Human Medicines Regulations 2012 Advisory Bodies

Annual Report 2014

Commission on Human Medicines

British Pharmacopoeia Commission

Medicines & Healthcare products Regulatory Agency

HUMAN MEDICINES REGULATIONS 2012
ADVISORY BODIES ANNUAL REPORT 2014

Presented to Parliament pursuant to Part 2, Section 12 (2) of the Human Medicines Regulations 2012

Commission on Human Medicines

British Pharmacopoeia Commission

Contact for information about these reports:
Fay Norris
151 Buckingham Palace Road
020 3080 6060

Published by the Medicine & Healthcare products Regulatory Agency

ISBN 978-1-900731-14-0

Any enquiries regarding this publication should be sent to the MHRA at:

Medicines & Healthcare products Regulatory Agency
Information Services
151 Buckingham Palace Road
London SW1W 9SZ
020 3080 6000

E-mail: info@mhra.gsi.gov.uk

You can download this publication from https://www.gov.uk/mhra

LIST OF CONTENTS

FOREWORD BY THE PARLIAMENTARY UNDER SECRETARY OF STATE FOR LIFE SCIENCES

It gives me great pleasure to present the Annual Reports for 2014 of the Human Medicines Regulations Advisory Bodies: the Commission on Human Medicines and the British Pharmacopoeia Commission. These reports include a record of Members' interests in the pharmaceutical industry and code of practice.

I also take great pleasure in recognising 2014 as a landmark year for the British Pharmacopoeia, marking 150 years since publication of the first edition.

On behalf of all Health Ministers I would like to thank the Chairs and Members of both Expert Committees and all those who contribute to their many expert advisory groups and working parties 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.

George Freeman

COMMISSION ON HUMAN MEDICINES ANNUAL REPORT 2014

TERMS OF REFERENCE

1. The Commission on Human Medicines was established in October 2005. Its functions are set out in regulation 10 of the Human Medicines Regulations 2012 (SI 2012/1916).

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 medicinal 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 similarly involved in respect of medicinal products to which relevant EC legislation applies.

OBITUARY

3. It was with great sadness and regret that the Commission learnt of the death of Professor Roger Griffin, a former member of the Chemistry Pharmacy and Standards sub-committee and Expert Advisory Group from 2002-2009. He was a much valued expert who made a significant contribution to the Commission's work and had limitless enthusiasm for his research work and development of medicines.

APPOINTMENTS

4. In April 2014, the Secretary of State for Health made the following appointments to the Commission:

    Dr Jamie Fraser BSc MB ChB MRCGP
    GP Partner, Southside Surgery, Inverness

Professor Jonathan S Friedland MA PhD FRCP FRCPE FMedSci
Hammersmith Campus Director & Head of Section of Infectious Diseases & Immunity, Imperial College London; Hon Consultant in Infectious Diseases ICHT

Professor Martin Gore MBBS PhD FRCP
Medical Director and Consultant Medical Oncologist, The Royal Marsden NHS Foundation Trust and Professor of Cancer Medicine, Institute of Cancer Research

Professor Malcolm R Macleod BSc MBChB MRCP PhD FRCP (Edin)
Professor of Neurology and Translational Neurosciences, University of Edinburgh and Honorary Consultant Neurologist, NHS Forth Valley

Dr Rebecca Mann BMBS FRCPCH
Consultant Paediatrician, Taunton and Somerset NHS Foundation Trust

Professor Shirley Price MSc PhD FBTS ERT FHEA FSB
Head of Academic Appeals and Academic Quality and Professor of Toxicology, University of Surrey.

5. In December 2014, the Secretary of State for Health made the following appointments to the Commission:

Mrs Eileen J Barrett BSc PGCE CPE LPC
HR and Legal Director, Source BioScience, Nottingham

Dr Richard Gilson MD FRCP
Director, Centre for Sexual Health & HIV Research and Head, Research Department of Infection and Population Health, University College London

Dr Sarah Meredith
Deputy Director, MRC Clinical Trials Unit and Honorary Senior Lecturer, Department of Primary Care and Population Sciences, University College London

Dr Christopher Weir BSc (Hons) PhD MSc FRSS C.Stat C. Sci
Reader in Medical Statistics, Centre for Population Health Sciences, University of Edinburgh

6. In January 2014, the following re-appointments to the Commission were made:

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

Professor B Kevin Park BSc PhD FMedSci FRCP (Hon) FBTS
Director of MRC Centre for Drug Safety Science, Professor of Pharmacology & Head of Institute of Translational Medicine, University of Liverpool

Professor Munir Pirmohamed MB ChB (Hons) PhD FRCP FRCP (Edin) FMedSci
Professor of Clinical Pharmacology, University of Liverpool, NHS Chair of Pharmacogenetics and Director of the Wolfson Centre for Personalised Medicine

Dr Angela E Thomas MB BS PhD FRCPE FRCPath FRCPCH
Consultant Paediatric Haematologist, Royal Hospital for Sick Children, Edinburgh

Professor Simon H L Thomas BSc MBBS MD FRCP FRCP (Edin)
Professor of Clinical Pharmacology and Therapeutics, Newcastle University and Consultant Physician, Newcastle Hospitals NHS Foundation Trust.

