle | | | |
| | Bioanalab | Sponsorship of CPD-approved workshop in Newcastle | | | |
| Professor Kevin Park | None | None | Pfizer | Non-specific | Yes |
| | | | AstraZeneca | Non-specific | Yes |
| | | | Novartis | Non-specific | Yes |
| | | | GSK | Non-specific | Yes |
| Mrs Vivienne Parry | Johnson & Johnson | Fee for one-off one-day communication training (general, not specific product related) | None | None | |

| MEMBER | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
|----------------------------|---------------------------------------|---|---|--|--------------------------------|
| Professor Munir Pirmohamed | None | None | GSK | Attended a meeting but costs met by MHRA | No |
| Dr Stephen Poole | None | None | None | None | |
| Professor Stuart Ralston | Novartis Proctor & Gamble Merck | Consultancy Consultancy Consultancy | Novartis Eli Lilly Merck Pfizer Wyeth | Research grant Commission for advice Research grant Commission for advice Research grant | Yes Yes Yes No Yes |
| Lady Sarah Riddell | None | None | None | None | |
| Mrs Madeleine Wang | None | None | None | None | |
| Professor Faith Williams | None | None | AstraZeneca Nycomed Pfizer | Research funding Research funding Research funding | Yes No No |

DERMATOLOGY EXPERT ADVISORY GROUP: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|--------------------------------------|--|--|------------------------|---|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Professor David Gawkröger (Chair) | Novartis Pharmaceutical Corporation, New Jersey, USA | Consultant to Internal Medicine Adjudication Committee (IMAC) for 'Galvus' (drug for diabetes that can have skin side effects); December 2008 to present; paid a fee for telephone conferences with other physicians | York Pharma | Professor MJ Cork in my department has research supported by this company | Yes |
| | Leo Pharmaceuticals, UK | Fee for lecture; travel expenses (Sheffield to Wolverhampton return by train) to general practitioners as part of a half-day education session on 12 November 2009 | Merck Pharma | Dr AG Messenger in my department is a consultant to this company | Yes |
| | GlaxoSmithKline UK | Family member holds shares in this company | | | |
| | Basilea Pharmaceutica, Switzerland | Invited to lecture on hand dermatitis (for which I will be paid a fee) by Basilea, at the Royal Society of Medicine in February 2010 | | | |
| | Janssen-Cilag Ltd | Air tickets and accommodation provided for attendance at the European Academy of Dermatology and Venereology, Berlin, 7-10 October 2009 | | | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|--------------------------|--------------------------------|--|---|---|-----------------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Mrs Alison Bowser | None | None | Valeant Pharma | Consultancy for public events | No (expired March 08) |
| | | | ABPI | Travelling expenses to attend meeting on medicine legislation in Europe in October 2008 | No |
| Dr Clive Grattan | GlaxoSmithKline CSL Behring | Consultancy Consultancy | GlaxoSmithKline | Research | Yes |
| Dr Richard Groves | Pfizer | Consultant (dermatology adverse reactions) | None | None | |
| | Karus Therapeutics | Research grant | | | |
| Professor Martin Kendall | None | None | None | None | |
| Dr Celia Moss | None | None | Molnlycke Health Care | Donations towards educational activities and patient and staff amenities | |
| | | | Alliance Pharmaceuticals Ltd | | |
| | | | GSK | | |
| | | | Sinclair Pharma UK Ltd Reckitt Benckiser Healthcare UK Ltd Astellas | Principle investigator in clinical trial | |
| | | | Dermal Laboratories Ltd | Donations towards educational activities and patient and staff amenities | |
| Dr Ross Taylor | None | None | None | None | |

GASTROINTESTINAL AND HEPATOLOGY EXPERT ADVISORY GROUP: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|------------------------------------|---------------------------------------|---|------------------------|---|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Professor Michael Farthing (Chair) | None | None | None | None | |
| Dr Alison Linda Jones | | | | | |
| Professor Roger Jones | | | | | |
| Dr John Mansfield | Shire 2000-08 | Balsalazide/ SPD476: under consideration | Alizyme | Coalpred: under consideration | No |
| | Proctor and Gamble 2006-07 | Asacol: under consideration | Shire | Mesavant/SPD476: under consideration | No |
| | Schering Plough 2005-07 consideration | Infliximab: under consideration | Centocor Celgene | Infliximab: Crohn's disease | No |
| | UCB 2006-07 | Certolizumab: Crohn's disease | Otsuka | Lenalidomide: Crohn's disease Phosphodiesterase 4 inhibitor: under consideration | No |
| Professor Kevin Moore | Ferring | I gave a series of lectures in Sept/Oct 2007 sponsored by Ferring in the Far East; included discussing their product, glypressin; was paid an honorarium for my talks I have been advising Servier, France, on the potential hepatotoxicity of one of their drugs (agomelatine) and have been paid for my services | None | None | |
| | Servier | | | | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|---------------------------------|--------------------|--|------------------------|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Professor Kevin Moore (cont) | Antipodean | I have been advising this company about the potential for their product to be used in the treatment of non-alcoholic fatty liver disease; have not been paid but have been promised an offer of share options in lieu of payment | | | |

MEDICINES FOR WOMEN'S HEALTH EXPERT ADVISORY GROUP: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|---------------------------|--|---|------------------------|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Dr Mary Armitage (Chair) | None | | None | | |
| Dr Sarah Atkinson | None | | None | | |
| Professor Valerie Beral | None | | None | | |
| Professor Juliet Compston | Amgen | Consultancy (DMC); advisory and speaking fees | Osteotronix | Grant funding | Yes |
| | Novartis | Consultancy (DSMB) | Nycomed | Grant funding | Yes |
| | Nycomed | Advisory and speaking fees | | | |
| | Servier | Speaking fees | | | |
| | GSK | Advisory fees | | | |
| | Gilead | Advisory and speaking fees | | | |
| | Procter & Gamble/ Sanofi-Aventis Eli Lilly | Advisory fees Advisory and speaking fees | | | |
| Dr Ailsa Gebbie | None | | None | | |
| Dr Annabelle Glasier | HRA Pharma | Research grant | Merck (Organon) | Support to clinic | Yes |
| | Pfizer | Research grant | Bayer Schering | Support to clinic | Yes |
| Dr Sally Hope | None | None | None | None | |

Additional information: Employer – General Practitioner at Woodstock Surgery (Oxfordshire Primary Care Trust) 50%; full-time freelance health writer for 'Best' (Women's magazine) [£12 000 pa]; advisor to Alliance for Better Bone Health, an educational charity funded through educational grants from Servier, Roche and GSK (total in last year around £750).

Voluntary Positions – member on the National Institute for Health and Clinical Excellence Osteoporosis Clinical Guidelines Committee (as representative of the Royal College of General Practitioners) since 2002; member of the Medical Committee Advisory, Committee for the National Osteoporosis Society since 2007; deputy editor of 'Menopause International' journal since 1999; NE ox PCT lead on osteoporosis since 2002

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|----------------------------|---------------------------------------|---|---|---|--------------------------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Professor Mary Lumsden | None | None | None | None | |
| Professor Kim McPherson | | | | | |
| Professor Julietta Patnick | AstraZeneca | 19 shares | None | None | |
| Dr Sioban Quenby | None | None | Besins Healthcare International | Supplying drugs and placebo; NHS/ NIHR/ HTA funded randomised controlled trial I'm involved in (progsterone in recurrent miscarriage) | Yes |
| | | | MERCK | Supplying drugs and placebo; NHS/ NIHR/ HTA/ MRC funded randomised controlled trial I'm involved in (metformin in obesity) | Yes |
| Professor Stuart Ralston | Novartis Proctor & Gamble Merck | Consultancy Consultancy Consultancy | Novartis Eli Lilly Merck Pfizer Wyeth | Research grant Commission for advice Research grant Commission for advice Research grant | Yes Yes Yes No Yes |
| Carolyn, Lady Roberts | None | None | None | None | |
| Dr Connie Smith | None | None | None | None | |
| Professor Martin Vessey | None | | | | |

Additional information: 1) My wife and I hold PEPs and ISAs which are now managed by Lloyds TSB Private Banking. The fund manager may from time to time buy or sell shares in the pharmaceutical industry. I do not monitor these portfolios which are constantly changing. 2) My eldest son is a Vice-President of Merck and now works mostly in Boston USA. His wife also works for Merck within Clinical Pharmacology.