7. Details of Commissioners' appointment and re-appointment dates can be found at **Appendix I**.

8. The Commission also appointed and re-appointed members to its Expert Advisory Groups (EAGs). The details are listed at **Appendix II**.

MEMBERSHIP

9. Commissioners' details are listed at **Appendix I**. There are currently 11 EAGs that report to the Commission, their remits and membership are listed at **Appendix II**.

10. The Commission warmly congratulates **Mr Harry Cayton**, Chair of the Patient and Public Engagement EAG, on receiving a CBE in the Queen's Birthday Honours.

11. The Commission warmly congratulates **Professor Juliet Compston**, member of the Medicines for Women's Health EAG, on receiving an OBE in the New Year Honours List.

12. The Commission wishes to record its gratitude and appreciation of the valuable work of its Expert Advisory Groups and Working Groups listed below. Members' details are listed at **Appendix II**.

Expert Advisory Groups 2014

Anti-Infectives, HIV/AIDS and Hepatology (AIHHEAG)
Chaired by **Dr Barbara A Bannister MBE** (until 31 December 2014)

Cardiovascular, Diabetes, Renal, Respiratory and Allergy (CDRRAEAG)
Chaired by **Dr J Colin Forfar**

Chemistry, Pharmacy and Standards (CPSEAG)
Chaired by **Professor Kevin M G Taylor**

Clinical Trials, Biologicals & Vaccines (CTBVEAG)
Chaired by **Dr Angela E Thomas**

Gastroenterology, Rheumatology, Immunology & Dermatology (GRIDEAG)
Chaired by **Professor Anthony G Wilson**

Medicines for Women's Health (MWHEAG)
Chaired by **Dr Ailsa Gebbie**

Neurology, Pain & Psychiatry (NPPEAG)
Chaired by **Professor David G C Owens**

Oncology and Haematology (OHEAG)
Chaired by **Dr Angela E Thomas** (acting Chair until 31 August 2014)
Chaired by **Professor Martin Gore** (from 01 September 2014)

Paediatric Medicines (PMEAG)
Chaired by **Dr Rebecca Mann** (from 01 April 2014)

Patient and Public Engagement (PPEEAG)
Chaired by **Mr Harry Cayton CBE**

Pharmacovigilance (PEAG)
Chaired by **Professor Munir Pirmohamed**

Working Groups 2014

Alteplase Working Group
Chaired by **Professor Ian V D Weller**

Isotretinoin Working Group
Chaired by **Professor Munir Pirmohamed**

National Emergency Stockpile Quality Panel
Chaired by **Professor Stuart Ralston**

Nicotine Containing Products Working Group
Chaired by **Professor Ian V D Weller**

Review of Non-Prescription Analgesics Working Group
Chaired by **Professor Stuart Ralston**

13. The Committee for Medicinal Products for Human Use (CHMP) is the medicines regulatory committee for all EU member states. The Commission notes with great pleasure the extent of its influence within the CHMP's Scientific Advisory Groups (SAGs).

Commissioners and EAG members serving as SAG members are as follows:

- Professor Deborah Ashby (Cardiovascular Issues SAG)
- Dr Barbara A Bannister (Anti-Infectives SAG - **Vice-Chair**)
- Dr J Colin Forfar (Cardiovascular Issues SAG)
- Professor Martin Gore (Inter-Committee SAG on Oncology)
- Dr Anthony Johnson (Neurology SAG)
- Professor Malcom Macleod (Neurology SAG)
- Professor Elizabeth Miller (Vaccines SAG)
- Professor David G C Owens (Psychiatry SAG)
- Professor Andrew Pollard (Vaccines SAG - **Chair**)
- Professor Robert C Read (Anti-Infectives SAG)
- Professor Ian V D Weller (HIV/Viral Diseases SAG - **Vice-Chair**)

14. **Professor Deborah Ashby** retired from her role as a member of CHM in December. The Commission wishes to extend its thanks to Professor Ashby for her valuable and very long-standing contribution to the work of CHM, the Committee on Safety of Medicines (CSM) and its subcommittees, which has spanned over 21 years in total.

15. **Dr Barbara A Bannister** stepped down as a standing external expert of CHM and as the chair of AIHHEAG in December. The Commission wishes to extend its thanks to Dr Bannister for her valued contribution to the work of CHM, CSM and its subcommittees, which has spanned over 12 years in total.

16. **Mrs Alison Bowser** retired from her role as a member of CHM in December. The Commission wishes to extend its thanks to Mrs Bowser for her valued contribution to the work of CHM, and its Expert Advisory Groups, which has spanned over 8 years in total. Mrs Bowser will continue to contribute to the work of the Commission in the coming year via her role as a member of PPEEAG.

17. **Professor Janet Darbyshire** retired from her role as a member of CHM and vice-chair of CTBVEAG in December. The Commission wishes to extend its thanks to Professor Darbyshire for her valuable and very long-standing contribution to the work of CHM, CSM and its subcommittees, which has spanned over 21 years in total.

18. **Ms Amanda Hoey** retired from her role as a member of CHM in December. The Commission wishes to extend its thanks to Ms Hoey for her valued contribution to the work of CHM and its Expert Advisory Groups, which has spanned over 8 years in total. Ms Hoey will continue to contribute to the work of the Commission in the coming year via her role as a member of PPEEAG.

19. **Professor Ian Weller** retired from his role as vice-chair of CHM and member of AIHHEAG in December. Professor Weller has served as vice chair to CHM since 2005 and was vice chair to CSM from 1999 to 2005. The Commission wishes to place on record its sincere gratitude to Professor Weller for his outstanding contribution over 23 years, including chairmanship of 12 working groups of the CSM and CHM.

20. The Commission wishes to record its gratitude to those members of its External Expert Panel and Ophthalmic Panel who attended meetings or provided written advice to the Commission and its Expert Advisory Groups during the course of the year. Members' details are listed at the end of this report at **Appendix III**.

MEETINGS

21. The Commission held 11 meetings during 2014. Two day meetings were held in January, March, July, September and November. One day meetings normally lasted between five and six hours. Meetings were held at the Medicines and Healthcare Products Regulatory Agency, 151 Buckingham Palace Road, London, SW1W 9SZ.

SECRETARIAT

22. 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

23. Commissioners are entitled to claim an attendance fee of £325 per day (Chairman's fee £500). Expert Advisory Group members are entitled to claim an attendance fee of £200 (Chairman's fee £325). Travel and subsistence is also payable within Department of Health guidelines.

FIRST CONSIDERATION BY THE COMMISSION

24. The Commission considered and advised on a total of 109 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 (i.e. before appeals).

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

	Grant advised	**Grant not advised**
New Active Substances	**11**	**46**
Abridged Applications	**7**	**42**

25. The Commission was extensively involved in applications made through the European centralised procedure. The Commission considered 53 new active substances, or new combinations of active substances, authorised through the Centralised Procedure.

APPEALS

26. The Commission considered a total of two oral hearings covering six applications. Of these, one hearing covering four applications ended positively with the products receiving recommendation for grant of marketing authorisations, provided the product particulars were amended. For the remaining hearing covering two applications, the Commission advised that the products should be reclassified as prescription only medicines.

27. The Commission considered a total of 6 written representations covering 12 applications. Of these, for one written representation covering two applications, the Commission advised that the medicines should be reclassified as prescription only medicines. For the remaining five written representations covering ten applications, the commission did not recommend grant of marketing authorisation.

28. The Commission considered an average of 10 applications at each of its 11 meetings in 2014, in addition to clinical trial applications, appeals, reclassifications, pharmacovigilance issues and other matters.

EXTERNAL STAKEHOLDERS

29. The Commission received the following as observers:

Dr Keith Bragman MD FRCP FRCPath
President of the Faculty of Pharmaceutical Medicine

Mr David Dipple
Lead Triennial Reviewer and Head of Triennial Review Programme Assurance, Department of Health

Mrs Joyce Epstein
Former Director of the Foundation for the Study of Infant Deaths (FSID) and member of the Patient and Public Engagement Expert Advisory Group

Mr Jamie Grant
Assistant Reviewer, Triennial Review Team, Department of Health

Dr Iain M MacIntyre MBChB PhD MRCP
Registrar in Clinical Pharmacology & Renal Medicine, Royal Infirmary of Edinburgh, Edinburgh

Dr Sarah Meredith
Deputy Director, MRC Clinical Trials Unit and Honorary Senior Lecturer, Department of Primary Care and Population Sciences, University College London

Dr Emma Morrison MB ChB BSc MRCP
Clinical Research Fellow, Centre for Cardiovascular Sciences, Queen's Medical Research Institute, University of Edinburgh

Mr Nathaniel Nkrumah
Acting Head, Foreign Medicines Evaluation Registration Unit, Ghanaian Food and Drugs Authority

Mrs Mercy Owusu-Asante
Head, Drug Evaluation and Registration Department, Ghanaian Food and Drugs Authority

Professor David Webb MB BS MD DSc FRCP FRSE FMedSci
Christison Professor of Therapeutics and Clinical Pharmacology, University of Edinburgh and Royal Infirmary (and member of the Agency Board)