NEUROLOGY AND PAIN MANAGEMENT EXPERT ADVISORY GROUP: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|----------------------------|----------------------|--|------------------------|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Dr Michael Donaghy (Chair) | None | None | None | None | |
| Dr Richard Coleman | None | None | None | None | |
| Dr Beverley Collett | NAPP Pharmaceuticals | Grunenthal is a corporate member of the Chronic Pain Policy Coalition (which I chair; President is Dame Rennie Fritchie) and pay a yearly fee for that membership; lecture fees for primary and secondary healthcare professional independent lectures; Advisory Boards: received consultancy fees and travel expenses – advised them on an e-learning proposal; Interest: Their product is Lidoderm plasters (Versatis plasters) and new agent tapentadol | None | None | |
| | Medtronic | Medtronic is a corporate member of the Chronic Pain Policy Coalition (which I Chair; President is Dame Rennie Fritchie) and pay a yearly fee for that membership; Interest: Spinal cord and peripheral nerve stimulators | | | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|----------------------------|--------------------|--|------------------------|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Dr Beverley Collett (cont) | Sanofi-Pasteur MSD | Sanofi Pasteur is a corporate member of the Chronic Pain Policy Coalition (which I Chair; President is Dame Rennie Fritchie) and pay a yearly fee for that membership; product is a vaccine against herpes zoster | | | |
| | Archimedes | I am chairing a meeting for them in April 2010 and receiving payment and travel expenses for this; product is Zomorph capsules and PecSys (fentanyl nasal spray) | | | |
| | Astellas | January and March 2010: Member (1) and Chair (1) of Advisory Board meeting; received payment and travel expenses for both; product is Capsaicin 8% patches | | | |
| | Novartis | Novartis is a corporate member of the Chronic Pain Policy Coalition (which I Chair; President is Dame Rennie Fritchie) and pay a yearly fee for that membership | | | |
| | Janssen-Cilag | Janssen-Cilag is a corporate member of the Chronic Pain Policy Coalition (which I Chair; President is Dame Rennie Fritchie) and pay a yearly fee for that membership; their product is Transdermal fentanyl matrix patches | | | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|----------------------------|--------------------|---|------------------------|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Dr Beverley Collett (cont) | Mundipharma | European partner of NAPP; Advisory Board meeting for which I received consultancy fees and travel expenses; their product is Targinact (naloxone and oxycodone) | | | |
| | Pfizer | Lecture fees for independent lectures to primary and secondary healthcare professionals; Pfizer is a corporate member of the Chronic Pain Policy Coalition (which I Chair; President is Dame Rennie Fritchie) and pay a yearly fee for that membership | | | |
| | Grunenthal | Grunenthal is a corporate member of the Chronic Pain Policy Coalition (which I Chair; President is Dame Rennie Fritchie) and pay a yearly fee for that membership; lecture fees for primary and secondary healthcare professional independent lectures; Advisory Boards: Received consultancy fees and travel expenses; advised them on an e-learning proposal; Interest: Their product is Lidoderm plasters (Versatis plasters) and new agent tapentadol | | | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|-------------------------------|--|--|------------------------|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Professor D Alastair Compston | Genzyme Inc | Consultancy and clinical trials agreement | None | None | |
| Dr Helen Cross | | | | | |
| Professor John Duncan | UCB Pharma | Lecture fees (paid to UCL); grant to attend American Epilepsy Society, December 2009; grant for educational meeting | None | None | |
| | Sanofi-Aventis | Advice on litigation | | | |
| | Eisai | Lecture fee.; Advisory Board; grant for educational meeting | | | |
| | Janssen Cilag | Lecture fee; Advisory Board; grant for educational meeting | | | |
| Dr Nicholas Fletcher | GSK/ Ipsen/ Boehringer/ UCB | Occasional assistance (financial support) with expenses for academic meetings/ conferences (accommodation, travel, subsistence); occasional lecture fees at medical meetings | None | None | |
| Professor Karen Forbes | None | None | None | None | |
| Professor Ralph Gregory | None | None | None | None | |
| Mr Michael Harnor | Smith and Nephew AstraZeneca GlaxoSmithKline Finsbury Worldwide Pharmaceutical Trust | 197 ordinary shares 37 ordinary shares 56 ordinary shares 440 ordinary shares (equity investment company) | None | None | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|--------------------------|----------------------------------|--|------------------------|---------------------------------|-------------------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Ms Susan Haydon | None | None | Merck, Sharpe & Dohme | Donation to the migration trust | Yes 2009 financial year |
| Dr Anthony Johnson | Arnold & Porter LLP | Expert witness (medical statistician) sodium valproate | None | None | |
| Dr Russell Lane | None | None | None | None | |
| Professor Martin Rossor | | | | | |
| Professor Peter Rothwell | Bayer Pharmaceuticals Ltd | Fees for membership of executive committee of a randomised controlled trial of aspirin (ARRIVE study) – 2007 onwards | | | |
| | Servier Pharmaceuticals Ltd | Fees for membership of executive committee of a new antiplatelet drug (perform study) – 2006 onwards | | | |
| | Sanofi - BMS Pharmaceuticals Ltd | Occasional honorarium for talk/ meeting | | | |
| | Shire Pharmaceuticals Ltd | Research donation to Oxford vascular study | | | |
| Dr Christopher Verity | None | None | None | None | |

NEUROLOGY, PAIN AND PSYCHIATRY EXPERT ADVISORY GROUP: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|----------------------------|----------------------|--|------------------------|------------------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Dr Michael Donaghy (Chair) | None | None | None | None | |
| Professor Ian Anderson | None | None | AstraZeneca | Investigator-initiated grant | Yes |
| Dr Richard Coleman | None | None | None | None | |
| Dr Beverley Collett | NAPP Pharmaceuticals | Grunenthal is a corporate member of the Chronic Pain Policy Coalition (which I chair; President is Dame Rennie Fritchie) and pay a yearly fee for that membership; lecture fees for primary and secondary healthcare professional independent lectures; Advisory Boards: received consultancy fees and travel expenses – advised them on an e-learning proposal; Interest: Their product is Lidoderm plasters (Versatis plasters) and new agent tapentadol | None | None | |
| | Medtronic | Medtronic is a corporate member of the Chronic Pain Policy Coalition (which I Chair; President is Dame Rennie Fritchie) and pay a yearly fee for that membership; | | | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|----------------------------|--------------------|---|------------------------|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Dr Beverley Collett (cont) | Medtronic (cont) | Interest: Spinal cord and peripheral nerve stimulators Sanofi Pasteur is a corporate member of the Chronic Pain Policy Coalition (which I Chair; President is Dame Rennie Fritchie) and pay a yearly fee for that membership; product is a vaccine against herpes zoster I am chairing a meeting for them in April 2010 and receiving payment and travel expenses for this; product is Zomorph capsules and PecSys (fentanyl nasal spray) January and March 2010: Member (1) and Chair (1) of Advisory Board meeting; received payment and travel expenses for both; product is Capsaicin 8% patches Novartis is a corporate member of the Chronic Pain Policy Coalition (which I Chair; President is Dame Rennie Fritchie) and pay a yearly fee for that membership Janssen-Cilag is a corporate member of the Chronic Pain Policy Coalition (which I Chair; President is Dame Rennie Fritchie) and pay a yearly fee for that membership; | | | |
| | Sanofi-Pasteur MSD | | | | |
| | Archimedes | | | | |
| | Astellas | | | | |
| | Novartis | | | | |
| | Janssen-Cilag | | | | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|----------------------------|----------------------|---|------------------------|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Dr Beverley Collett (cont) | Janssen-Cilag (cont) | their product is Transdermal fentanyl matrix patches | | | |
| | Mundipharma | European partner of NAPP; Advisory Board meeting for which I received consultancy fees and travel expenses; their product is Targinact (naloxone and oxycodone) | | | |
| | Pfizer | Lecture fees for independent lectures to primary and secondary healthcare professionals; Pfizer is a corporate member of the Chronic Pain Policy Coalition (which I Chair; President is Dame Rennie Fritchie) and pay a yearly fee for that membership | | | |
| | Grunenthal | Grunenthal is a corporate member of the Chronic Pain Policy Coalition (which I Chair; President is Dame Rennie Fritchie) and pay a yearly fee for that membership; lecture fees for primary and secondary healthcare professional independent lectures; Advisory Boards: Received consultancy fees and travel expenses; advised them on an e-learning proposal; Interest: Their product is Lidoderm plasters (Versatis) | | | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|----------------------------|--|---|------------------------|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Dr Beverley Collett (cont) | Grunenthal (cont) | plasters) and new agent tapentadol | | | |
| Professor John Duncan | UCB Pharma | Lecture fees (paid to UCL); grant to attend American Epilepsy Society, December 2009; grant for educational meeting | None | None | |
| | Sanofi Aventis Eisai | Advice on litigation Lecture fee.; Advisory Board; grant for educational meeting | | | |
| | Janssen Cilag | Lecture fee; Advisory Board; grant for educational meeting | | | |
| Mr Michael Harnor | Smith and Nephew AstraZeneca GlaxoSmithKline Finsbury Worldwide Pharmaceutical Trust | 197 ordinary shares 37 ordinary shares 56 ordinary shares 440 ordinary shares (equity investment company) | None | None | |
| Dr Russell Lane | None | None | None | None | |
| Professor John O'Brien | Shire Janssen Pfizer/ Eisai Lunbeck Bayer Servier GE Healthcare | Lecture fees Lecture fees Lecture fees Lecture fees Consultancy Consultancy Lecture fees | None | None | |
| Mrs Meredith Robson | None | None | None | None | |
| Mrs Kay Sheldon | None | None | None | None | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|-------------------------|--------------------|--|------------------------|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Professor Eric Taylor | Equazene Ltd | I am conducting a trial of omega-3 fatty acids in ADHD (this is a food product rather than a drug) which is receiving grant support from the company | None | None | |
| Professor Ken Woodhouse | None | None | None | None | |