CONSIDERATION OF OTHER MATTERS

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

INDEPENDENT PRESCRIBING BY RADIOGRAPHERS, PARAMEDICS, DIETICIANS AND ORTHOPTISTS

31. The Human Medicines Regulations 2012 restricts the availability of pharmacy and prescription medicines. They can generally only be sold or supplied at registered pharmacy premises and in the case of prescription medicines must be dispensed against a prescription written by an appropriate practitioner such as a doctor. Patient Group Directions (PGDs) provide exemptions from these restrictions. A PGD is a written instruction for the supply or administration of medicines to patients in a defined clinical situation. They can only be used by certain groups of registered health professionals and must be authorised by a relevant appropriate body. Additionally, the use of PGDs is restricted to NHS bodies and other specific settings such as the armed forces.

32. Provision for helicopter search and rescue services is moving from a service provided by the armed forces and civilian operators under contract to the Maritime and Coastguard Agency to a wholly contracted service in 2016. In September, the MHRA asked the Commission to advise on proposals to amend the Regulations to allow supply and administration of medicines under PGDs by paramedics employed by the contracted helicopter rescue operators as there was no existing provision for them to do so. This meant that the paramedics were unable to access the same range of medicines as their counterparts in the NHS and armed forces. After being updated on the operators' current and future governance arrangements, which were in line with those set out by the Care Quality Commission, Commissioners agreed to the proposals.

33. In November, the Commission also discussed a proposal to consult on amendments to legislation to allow: independent prescribing by radiographers, independent prescribing by appropriately trained paramedics, supplementary prescribing by dieticians, and a specific list of exemptions from Medicines Act restrictions for orthoptists.

SAFETY OF MARKETED MEDICINES

Sodium containing effervescent dispersible and soluble medications and cardiovascular events

34. The Commission considered an assessment of a study by George et al (BMJ November 2013) which concluded that effervescent, dispersible and soluble medicines can contain high levels of sodium and that this may be associated with an increased risk of cardiovascular events. Sodium salts are used in medicines to improve solubility or generate effervescence. The Commission noted several limitations of the study but advised that an association between high sodium levels in medicines and hypertension and stroke was plausible and that regulatory action was required to minimise risk. This issue was raised at the European Pharmacovigilance Risk Assessment Committee (PRAC) for further consideration.

Risk of use of chlorhexidine in premature infants

35. The Commission considered an assessment of the risks of severe chemical injuries associated with use of chlorhexidine for skin disinfection prior to central venous catheterisation in premature infants. The Commission supported the

initiation of a Europe-wide review of this issue and advised that there should be communication with healthcare professionals while the review was being conducted. An article was published in the June edition of the Drug Safety Update bulletin together with a further reminder in November 2014 following conclusion of the European review, which confirmed the advice given to healthcare professionals.

Paracetamol safety review

36. The Commission considered an updated assessment of the safety of paracetamol which outlined the data considered and action taken since the previous assessment in June 2013. The Commission endorsed the conclusions of the working group review on non-prescription analgesics, that the available data did not support a causal association between paracetamol and cardiovascular, renal and gastrointestinal disorders and that the balance of risks and benefits of paracetamol remained favourable for the licensed indications.

Diclofenac and cardiovascular risk; availability as a Pharmacy medicine

37. The Commission considered the availability of diclofenac (a non-steroidal anti-inflammatory drug used to treat pain and inflammation) as a pharmacy medicine in the context of the outcome of a Europe-wide review of the cardiovascular safety and following a UK public consultation. The Commission advised that a small but potentially important increased risk of serious cardiovascular events may be associated with oral diclofenac at doses and durations of treatment applicable to pharmacy use. The Commission considered the measures proposed by the marketing authorisation holder to manage the risk would be difficult to implement in the pharmacy setting and could not be relied upon to adequately identify and exclude patients at increased risk of cardiovascular events. The Commission therefore advised that oral products containing diclofenac at all doses are considered to meet the requirements for prescription only supply. The change in legal classification was notified to healthcare professionals in January 2015 and an article was published in that month's edition of Drug Safety Update.

Review of risks and benefits of domperidone; availability as a Pharmacy medicine

38. The Commission considered the implications for the UK of a Europe-wide review of the risks and benefits of domperidone (a medicine used to relieve nausea and vomiting, bloating and heartburn) which recommended restriction of the indication to nausea and vomiting, new contraindications, new warnings and a reduction in the dose and duration of treatment due to the increased risk of serious cardiac side effects. The new advice was communicated to healthcare professionals through the Central Alerting System and an article in the May 2014 edition of Drug Safety Update. In the context of the evidence for cardiovascular risk and the extensive risk minimisation measures recommended by the European review, the Commission advised that all products containing domperidone should be reclassified as prescription only medicines. The change in legal status was notified to healthcare professionals in September 2014 and an article was published in Drug Safety Update in the same month.

Safety review of oral methadone medicines containing povidone

39. The Commission considered an assessment of the safety of oral methadone medicines containing povidone in the context of an urgent Europe-wide review initiated because of evidence of harm associated with injection of a methadone product containing high molecular weight povidone. The Commission noted that povidone was added to mitigate the risk of misuse by injection. The Commission advised that the addition of high molecular weight povidone had failed to prevent misuse of the product and the available evidence suggested that it may be associated with a risk of organ damage due to toxic effects of povidone following accumulation in the body. The Commission advised that the benefit risk balance of methadone products containing high molecular weight povidone was negative. The Commission also advised that the benefit risk balance for low molecular weight povidone containing products was positive as the available data did not suggest that storage of povidone in tissues and organs was likely to occur if the products were administered intravenously. In July the European review concluded that the marketing authorisation for the methadone product containing high molecular weight povidone should be suspended pending reformulation. The methadone product which was the subject of the review was licensed, but not marketed in the UK, so communications were not issued in UK.

Isotretinoin and psychiatric reactions

40. The Commission convened a working group to consider the latest evidence for a link between isotretinoin and psychiatric reactions. This followed ongoing public concern about the risk of depression and suicidal behaviour with isotretinoin (Roaccutane), a treatment for severe acne resistant to other treatments. On consideration of the available evidence and the advice of the working group, the Commission advised that the available study data were insufficient to establish a causal association between isotretinoin and psychiatric disorders, however, an association could not be excluded. The Commission advised that the individual reports of suicidal behaviour were important, but that the underlying risk of psychiatric disorders with the age group treated with isotretinoin was significant. The Commission advised that the current warnings in the Summary of Product Characteristics reflected the currently available evidence; however awareness of this issue could be improved by providing clearer information in the patient information leaflet (PIL). The Commission noted that the PIL was being considered by the Patient and Public Engagement Expert Advisory Group. The outcome of the review was published in the December edition of Drug Safety Update.

Valproate and abnormal pregnancy outcomes

41. The Commission advised on the UK implementation of the Europe-wide review of the risk of developmental disorders in children born to women who took valproate during pregnancy. The Commission noted its conclusions that use of sodium valproate in pregnancy was associated with a risk of developmental problems of up to 40% in pre-school children exposed to valproate in the womb, including delayed walking and talking, memory problems, difficulty with speech and language and lower intellectual ability. The Commission endorsed the need for better information on this risk to be made available to patients. The Commission noted that the marketing authorisation holders for valproate containing products were updating product information for prescribers and patients with stronger warnings and would supply educational materials to support better communication on this risk. The Commission emphasised the

importance of working with the Department of Health (DH) and clinical guideline bodies on the UK implementation and communication of the outcome of the European review. A message was sent to healthcare professionals informing them of the new advice in January 2015 and an article was published in the January edition of Drug Safety Update.

MEDICINES AVAILABLE WITHOUT PRESCRIPTION

Reclassification of medicines from POM to P and P to GSL

42. The Commission considered six applications for change of legal status during the year. Four applications were for medicines for General Sales List (GSL) availability. The Commission advised that two of the applications might be approvable. One application has since been granted:

    - Esomeprazole 20mg Gastro-resistant Tablets containing esomeprazole magnesium trihydrate for the treatment of reflux symptoms (e.g. heartburn, acid regurgitation) in adults aged 18 years and over, at a maximum dose and daily dose of 20mg and for a maximum treatment period of 2 weeks without consulting a doctor.

43. Public consultation is underway on the second application:

    - Soleve Sunburn Relief Cutaneous Emulsion containing ibuprofen 1% w/w and isopropyl myristate 10% w/w for topical use for the relief of pain associated with mild to moderate sunburn in adults and children over the age of 12 years

44. The Commission advised against two of the applications for GSL availability as the products could not, with reasonable safety be sold or supplied otherwise than by or under the supervision of a pharmacist. In relation to one application the Commission considered that the input of the pharmacist minimised the risk of potentially serious adverse effects. Regarding the second application, the Commission considered that the intervention from the pharmacist was important to ensure the correct diagnosis of the proposed indication.

45. The other two applications were for Pharmacy Only (P) availability. Firstly the Commission advised that an application for Prescription Only Medicine (POM) to Pharmacy Only (P) reclassification could be approvable subject to proposed changes in the product information and review of the product information by the Patient and Public Engagement Advisory Group.

46. The second application was for reclassification through the centralised procedure for which the Commission advised in favour of P availability. This reclassification has since been approved by the European Commission:

    - Ulipristal acetate 30mg for emergency contraception or up to 120 hours after unprotected intercourse

47. In addition to the six new applications the Commission considered a written representation in respect of an application to reclassify a product from P to GSL. In respect of this application the Commission had previously advised, in 2013

that, on grounds related to safety they may be unable to advise the Licensing Authority to grant a marketing authorisation with GSL classification.