ONCOLOGY AND HAEMATOLOGY EXPERT ADVISORY GROUP: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|------------------------------|-------------------------|-------------------------------------|------------------------|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Professor John Smyth (Chair) | Antigenics | Consultancy | None | None | |
| | Pharmamar | Consultancy; shares; Board Member | | | |
| | Helsinn | Consultancy | | | |
| | Protherics | Consultancy | | | |
| | Bristol-Myers Squibb | Data Monitoring Committee | | | |
| | Bayer Healthcare | Data Monitoring Committee | | | |
| | Ziopharm | Medical Advisory Board | | | |
| | Propanc Pty Ltd | Consultancy | | | |
| | Oncogenex | Consultancy | | | |
| | Biomarine | Consultancy | | | |
| | Celgene | Consultancy | | | |
| Nexus Pharmaceuticals | Consultancy | | | | |
| Mrs Eileen Barrett | None | None | None | None | |
| Professor James Cassidy | Roche | Consultancy; grants | Roche | Grants | Yes |
| | Sanofi | Consultancy; grants | Sanofi | Grants | Yes |
| | Merck | Consultancy | Novo-Nordisk | Grants | Yes |
| | Novo-Nordisk | Consultancy; grants | Amgen | Grants | Yes |
| | Amgen | Grants | | | |
| Professor Jack Cuzick | AstraZeneca | Consultancy; grant; speakers bureau | None | None | |
| | Aventis | Grant | | | |
| | Roche/ Lilly/ Novartis/ | Advisory Board | | | |
| | GenProbe/ Merck | | | | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|--|---|---|--|--|-------------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Professor Barry Hancock | GSK | Consultancy | None Shortly to be involved in a further study in renal (with grant from GSK) | None | |
| Dr Alison Louise Jones | Roche Sanofi Aventis GSK Novartis BMS Pfizer AstraZeneca | Consultancy Consultancy Consultancy Consultancy Consultancy Consultancy Consultancy | None | None | |
| Professor Jonathan Ledermann | Pharma Mar Boehringer Ingelheim GlaxoSmithKline Yakult Schering Plough AstraZeneca | Advisory Board; consultancy; meeting support Advisory Board; speaker honorarium Advisory Board consultancy Lecture fee and travel Speaker honorarium Trial steering committee; fee | AstraZeneca AstraZeneca AstraZeneca Roche | Grant support; Cediranib trial International PI AZD2281 AZD 0530; co-investigator Co-investigator; Meoc Bevacizumab; support | Yes Yes Yes |
| Professor David Linch | Roche Chugai Amgen Celgene Hospira | Consultancy Consultancy Consultancy DMC Member Consultancy | Chugai | Grant | Yes |
| Emeritus Professor Edward Gordon Smith | Immunotech Holdings Ltd | One share | None | None | |

Additional information: Immunotech Holdings Ltd is a private company developing cellular immunotherapy for cancer in China.

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|---------------------------|--------------------|--------------------|------------------------|--|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Professor Michael Stevens | None | None | Chugai Pharma Europe | Unrestricted educational grant to support an international postgraduate meeting in November 2008 | No |

PAEDIATRIC MEDICINES EXPERT ADVISORY GROUP: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|-------------------------------------|--------------------|---|---------------------------------|--------------------------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Professor Rosalind Smyth (Chair) | None | None | GlaxoSmithKline | Grant for other member in Department | Yes |
| | | | Auralis | As above | Yes |
| | | | CDSS | As above | Yes |
| | | | Pharmaceutical Service | As above | Yes |
| | | | Pharmalys | As above | Yes |
| | | | Quay Pharmaceuticals | As above | Yes |
| | | | Shire Human Genetic | As above | Yes |
| | | | Takeda Global R&D | As above | Yes |
| | | | Therakind | As above | Yes |
| | | | Walker Graham Pharma Consulting | As above | Yes |
| Dr Eileen Baildam | Roche | PI on two trials of Tocilizumab but no personal payments received, funding being routed through the LRN Previously sponsorship received for attendance at the American College of Rheumatology meeting in 2008 | None | None | |
| | Wyeth | | None | None | |
| Mrs Alison Bowser | None | None | Valeant Pharma | Consultancy for public events | No |
| Professor Richard Cooke | None | None | None | None | |
| Dr Steven Cunningham | Schering GSK | Lecture fee | None | None | |
| | | Lecture fee | None | None | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|---------------------------|--------------------|--|---|--|-------------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Dr Paul Ewings | | | | | |
| Professor Diana Gibb | None | None | Cipla | In all instances, the drug companies provide same drugs and support for trials and studies at CTU with which ProfessorGibb is involved | Yes |
| | | | Gilead GlaxoSmithkline Boehringer Ingelheim | | Yes Yes Yes |
| Professor Ruth Gilbert | Wyeth | Co-applicant on a research grant £180,000 ending in 2010 | None | None | |
| Professor Peter Hindmarsh | Medtronic Diabetes | Consultancy fees of £600 per annum | None | None | |
| Mrs Jane Houghton | | | | | |
| Dr Rebecca Mann | None | None | None | None | |
| Dr Vas Novelli | | | | | |
| Professor Anthony Nunn | None | None | None | None | |
| Dr Shirley Price | None | None | None | None | |
| Dr George Rylance | None | None | None | None | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|---------------------------|-----------------------|--|------------------------|--|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Professor Michael Stevens | Chugai Pharma Europe | Unrestricted educational grant to support an international postgraduate meeting in November 2008 | None | None | |
| Dr Jane Tizard | GlaxoSmithKline | Shares | None | None | |
| Dr Heather Wallace | None | None | Wyeth | Support of a research project until June 2009 | No |
| Mrs Madeleine Wang | None | None | None | None | |
| Dr William Whitehouse | UCB sponsored charity | Funding for my attendance and travel to European paediatric neurology meeting, Harrogate, UK, October 2009 | Eisai | Funding for departmental meetings and regional clinical meetings, eg Midland-Trent Paediatric Neurology Group, Trent Epilepsy Interest Group | Yes |
| | | | Novartis | As above | Yes |
| | | | Janssen-Cilag | As above | Yes |
| | | | Pfizer | As above | Yes |
| | | | UCB | As above | Yes |
| Professor Andrew Wolf | None | None | None | None | |
| Dr Geoffrey Wong | None | None | None | None | |
| Dr Edwards Wozniak | None | None | None | None | |
| Dr Morris Zwi | None | None | None | None | |