48. On consideration of the written representation the Commission was unable to advise reclassification of the product to GSL unless further conditions could be met.

Increasing Stakeholder Engagement in Reclassification

49. The Commission considered a paper updating them on progress with implementation of the revised reclassification guideline that was published in December 2012, and informing the Commission of other work undertaken within the MHRA on stakeholder engagement in the reclassification process. The Commission agreed that stakeholder involvement earlier in the reclassification process and the establishment of a national stakeholder platform to consider strategic issues related to reclassification would both contribute to greater stakeholder engagement. It was particularly important to ensure patient involvement at both levels

50. The Commission agreed to a proposal to establish an external stakeholder group to consider a major application to reclassify a medicine from POM to P.

THE COMMISSION'S EXPERT ADVISORY GROUPS AND WORKING GROUPS

51. The remit and membership of the Expert Advisory Groups and Working Groups are listed in **Appendix II**.

Anti-Infectives, HIV/AIDS and Hepatology Expert Advisory Group (AIHHEAG)

52. The Anti-Infectives, HIV/AIDS and Hepatology EAG did not meet during 2014. EAG members provided written comments and advice on five items.

53. In February, the EAG provided written comments on:

- a paper discussing a medicine indicated for the induction, maintenance and prevention treatment of cytomegalovirus (CMV) retinitis in adult patients with AIDS. CMV is a virus that may infect the retina and potentially cause irreversible vision loss
- an application for a product for the treatment of bacterial vaginosis, a bacterial infection of the vagina.

54. In March, the EAG provided written comments on:

- a medicine proposed for use in adults to treat invasive candidiasis, an infection caused by fungal cells (yeasts) called Candida.

55. In July, the EAG provided written comments on:

- a medicine indicated for the treatment of chronic hepatitis C in adults.

56. In September, the EAG provided written comments on:

- a medicine indicated for the topical treatment of mild-moderate rosacea as a non-prescription product.

57. In October, the EAG provided written comments on:

    - the cardiovascular safety of a medicine used in respiratory and skin infections
    - an antibacterial medicine for systemic use in lower respiratory tract infections

Cardiovascular, Diabetes, Renal, Respiratory and Allergy Expert Advisory Group (CDRRAEAG)

58. The CDRRAEAG met twice in 2014, convened three times via teleconference, and provided advice by written correspondence on 11 items.

59. In January, the Chair and a renal expert of the EAG provided written comments on a medicine for the treatment of cystic fibrosis.

60. In January, the Chair and a renal expert provided written comments on a medicine in the use of dialysis.

61. In January, the EAG convened and made recommendations on:

    - a medicine indicated to improve blood sugar control in adults with type 2 diabetes mellitus
    - a medicine indicated to prevent asthma attacks in adults and children over 16 years of age
    - a medicine to treat and prevent blood clots in the veins of the leg (deep vein thrombosis) and in the blood vessels of the lung (pulmonary embolism)
    - a review of the cardiovascular risks of sodium-containing products
    - a review of auto-injectors used in the delivery of adrenaline in the event of an acute anaphylactic reaction.

62. In February, the EAG provided written comments on a medicine indicated as a maintenance bronchodilator treatment for airflow obstruction and relief of symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

63. In March, the EAG convened and made recommendations on:

    - a medicine to slow the progression of kidney disease in adults suffering from autosomal dominant polycystic kidney disease (ADPKD). This is an inherited disease characterised by multiple cysts in the kidney and other organs
    - a medicine for the reduction of atherothrombotic events in patients with a history of myocardial infarction (MI), commonly known as a heart attack.
    - a medicine for the treatment of asthma in adults
    - a review of the cardiovascular risks of sodium-containing products
    - an update on several previous items (for information only).

64. In April, the EAG provided written comments on a medicine indicated for the long-term management of chronic pulmonary infections due to Pseudomonas aeruinosa in patients with cystic fibrosis (CF) aged 12 years and older.

Pseudomonas aeruinosa is a Gram-negative bacterium often found in soil and ground water. It can cause a wide range of infections, particularly in those with weakened immune system.

65. In May, the EAG convened via teleconference and made recommendations on:

- a medicine for the short term therapy of patients with severe heart failure when their symptoms get suddenly worse
- an update on the balance of benefits and risks of a product used in the treatment of acute ischaemic stroke
- an update on intensive therapy with the lipid-lowering drug simvastatin
- an update on possible restrictions on the use of a product for the treatment of coronary artery disease.

66. In May, the cardiologists provided written comments on a medicine indicated for the treatment of angina in patients with mild to moderate heart failure.