PATIENT INFORMATION EXPERT ADVISORY GROUP: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON- PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|-------------------------|--------------------|--|------------------------|--|-----------------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Ms Joanne Rule (Chair) | | | | | |
| Dr Keith Beard | None | None | None | None | |
| Professor Dianne Berry | | | | | |
| Mr Andrew Boag | None | None | ABPI | Paid travelling expenses to attend a meeting on medicine legislation in Europe in October 2008 | No |
| Mrs Alison Bowser | None | None | Valeant Pharma | Consultancy for public events | No (expired march 08) |
| Dr Katherine Darton | None | None | None | None | |
| Dr Nicola Gray | AstraZeneca | Consultancy – Medicines programme including four specific products: Arimidex, Crestor, Nexium, Symbicort | None | None | |
| | Datapharm | Travel expenses for attendance and presentation at a meeting that they hosted | None | None | |
| Professor Jennifer Hunt | None | None | None | None | |
| Mr Ian Pearson | None | None | None | None | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|-----------------------|----------------------------------|--|------------------------|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Carolyn, Lady Roberts | None | None | None | None | |
| Dr Ross Taylor | None | None | None | None | |
| Mrs Madeleine Wang | None | None | None | None | |
| Dr Bruce Warner | Associated Chemists (Wicker) Ltd | Both myself and wife have a small share holding in this community Pharmacy | None | None | |

PHARMACOVIGILANCE EXPERT ADVISORY GROUP: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|------------------------------------|--------------------|--------------------|------------------------|--|-----------------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Professor Munir Pirmohamed (Chair) | None | None | GSK | Attended a meeting but costs met by MHRA | No |
| Professor Nicholas Bateman | None | None | AstraZenca | The poisons bureau provides a code-breaking service for trials out of hours (contract within MHS Lothian) | Yes |
| Dr Keith Beard | None | None | None | None | |
| Mrs Alison Bowser | None | None | Valeant Pharma | Consultancy for public events | No (expired March 08) |
| | | | ABPI | Paid travelling expenses to attend a meeting on medicine legislation in Europe in October 2008 | No |
| Dr Robert Bracchi | None | None | None | None | |
| Miss Alison Ewing | None | None | Pfizer | Grant to Royal Liverpool Hospital pharmacy department; £40,000 for research donated 2009; non-personal, non-specific interests | Yes |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|-------------------------|--|------------------------------------|--|---|--|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Professor Robin Ferner | None | None | None of Prof Ferner, but wife Professor Cilia Moss | Has undertaken research sponsored by Fujisawa | |
| Professor David Gunnell | None | None | None | None | |
| Ms Jane Harris | None | None | None | None | |
| Professor Simon Maxwell | None | None | None | None | |
| Dr Nicholas Plant | Committee on Toxicity in Food, Consumer Products and the Environment | Committee member (fees paid) | None | None | |
| Professor Alan Silman | None | None | None | None | |
| Professor Simon Thomas | Lundbeck | Consultancy (ended September 2009) | Boehringer Ingelheim AstraZenca PPD Servier R&D GlaxoSmithKline Baxter EUSAPharm Symphogen A/S Newcastle University) MDS Pharma Services Hoffmann-La Roche Bristol-Myers Squibb Company | Non-personal research grant Non-personal research grant Non-personal research grant Non-personal research grant Non-personal research grant Non-personal research grant Non-personal research grant DMC chair (charged to DMC chair (charged to Newcastle University) Non-personal research grant Non-personal research grant | Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes |
| Dr Caroline Vaughan | RioTech Pharmaceuticals | Shares | None | None | |
| Professor Ken Woodhouse | None | None | None | None | |

PSYCHIATRY AND OLD AGE PSYCHIATRY EXPERT ADVISORY GROUP: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|---------------------------------|----------------------|--|--|---|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Professor Ken Woodhouse (Chair) | None | None | None | None | |
| Professor Ian Anderson | None | None | AstraZenca | Investigator-initiated grant | Yes |
| Professor Paul Bebbington | None | None | None | None | |
| Dr Simon Fleminger | None | None | None | None | |
| Professor Ian Goodyear | None | None | None | None | |
| Dr Paul Kinnersley | Aortech | Shares | UCB Pharma | Grant of £49,000 awarded to Dr Smith and myself for research | Yes |
| Dr Anne Lingford-Hughes | Bristol Myers Squibb | Member of core faculty; received no monies this year | Archimedes Pharma/ Lundbeck/ Pfizer/ Schering | Support of Consensus meeting for evidence-based guidelines in substance misuse and co-morbidity for British Association for Psychopharmacology – coordinated by myself; meeting held on 8/12/2009 | Yes |
| | Servier | Lecture for CINP Certificate in Psychopharmacology – sponsored by Servier | | | |
| | GSK | PI on MRC grant jointly with GSK | | | |
| | NET Device Corp | Advisor on neuroimaging aspect of trial undertaken about neuroelectric therapy in opiate addiction at University of Glasgow, | | | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|---|---|--|------------------------|--|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Dr Anne Lingford-Hughes (cont) Additional information: Member of NICE core development group for 'Alcohol Dependency Guideline Development Group'; PI on NIHR grant for feasibility study looking at pharmacological regimens in alcohol detox (acamprosate + chlordiazepoxide vs placebo + chlordiazepoxide); PI on submitted HTA grant for RCT of baclofen in alcohol dependence. | NET Device Corp (cont) | sponsored by this company | | awarded a studentship by Wellcome-Imperial-GSK | |
| Professor Ian McKeith | GE Healthcare Sanofi-Aventis Astellas Otsuka Bayer-Schering Numico | Consultancy and fees Consultancy Consultancy Consultancy Consultancy Consultancy | None | None | |
| Professor John O'Brien | Shire Janssen Pfizer/ Eisai Lunbeck Bayer Servier GE Healthcare | Lecture fees Lecture fees Lecture fees Lecture fees Consultancy Consultancy Lecture fees | None | None | |
| Professor David Owens | None | None | None | None | |
| Mrs Meredith Robson | None | None | None | None | |
| Mrs Pauline Robson | None | None | None | None | |
| Mrs Kay Sheldon | None | None | None | None | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|-----------------------|--------------------|---|------------------------|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Professor Eric Taylor | Equazene Ltd | Conducting a trial of omega-3 fatty acids in ADHD (this is a food product rather than a drug) which is receiving grant support from the company | None | None | |

RESPIRATORY AND ALLERGY EXPERT ADVISORY GROUP: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|-------------------------------|----------------------------------|--|------------------------|--|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Professor Peter Helms (Chair) | None | None | None | None | |
| Dr Iolo Doull | MSD GSK AstraZeneca | Advisory Lecture fee Lecture fee | None | None | |
| Ms Monica Fletcher | Boehringer Ingelheim | Travel grant received for conference attendance | GSK | Speaker at conference; participation in Advisory Board | No |
| | AstraZeneca | Travel grant received for conference attendance | Novartis | Research grant | Yes |
| Professor Anthony Frew | Allergy Therapeutics | Consultancy; principal investigator; speaker fees; travel expenses | None | None | |
| | ALK-Abello UK | Consultancy; speaker fees | None | None | |
| | GSK | Consultancy | | | |
| | Merck Sharp & Dohme | Speaker fees | | | |
| | Schering-Plough Allergopharma | Speaker fees Consultancy | | | |
| Dr Vanessa Graham | AstraZeneca | Limited shares | None | None | |
| | GlaxoSmithKline | Limited shares | | | |
| | Genus | Sponsorship for TB field trip to Malawi - November 2009 | | | |
| Dr Philip Ind | GSK | Advisory Board (Asthma/COPD Therapy) | None | None | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|--------------------------------------|--------------------|--|------------------------|--------------------------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Dr Philip Ind (cont) | AstraZeneca | Conference accomodation and travel expenses; my father holds some shares | | | |
| | Nykomed | Conference accomodation and travel expenses; | | | |
| | Aerovance | Advisory Board (roflumilast) Expert Advisory Board (pitrakinra); lecture fee; clinical trial PI hospitality (Dinner) | | | |
| | Pfizer/ Boehringer | Lecture fees (Tiotropium and COPD TherapyY) hospitality (Lunch) | | | |
| | Trinity-Chiesi | Conference accomodation and travel expenses; Advisory Board (Fostair) | | | |
| | Vectura Group Plc | Expert Advisory Board (no fee paid) | | | |
| Dr Ann Millar | Intermune | Clinical trial | None | None | |
| | Astra | Clinical trial | | | |
| | Boehringer | Clinical trial | | | |
| Professor Richard Powell | None | None | None | None | |
| Professor Stephen Spiro | None | None | None | None | |
| Emeritus Professor Anne Tattersfield | None | None | None | None | |
| Dr Michael Thomas | GlaxoSmithKline | Advisory panel and consultancy on research study | Asthma UK | Fellowship and Chief Medical Advisor | Yes |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|--------------------------|--------------------|----------------------|------------------------|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Dr Michael Thomas (cont) | Merck and Co | Speaker's honorarium | | | |
| Dr Charles Twort | None | None | None | None | |