67. In May, the Chair a renal expert provided written comments on a medicine used to supress the immune system to help prevent rejection of transplanted organs.

68. In July, the respiratory experts provided written comments on a medicine indicated for the regular treatment of asthma in adults and adolescents aged 12 years and older.

69. In September, the EAG convened via teleconference and made recommendations on a medicine for the treatment of Idiopathic Pulmonary Fibrosis (IPF) and to slow disease progression. IPF is a disease where the alveoli (the tiny air sacs of the lungs) and the lung tissue next to the alveoli become damaged.

70. In October, the EAG provided written comments on:

- a medicine indicated to assist with weight loss in overweight patients
- a paper on cardiovascular events associated with a medicine used to reduce itching caused by hives and skin inflammation (eczema).

71. In October, the cardiology experts provided written comments on a paper for a medicine used to treat certain bacterial infections of the airways, skin, and soft tissue. It is also used to treat stomach ulcers.

72. In November, the EAG provided written comments on a medicine for the treatment and prevention of blood clots.

73. In December, the EAG convened via teleconference and made recommendations on two medicines indicated for the treatment of asthma in adults and children over 4 years or age.

Chemistry, Pharmacy and Standards Expert Advisory Group (CPSEAG)

74. The CPSEAG met 10 times and considered and advised on applications for new drugs, abridged applications, variations and pre-hearings. The EAG also provided advice by written correspondence on 14 occasions.

75. In January, the EAG considered and made recommendations on the following:

- a medicine for adults who have breathing difficulties due to a lung disease called chronic obstructive pulmonary disease (COPD)
- a medicine for the treatment of schizophrenia
- a medicine indicated to reduce pain
- a medicine indicated for use in combination with other medicines for the treatment of hepatitis C virus infection in adults
- a medicine indicated for use during a surgical procedure for intraocular lens replacement (ILR) in adults
- a medicine indicated to prevent asthma attacks for adults and adolescents over 16 years of age who need regular treatment
- a medicine indicated for the treatment of adults suffering from ocular hypertension or open angle glaucoma, raised pressure within the eye
- a medicine indicated to aid smokers wishing to quit smoking
- adrenalin products, which are subject to ongoing regulatory activity
- a proposal for a UK early access to medicines scheme.

76. In February, the EAG provided written comments on the following:

- a medicine for the treatment of adult patients with Gaucher disease type 1, a rare, inherited condition in which a substance called glucosylceramide is not effectively removed from the body
- a medicine for the treatment of bacterial vaginosis, a condition in which the balance of bacteria in the vagina becomes disrupted
- the use of an excipient in medicines for adults and children

77. In March, the EAG considered and made recommendations on the following:

- a medicine indicated to be used in combination with other medicines for the treatment of chronic hepatitis C virus (HCV) infection in adults
- a medicine indicated for the treatment of psoriatic arthritis, inflammatory disease of the joints and psoriasis, inflammatory disease of the skin, in adults
- a medicines indicated for the treatment of Chronic Lymphocytic Leukaemia (CLL), a cancer of the lymphatic system affecting a type of white blood cell called lymphocytes, and Indolent non-Hodgkin Lymphoma (iNHL), a cancer of the lymphatic system affecting a type of white blood cell called lymphocytes
- a medicine indicated for the treatment of Mantle Cell Lymphoma (MCL) and Chronic Lymphocytic Leukaemia (CLL), which are particular forms of blood cancer
- a medicine indicated to slow the progression of kidney disease in adults with autosomal dominant polycystic kidney disease (ADPKD), a disease that causes growth of cysts in the kidneys which results in problems because of their size and the space they occupy
- a medicine indicated to treat symptoms of Cushing's syndrome, a syndrome caused by overproduction of a hormone called cortisol produced by the adrenal glands
- a medicine indicated for the treatment of Parkinson's disease, a degenerative neurological disorder in which there is a loss of cells that produce dopamine in the brain

- a medicine indicated to reduce the risk of heart problems for adults who have had a heart attack
- a medicine indicated to treat open angle glaucoma and ocular hypertension in adults
- a medicine indicated for local symptoms caused by inflammatory or rheumatic conditions
- a medicine indicated for treatment of breast, prostate, head and neck, gastric and non-small cell lung cancers
- MHRA guidance on stability data to support maximum shelf-life for sterile products after first opening; this guidance is in line with EU CPMP (Committee for Proprietary Medicinal Products) Guidance.

78. In March, the EAG also provided written comments on a medicine indicated to treat Cushing's syndrome.

79. In April, the EAG considered and made recommendations on the following:

- a medicine indicated for the treatment of infections caused by the bacteria (Pseudomonas aeruginosa) in patients with cystic fibrosis
- a medicine indicated for the treatment of dry eye disease in adult patients with severe keratitis, an inflammation of the cornea
- a medicine indicated to reduce blood clots
- a medicine indicated for the treatment of estrogen deficiency, commonly associated with menopause
- a medicine indicated for fluid replacement.