RHEUMATOLOGY AND IMMUNOLOGY EXPERT ADVISORY GROUP: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|-------------------------------------|----------------------|--------------------|------------------------|---------------------------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Professor Stuart Ralston (Chair) | Novartis | Consultancy | Novartis | Research grant | Yes |
| | Proctor & Gamble | Consultancy | Eli Lilly | Commission for advice | Yes |
| | Merck | Consultancy | Merck | Research grant | Yes |
| | | | Pfizer | Commission for advice | No |
| | | | Wyeth | Research grant | Yes |
| Dr Deborah Bax | None | None | Abbott | Education | No |
| | | | Abbott | Grant | No |
| | | | Alchemy Pharma | Education | No |
| | | | Almirall | Education | No |
| | | | Amgen | Consultancy | Yes |
| | | | Amgen | Honoraria | No |
| | | | Amgen | Research Grant | Yes |
| | | | Astellas | Education | No |
| | | | AstraZeneca | Trial | Yes |
| | | | Basilea Pharma | Advisory Panel | Yes |
| | | | Baxter | Advisory | No |
| | | | Baxter | Safety Surveillance Project | Yes |
| | | | Baxter | Sponsorship; international meeting | No |
| | | | Bayer | Advisory committee | No |
| | | | Bayer | Lectures | Yes |
| | | | Bayer | Lecture fees | No |
| | | | Bayer | Research funding | No |
| | | | Bayer | Safety Surveillance Project | Yes |
| | | | Biotest and Grifols | Safety Surveillance Project | Yes |
| | | | Boehringer Ingelheim | Workshops | No |
| Boehringer Ingelheim | Overseas sponsorship | Yes | | | |
| CSL Behring | Advisory committee | No | | | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|-----------------------|--------------------|--------------------|------------------------|-----------------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Dr Deborah Bax (cont) | | | CSL Behring | Lecture fees | No |
| | | | CSL Behring | Safety Surveillance Project | Yes |
| | | | Fonterra Brands | Consultancy | Yes |
| | | | Genus | Education | No |
| | | | GSK | Consultancy | Yes |
| | | | Hermal | Education | No |
| | | | Interleukin Genetic | Consultancy | Yes |
| | | | Inverness Medical | Consultancy | Yes |
| | | | Kyphon Europe | Consultancy | Yes |
| | | | Kyphon Inc | Consultancy | Yes |
| | | | LFB | Safety Surveillance Project | Yes |
| | | | Lilly | Honoraria | No |
| | | | Nestec | Consultancy | Yes |
| | | | Nestle | Consultancy | Yes |
| | | | Nordic Pharma | Lecture | No |
| | | | Novartis | Research Grant | Yes |
| | | | Novartis UK | Trial | Yes |
| | | | Novartis USA | Trial | Yes |
| | | | Novo Nordisk | Advisory Committee | No |
| | | | Novo Nordisk | Safety Surveillance Project | Yes |
| | | | Octapharma | Safety Surveillance Project | Yes |
| | | | Ono Pharmaceutical | Consultancy | Yes |
| | | | Osteologix | Consultancy | Yes |
| | | | Proctor & Gamble | Honoraria | No |
| | | | Proctor & Gamble | Research grant | Yes |
| | | | Roche | Conference sponsorship | No |
| | | | Schering Plough | Education | No |
| | | | SPD Development | Consultancy | Yes |
| | | | Tethys Bioscience | Consultancy | Yes |
| | | | Tethys Bioscience | Honoraria | No |
| | | | Unilever | Research grant | Yes |
| | | | Unilever Research | Consultancy | Yes |
| | | | Unipath | Research grant | Yes |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|-----------------------|-----------------------|---|------------------------|----------------------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Dr Deborah Bax (cont) | | | Wyeth | Education | No |
| | | | Wyeth | Research project | No |
| | | | Wyeth | Safety Surveillance Project | Yes |
| | | | Wyeth | Trial | Yes |
| Mrs Caroline Dore | GlaxoSmithKline | Shares | None | None | |
| | Smith & Nephew | Shares | | | |
| | AstraZeneca | Shares | | | |
| Dr Michael Ehrenstein | GSK | Consultancy (anti-CD3) | Wyeth | Educational grant to department | Yes |
| | Biogen | Consultancy | Abbott | Educational grant to department | Yes |
| | BMS | Consultancy (anti-TNF) | | | |
| | UCB | Consultancy | | | |
| | Shering Plough | Consultancy (anti-TNF) | | | |
| Professor John Gaston | Schering Plough China | Lecturing at a conference in China sponsored by SPC; March 2010 | UCB | Collaborative research agreement | Yes |
| | Roche | Sponsorship to attend EULAR conference; June 2009 | GSK | Collaborative research agreement | Yes |
| Professor Alan Silman | None | None | None | None | |
| Dr Anthony Wilson | GSK | Consultancy (2002-2006) | None | None | |
| | BMS | Consultancy (2006) | | | |
| | AKP | Advisory meeting (2010); honorarium payment | | | |
| | GSK | Research grants (2001-2008) | | | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|------------------------|--------------------|---|------------------------|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Professor Patricia Woo | Roche | Steering committee on a clinical trial of tocilizumab in sJIA (TENDER); country PI; no fees paid to me personally – ICH charges Roche for my time; participant PI for the CHERISH study: phase III RCT of tocilizumab in polyarticular JIA; no fees paid to me personally – ICH charges Roche for my time | None | None | |
| | Novartis | Steering committee member and participant in the phase II clinical trials of canakinumab (CAZ); no fees paid to me personally – ICH recharges money; country PI for the phase III study; no fees paid to me personally – ICH charges Novartis for my time | | | |

EXTERNAL EXPERT PANEL: 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 |
| Dr Janet Audrey Barter | | | | | |
| Dr Nick Bateman | None | None | AstraZeneca | Contract with NHS | Yes |
| Professor John Betteridge | | | | | |
| Professor Roger J Buckley | Sanofi-Aventis | One-off consultancy on an application for the re-classification of an ocular formulation of sodium cromoglicate as a GSL product | None | None | |
| | Allergan | Chairmanship of one-day Dry Eye Seminar for which I was paid an honorarium | | | |
| Professor Andrew J Cant | | | | | |
| Mr Chris R Chapple | Pfizer | Consultant, researcher | None | None | |
| | | Astellas | Consultant; researcher | | |
| | | Recordati | Consultant; researcher | | |
| | | Allergan | Consultant; researcher | | |
| | | Xention | Consultant | | |
| | | ONO | Consultant | | |
| Professor Imti Choonara | None | None | None | None | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|---|--------------------|---|------------------------|--|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Professor Peter Clayton | Merck Serono | Related to growth hormone (chief investigator for PREDICT study); travel expenses and lecture fees | Merck Sorono | Consultancy fee paid to University of Manchester; Support research in my group | Yes |
| | Ipsen | Related to IGF-1 and G H; Chief investigator for EPIGROW study; travel expenses; consultancy fee for Advisory Board; lecture fees | | | |
| | Novo Nordisk | Related to growth hormone; travel expenses and lecture fees | | | |
| Additional information: From time to time, I am asked to give lectures at meetings supported by companies, including; Pfizer and Lilly. | | | | | |
| Dr Thomas H Clutton-Brock | None | None | None | None | |
| Professor Stuart M Cobbe | | | | | |
| Professor Marcela Contreras | | | | | |
| Dr Griselda M Cooper | | | | | |
| Miss Sarah Creighton | None | None | None | None | |
| Professor Hilary Octavia Dawn Critchley | | | | | |
| Ms Carol A Dealey | | | | | |
| Mr Michael Denham | | | | | |
| Dr Gordon B Drummond | None | None | None | None | |
| Professor Elwyn Elias | | | | | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|---|---|--|--------------------------------|--|---|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Mrs Christine F Farquhar | bene pharmaChem GmbH & Co KG Sylvan Pharmaceuticals, Australia | Supply pentosan polysulphate gratis for research purposes Supply pentosan polysulphate gratis for research purposes | None | None | |
| Dr Cecila H Fenerty | NHS Qualacept Ltd Royal Pharmaceutical Society Cardiff and Vale NHS Trust Strathclyde University British Pharmacopoeia | Consultant ophthalmologist Consultancy Fees Fees Fees Fees | Pfizer | Received funding for departmental research into patient persistence with glaucoma medication | No |
| Professor The Baroness Finlay of Llandaff | | | | | |
| Professor Karen Forbes | None | None | None | None | |
| Professor John Forrester | | | | | |
| Professor Jayne A Franklyn | None | None | None | None | |
| Professor Edwin Gale | None | None | None | None | |
| Dr Terence Gibson | | | | | |
| Dr Robin Grant | None | None | None | None | |
| Professor Christopher E M Griffiths | | | | | |
| Professor Paul D Griffiths | None | None | GSK Pfizer GE Healthcare | Research grant Research grant Research grant | Starts in 2010 Starts in 2010 Yes |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|------------------------------|--|--|---|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Professor Freddie Hamdy | Roche Diagnostics Amgen | Consultancy Consultancy | None | None | |
| Dr David Heaf | | | | | |
| Professor Peter G Isaacson | None | None | None | None | |
| Professor David A Isenberg | Merck Serono | Consultancy Roche Celltech Bristol Myers Squibb | None Consultancy Consultancy Consultancy | None | |
| Professor Ian Jeffrey Jacobs | | | | | |
| Dr Colin R Kennedy | None | None | None | None | |
| Professor Peng T Khaw | Pfizer/ Pfizer Ophthalmics Allergan Promedior Lumemed | Grant support; consultancy; scientific advisory board Consultancy Consultancy; scientific advisory board Shares | None | None | |
| Dr Denise Kitchiner | | | | | |
| Mr Alan J B Kirk | None | None | None | None | |
| Dr Paul Kletz | | | | | |
| Professor Ian Lauder | | | | | |
| Professor Ian D Learmonth | | | | | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|--------------------------------|----------------------|--|---|--|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Dr Phillip J Lee | | | | | |
| Dr Liz Lightstone | Roche | Support for attendance at the American Society of Nephrology in 2008 | None | None | |
| | Aspreva | Support for attendance at American Society of Nephrology in 2007; consultancy fees for advisory boards of £1000 | | | |
| | Amgen | Support for attendance at the American Society of Nephrology in 2009 | | | |
| | Sante | Fees for attendance at advisory boards of less than £5000 in total | | | |
| | BMS | Honoraria for talks to GPs of less than £1000 | | | |
| Professor Anne Lingford-Hughes | Bristol Myers Squibb | I am a member of Core Faculty; received no monies this year | Archimedes Pharma/ Lundbeck/ Pfizer/ Schering | Support of consensus meeting for evidence based guidelines in substance misuse and comorbidity for British Association for Psychopharmacology – coordinated by myself; meeting held on 8/12/09 | |
| | Servier | Lecture for CINP Certificate in Psychopharmacology – sponsored by Servier | | PI on MRC grant jointly with GSK | |
| | GSK | PI on MRC grant jointly with GSK | | PI on MRC grant jointly with GSK; GSK are part of 'MRC addiction cluster' of which I am also member; one of my PhD students awarded a studentship by Wellcome-Imperial-GSK | |
| | NET Device Corp | Advisor on neuroimaging aspect of trial undertaken about neuroelectric therapy in opiate addiction at University of Glasgow, sponsored by this company | GSK | | Yes |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|-----------------------------|-------------------------|--|------------------------|---|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Dr Alan Lobo | | | | | |
| Professor Richard F A Logan | GSK Proctor & Gamble | Shares Travel expenses and hospitality | None | None | |
| Professor Karen A Luker | None | None | None | None | |
| Dr Adrian Lloyd-Thomas | | | | | |
| Professor R Hugh MacDougall | None | None | None | None | |
| Professor James O'D McGee | | | | | |
| Professor James H McKillop | None | None | None | None | |
| Professor David R Matthews | | | | | |
| Professor Angus V PMackay | None | None | None | None | |
| Professor David Marsh | | | | | |
| Dr Harriet C Mitchison | None | None | Schering Plough | Funding for a clinic nurse – 6 hours per month | Yes |
| Professor Sameh Morcos | | | | | |
| Dr Bartholomew R O'Driscoll | None | None | None | None | |
| Dr Kevin Palmer | | | | | |
| Dr Ian Peart | | | | | |
| Dr Joan Pitkin | | | | | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|--------------------------------|--|---|---------------------------------------|---|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Professor Stephen H Powis | None | None | Roche | Research support held within department for which I was responsible until end March 2009 | No |
| Dr Shakeel A Qureshi | NuMED Inc, Hopkinton, New York, USA AGA | Consultancy agreement Consultancy and Proctor on an ad-hoc basis | None | None | |
| Professor Ian G Rennie | Teva UK | Consultancy | None | None | |
| Dr Jonathan Ross | None | None | None | None | |
| Professor David I Rowley | None | None | None | None | |
| Dr Lindsey T A Rylah | None | None | None | None | |
| Professor Robin A Seymour | Dendron Ltd | Consultancy | None | None | |
| Professor Pamela J Shaw | Oxford Biomedica | Consultancy | Trophos | Joint EU funding to evaluate a potential neuroprotective agent in laboratory models and in a human phase II/III trial | Yes |
| Mr Anthony Charles Silverstone | | | | | |
| Professor Stephen K Smith | | | | | |
| Dr Alan Smyth | Biocontrol Boehringer Ingelheim | Consultancy Consultancy | Pharmaxis Boehringer Ingelheim | Payment for taking part in a clinical trial As above | Yes Yes |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|-------------------------------|---|---|------------------------|--|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Dr Neil Soni | Portex Smiths Medical Nexstar Fresenius Kabi | Consultancy work – current Historical grant 10 years ago Consultancy work – current | Pfizer | Attended meeting they hosted last year | |
| Professor Paul M Stewart | AstraZeneca | Sponsorship to attend scientific meeting (ESC, Barcelona, Sept 09) | None | None | |
| Professor Roger D Sturrock | Abbott | Lecture Fee | None | None | |
| Dr Peter B Sullivan | Danone | Consultancy | Numico | Research grant | Yes |
| Dr Robert C Tasker | Covidien | Lecture fees on the topic of brain oxygenation | Novo Nordisk | Grant for research on pituitary function after head injury | Yes |
| Professor Gilbert R Thompson | None | None | None | None | |
| Mr David Tolley | Edap-TMS Boston Scientific | Consultant Fees for educational activities | None | None | |
| Professor Geoffrey G T Tucker | Napp (Mundipharma) Dermatech Teva Neurosearch Servier | Consultancy (retainer) Consultancy (one-off – Fentanyl Patch) Consultancy (occasional) Consultancy (one-off – investigational compound) Lecture fee | None | None | |
| Mr Keith Tucker | None | None | None | None | |
| Dr Mark A Turner | | | | | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|-----------------------------|----------------------------|---|------------------------|-----------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Dr John H Walter | Swedish Orphan | Educational grant to attend scientific symposium | None | None | |
| | Orphan Europe | Honorarium for teaching on sponsored courses and lecture fees | | | |
| Professor David A Warrell | None | None | None | None | |
| Dr Gordon Watkins | None | None | None | None | |
| Dr David C Wheeler | Amgen | Honoraria and travel funding | Amgen | Funding to Department | No |
| | Genzyme | Honoraria | Genzyme | Funding to Department | Yes |
| | Takeda | Honoraria | Roche | Funding to Department | Yes |
| | | Novartis | Honoraria | | |
| | | Novo Nordisk | Honoraria | | |
| Professor Ian Whittle | Archimedes Pharmaceuticals | Ad hoc lecture fees and consultancy fees | None | None | |
| | Ark Therapeutics | Ad hoc consultancy fees (not in the last 12 months) | | | |
| | Schering Plough | Ad hoc lecture fees (not in the last 12 mths) | | | |
| Dr Alastair Robert Williams | Preglem SA | Consultancy | None | None | |
| | HRA Pharma | Consultancy | None | None | |
| | Beyer-Schering Pharma | Consultancy | None | None | |
| | Pfizer | Consultancy | None | None | |
| | Repro Therapeutics Inc | Consultancy | None | None | |
| | TAP Pharmaceutical | Consultancy | None | None | |
| | Proxs Inc | | | | |
| Boehringer Ingelheim | Consultancy | None | None | | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|------------------------------|---------------------|---------------------|------------------------|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Professor Geraint T Williams | None | None | None | None | |
| Dr Christopher Wren | GlaxoSmithKline R&D | One-off consultancy | None | None | |
| Professor Nicholas A Wright | None | None | None | None | |

MIXING GROUP WORKING GROUP: 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 |
| Mrs Alison Bowser | None | None | Valeant Pharma | Consultancy for public events | No |
| | | | ABPI | Paid travelling expenses to attend a meeting on medicine legislation in Europe in October 2008 | No |
| Professor Derek Calam | None | None | None | None | |
| Professor Martin Kendall | None | None | None | None | |
| Mr Robert Lowe | Baxter Healthcare | Conculty work (April 2009) – one-off event | None | None | |
| Dr Rosalind Ranson | None | None | None | None | |
| Carolyn, Lady Roberts | None | None | None | None | |
| Professor Roger Walker | None | None | None | None | |

Additional information: I do place on record the fact that my wife is a community pharmacist and works for Boots.

NICOTINE REPLACEMENT THERAPY WORKING GROUP: 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 | |
| Ms Deborah Arnott | None | None | None | None | |
| Dr Paul Aveyard | McNeil | Consultancy (not within the last 12 months) | McNeil | Research grant | No |
| | Pfizer Xenova (now Celtic) | Consultancy Consultancy (not within the last 12 months) | | | |
| Professor John Britton | None | None | None | None | |
| Dr Richard Hubbard | GlaxoSmithKline | Consultancy fee of £300 for idiopathic pulmonary fibrosis in 2009 | GlaxoSmithKline | Research grant of £800,000 for a joint project on idiopathic pulmonary fibrosis starting in January 2010 | Yes |
| | Berenger Bank | Consultancy fee of £900 for a talk on treatment of idiopathic pulmonary fibrosis | | | |
| Professor Martin Jarvis | Pfizer | Member Varenicline Worldwide Scientific Advisory Board; consultancy fees | None | None | |
| | Pfizer | European Policy Advisory Board; consultancy fees | | | |
| Mr Gareth Jones | AstraZeneca | Shares | None | None | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|------------------|--|--|------------------------|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Dr Mike Knapton | British Heart Foundation | Voluntary organisation; salary; Associate Medical Director | None | None | |
| | Genetic Interest Group | Voluntary organisation; trustee | | | |
| | Royal College of General Practitioners | Voluntary organisation; trustee | | | |
| | NAPP Educational Foundation | This is an independent foundation support by an unrestricted grant from NAPP Pharmaceuticals | | | |
| Dr Marcus Munafo | Sepracor Inc | Invited lecture fee | None | None | |

PSEUDOEPHEDRINE WORKING GROUP: 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 |
| Mrs Alison Bowser | None | None | Valeant Pharma | Consultancy for public events | No |
| Dr Michael Donaghy | None | None | None | None | |
| Mr Roy Gilman | Leach and Burton | Locum Pharmacist | None | None | |
| Professor Peter Helms | None | None | None | None | |
| Dr Terrence Maguire | GlaxoSmithKline Ulster Career Foundation | Consultancy Director | None | None | |
| Professor Anthony Nunn | None | None | None | None | |
| Professor Munir Pirmohamed | None | None | GSK | Attended a meeting but costs met by MHRA | No |
| Dr Kevin Solomans | Nycomed (Roflumilast) Takeda (Candesartan) | Consultancy Consultancy | None | | |
| Dr Ross Taylor | None | None | None | None | |
| Dr Angela Timoney | None | None | None | None | |
| Professor Roger Walker | None | None | | | |

Additional information: I do place on record the fact that my wife is a community pharmacist and works for Boots.

PUMAR WORKING GROUP: 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 Deborah Ashby | None | None | GSK | Methodological collaboration | Yes |
| | | | Sanofi-Aventis | As above | Yes |
| | | | Pfizer Limited | As above | Yes |
| | | | F Hoffmann-La Roche AG | As above | Yes |
| | | | Novartis Pharma AG | As above | Yes |
| | | | Amgen NV | As above | Yes |
| | | | Genzyme Europe BV | As above | Yes |
| | | | Merck KGaA | As above | Yes |
| | | | Bayer Schering Pharma AG | As above | Yes |
| | | | AstraZenca A/S | As above | Yes |
| Novo Nordisk A/S | As above | Yes | | | |
| Dr Barbara Bannister | None | None | None | None | |
| Mrs Alison Bowser | None | None | Valeant Pharma | Consultancy for public events | No (expired March 08) |
| | | | ABPI | Paid travelling expenses to attend a meeting on medicine legislation in Europe in October 2008 | No |
| Professor Chris Butler | None | None | None | None | |
| Professor Peter Davey | | | | | |
| Professor Brian Duerden | None | None | None | None | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|------------------------|--|---|------------------------|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Professor Roger Finch | Bayer Bayer Healthcare Destiny Pharma Menarini Ricerche Novartis | Lecture fees Travel grant Consultancy Consultancy Consultancy | None | None | |
| Dr Steve Leach | None | None | None | None | |
| Dr Terrence Maguire | GlaxoSmithKline Ulster Career Foundation | Consultancy Director | None | | |
| Dr Christine McCartney | None | None | None | None | |
| Dr Rosalind Ranson | None | None | None | None | |
| Carolyn, Lady Roberts | None | None | None | None | |
| Professor Roger Walker | None | None | | | |

Additional information: I do place on record the fact that my wife is a community pharmacist and works for Boots.

ADVISORY BOARD ON THE REGISTRATION OF HOMOEOPATHIC PRODUCTS: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|---------------------------------|----------------------------------|---|------------------------|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Dr Timothy Chambers (Chair) | None | None | None | None | |
| Dr Steve Bennett Britton | None | None | None | None | |
| Professor Christopher Castledon | None | None | None | None | |
| Mrs Patricia Donnachie | None | None | None | None | |
| Dr Michael Erlewyn-Lajeunesse | None | None | None | None | |
| Dr Michael Evans | None | None | None | None | |
| Professor Andreas Gescher | None | None | None | None | |
| Mrs Christine Glover* | NAPP Pharmaceutical Cambridge UK | Advisory Board on Opiates and Pharmacy, paid per meeting; travel expenses | None | None | |
| Mrs Kiran Kumar | None | None | None | None | |
| Dr George Lockwood | None | None | None | None | |

* Resigned June 2009

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|-----------------|--------------------|--------------------|------------------------|---|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Dr Frank Mulder | None | None | Weleda Wala | Indirect: These companies occasionally and for a small part support the IVAA, the international umbrella organisations; as a council member of the IVAA my travel expenses for council meetings and loss of earnings in weekdays are reimbursed by the IVAA | Yes |
| | | | Aefmuta | Indirect: Aefmuta is the umbrella organisation of manufacturers of anthroposophic medicines; it occasionally and for a small part supports the IVAA, the International umbrella organisation of anthroposophic doctors associations; as a council member of the IVAA, my travel expenses for council meetings and loss of earnings in weekdays are reimbursed by the IVAA | Yes |
| | | | Boehringer Ingelheim | Indirect: Helios Medical Centre of which I am a partner has received the support for a nurse and training from Boehringer Ingelheim to help run a spirometry clinic | Yes |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|-----------------------|--------------------|--------------------|------------------------|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Professor Julie Stone | None | None | None | None | |
| Dr Thomas Whitmarsh | None | None | None | None | |

BRITISH PHARMACOPOEIA COMMISSION: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|-------------------|--|---|--|---|---------------------------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Prof D Woolfson | None | | Warner Chilcott Ltd | Research grant | Yes |
| Mr V Fenton-May | Cephalon Ltd Qualasept Ltd Cardiff and Vale NHS Trust Royal Pharmaceutical Society Strathclyde University Advisory Committee on Borderline Substances | Consultancy (specific product) Consultancy Fees Fees Fees Fees | None | | |
| Prof G Buckton | Eli Lilly Pharmaterials Ltd Allergan Teva | Wife employed Salary; shares Consultancy Consultancy | Pfizer | Research grant | Yes |
| Prof D Cairns | None | | GlaxoSmithKline Lifescan AAH Pharmaceuticals DM Wood Medical Equazen | Sponsor lecture Sponsor prize Sponsor prize Sponsor prize Hospitality for speaker | Yes Yes Yes Yes Yes |
| Prof A G Davidson | None | | None | | |
| Mrs M A Dow | Syner-Medica Ltd Holygene Biotech Corporation Bharat Serums and Vaccines Marvel LifeSciences GlaxoSmithKline | Consultancy Consultancy Consultancy Consultancy Shares | None | | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|-------------------|--|---|------------------------|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Dr T D Duffy | Ark Therapeutics AstraZeneca Deltex Medical Elan Fulcrum GW Pharmaceuticals GlaxoSmithKline MDY Healthcare | Shares Shares Shares Shares Shares Shares Shares Shares | None | | |
| Mr C T Goddard | Recipharm Ltd | Salary | None | | |
| Dr K Helliwell | William Ransom & Son PLC | Salary; shares | None | | |
| Dr R L Horder | Abbott Laboratories Hospira Inc | Consultancy; shares Shares | None | | |
| Dr A M T Lee | None | | None | | |
| Dr L Tsang | Arnold & Porter LLP BioIndustry Association British In Vitro Diagnostics Association Association of British Healthcare Industries | Partner (providing legal counsel to life sciences industry) Chairman, Regulatory Affairs Advisory Committee Member of Regulatory Affairs Committee Member of Legal Affairs Committee | None | | |
| Prof E Williamson | None | | GlaxoSmithKline | Research grant | Yes |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|----------------|-------------------------|-----------------------------|------------------------|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Prof P York | Pharmtech Ltd | Director; shares; dividends | Nektar Therapeutics | Research grant | Yes |
| | Osat Ltd | Director | AstraZeneca | Research grant | No |
| | Biosat | Director; shares; dividends | | | |
| | Lena Nanoceutics Ltd | Director | | | |
| | CrystePharma Ltd | Director; shares | | | |
| | Nektar Therapeutics Inc | Shares | | | |
| | Intelligensys Ltd | Director | | | |
| | GlaxoSmithKline | Consultancy | | | |
| | SkyePharma | Shares (spouse) | | | |
| Mr B Capon | None | | None | | |
| Mrs J Turnbull | None | | None | | |

HERBAL MEDICINES ADVISORY COMMITTEE: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|------------------------------------|--|--|------------------------|---|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Professor Philip Routledge (Chair) | None | None | AstraZeneca | Department of Pharmacology in Cardiff, has a lecturership funded via the ABPI Scheme | Yes |
| Professor Peter Aggett* | Cadbury International Alliance of Dietary/ Food Supplement Associations | Member of Global Nutrition Advisory Panel; fee and expenses Lecture fees and expenses | None | None | |
| Mr Anthony Booker | None | None | None | None | |
| Dr Robert Bracchi | None | None | None | None | |
| Ms Alison Denham | None | None | None | None | |
| Dr Michael Evans | None | None | None | None | |
| Dr Shantha Godagama | None | None | None | None | |
| Mrs Christine Gratus | None | None | Macmillan Cancer Care | Grant for user-led research project into cancer patients' use of herbal medicines (with University of Birmingham) | Yes |

* Appointed March 2009

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | |
|--|--------------------|--------------------|---|---|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | WHETHER CURRENT |
| Mrs Agnes Grunwald-Spier | None | None | None | None | |
| Professor Paul Harrison | None | None | None | None | |
| Professor Gabrielle Hawksworth | None | None | Servier R&D Pfizer Global R&D GSK | PhD Studentships Research collaboration Post-doctoral fellow | Yes Yes |
| Professor Michael Heinrich | None | None | None Bioforce, UK (A Vogel) | None Support for Annual A Vogel Lecture at the Centre for Pharmacognosy (one-off payment Feb 2009) | No |
| | | | Fa Natra, Spain BBSRC/ GSK | Support for a studentship CASE studentship for project on Basque food plants | Yes Yes |
| Additional information: There have been no changes to previous years and the BBSRC/ GSK Consumer Health Care project is with the Consumer Healthcare part of GSK and links with some other food producing companies as well as with companies interested in analytical aspects of pharmacognosy continue as in previous years. As a member of various learned societies I also regularly participate in meeting which receive some support from the relevant industry. | | | | | |
| Mrs Vivienne Hinks | None | None | None | None | |
| Dr Steven Kayne | None | None | None | None | |
| Dr Barbara Pendry | None | None | Nature's Laboratory | Commissioned research via the Medicines research group at the University of East London; I am not actively responsible but am a member of the group | Yes |
| Professor David Phillipson | None | None | None | None | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|----------------------------|--------------------|--------------------|------------------------|---|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Professor Raymond Playford | None | None | GlaxoSmithkline | Acted as advisor on non-herbal product on one day | |
| Dr Deborah Shaw | None | None | None | None | |
| Dr Jidong Wu | None | None | None | None | |

INDEPENDENT REVIEW PANEL FOR ADVERTISING: 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 | |
| Mr Kevin Mooney (Chair) | None | None | None | None | |
| Mr John Ferguson | | | | | |
| Dr Surendra Kumar | None | None | None | None | |
| Dr John Mucklow | | | | | |
| Dr Jane Richards | AstraZeneca GlaxoSmithKline | Shares on ISA Shares on ISA | None | None | |
| Dr Nuala Sterling | | | | | |
| Dr Sheila Stevens | None | None | None | None | |

INDEPENDENT REVIEW PANEL ON BORDERLINE PRODUCTS: 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 | |
| Mr Kevin Mooney (Chair) | None | None | None | None | |
| Professor Janet Bainbridge | None | None | None | None | |
| Dr Paramjit Gill | None | None | None | None | |
| Dr Shantha Godagama | None | None | None | None | |
| Mr Christopher Hedley | Neal's Yard Remedies | Acted as a consultant but not done anything for them since they changed hands | None | None | |
| Professor Peter Houghton | None | None | None | None | |
| Mrs Kiran Kumar | None | None | None | None | |
| Dr Surendra Kumar | None | None | None | None | |
| Dr Pamela Mason | Proprietary Association of Great Britain (PAGB) Nexus PR | Consultancy Occasional consultancy work on new OTC pharmaceutical products (eg, clinical reports, press releases) | None | None | |
| | Nutricia (tube feed company) | I shall be giving a talk on 11 March, 2010 | | | |
| | Wassen (vitamin supplements) | Consultancy work (none since 2006) | | | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT |
|-------------------------------|---|---|------------------------|--------------------|-----------------|
| | NAME OF COMPANY | NATURE OF INTEREST | NAME OF COMPANY | NATURE OF INTEREST | |
| Dr Pamela Mason (cont) | Wellards (training company that has pharmaceutical industry clients) | Medical writing | | | |
| | Pharmacy Magazine | Writing (some of which may be sponsored by pharmaceutical industry – I do not necessarily know) | | | |
| Mr Michael McIntyre | Chair, European Herbal and Traditional Medicine Practitioners Association | £12000 pa plus travel expenses | None | None | |
| | Health Food Manufacturers Association expert panel member | No recompense | | | |
| | Fellow of the Foundation for Integrated Health | No recompense | | | |
| Dr Namasivayam Sathiyamoorthy | White Pigeon Ltd | White Pigeon is a charity; I am director without payment | None | None | |
| Mr Ian Smith | None | None | None | None | |
| Dr Jidong Wu | None | None | None | None | |
| Mr Brian Yates | None | None | None | None | |

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