80. In May, the EAG considered and made recommendations on the following:

- a medicine indicated for the treatment of skin and soft tissue infections in adults
- a radionuclide precursor for radiolabelling of another substance prior to administration
- a medicine indicated for the treatment of Human Immunodeficiency Virus (HIV)
- a combination medicine indicated for the topical treatment of mild to moderate acne
- a medicine indicated for the treatment of vitamin D deficiency
- a medicine indicated for the short-term treatment of severe chronic heart failure in situations where conventional therapy is not sufficient.

81. In May, the EAG considered a company's response to questions and advised the Commission about two medicines proposed for the treatment of vitamin D deficiency.

82. In May, the EAG also provided written comments on a medicine indicated to treat Cushing's syndrome.

83. In June, the EAG considered and made recommendations on the following:

- a medicine indicated for the treatment of complicated skin and soft tissue infections in adults
- a medicine indicated for the treatment of bacterial conjunctivitis, an infection of the eye
- a combination medicine indicated for the topical treatment of eczema.

84. The EAG was updated on regulatory actions taken by the MHRA following previous discussion about the safety of the Cosopt container at meetings of Expert Advisory Groups and the Commission on Human Medicines.

85. The EAG considered the company's response to questions and advised the Commission about a medicine proposed for the treatment of chronic anal fissures.

86. The EAG received an update on a nicotine inhalation device for use as a smoking replacement product.

87. In June, the EAG also provided written comments on a medicine indicated for the treatment of chronic kidney disease.

88. In July, the EAG considered and made recommendations on the following:

- a medicine indicated for the treatment of chronic hepatitis C in adults
- a medicine indicated to treat Attention Deficit Hyperactivity Disorder (ADHD) in children and adolescents between the ages of 6 and 17
- a medicine indicated to treat seizures that have lasted for at least five minutes in patients aged 10 years and older
- a medicine indicated for the short-term treatment of moderate pain and fever
- a medicine indicated to prevent and treat urinary tract infections
- a medicine indicated for the regular treatment of asthma in adults and adolescents aged 12 years and older
- a medicine indicated to reduce intraocular pressure in chronic open-angle glaucoma and ocular hypertension in adults
- a diagnostic agent indicated for radiological examinations
- a terminal sterilisation technology.

89. The EAG also received an update on on-going work on Polymyxin-based products as part of a Committee for Medicinal Products for Human Use (CHMP) Referral procedure under Article 5(3) of Regulation (EC) No 726/2004.

90. In July, the EAG also provided written comments on a medicine used to improve blood sugar control in adults with type 2 diabetes mellitus.

91. In August, the EAG provided written comments on the following:

- two medicines indicated to be used in combination with other medicines for the treatment of chronic hepatitis C
- a medicine indicated to treat Idiopathic pulmonary fibrosis (IPF), a condition that causes scarring of the lungs.

92. In September, the EAG considered and advised on the following:

- a medicine indicated to treat narcolepsy, a condition that causes excessive daytime sleepiness or sleep attacks
- a medicine intended for the treatment of Non-24-Hour Sleep-Wake disorder in the totally blind
- a medicine indicated to control HIV infection by stopping a protein that the HIV needs for its multiplication

- a medicine indicated for the treatment of urea cycle disorders (rare disorders which are due to a deficiency of certain liver enzymes necessary to eliminate waste nitrogen in the form of ammonia)
- a medicine indicated to be used as local anaesthesia of the nasal passage and upper respiratory airway prior to minor surgical or investigative procedure
- a medicine indicated for the palliative treatment of locally advanced or metastatic prostate cancer
- a medicine indicated to treat epilepsy and facial nerve pain
- a medicine indicated to be used as part of a balanced intravenous diet, together with proteins, fat, carbohydrates, salts and vitamins
- a medicine indicated to make the muscles of the womb contract during induction of labour
- a medicine indicated to treat gout attacks, a type of arthritis where crystals of sodium urate form inside and around joints
- a medicine indicated to be injected into the eye at the beginning of cataract surgery, when the lens of an eye becomes cloudy and affects vision
- a sterility assurance system.

The EAG also received an update on proposed guidance in relation to nanomaterials.

93. In October, the EAG considered and advised on the following:

- a medicine indicated in the treatment of intra-abdominal and urinary tract infections
- a medicine indicated for the treatment of pimples and spots found with rosacea in adults
- a medicine indicated to treat various illnesses involving inflammation in the body and a number of different diseases of the immune system
- a topical treatment of mild to moderate atopic dermatitis, a type of eczema, in children over 1 year
- a medicine indicated for the relief of moderate to severe acute pain in adults
- a medicine indicated for the treatment of commonly occurring bacterial infections.

94. In October, the EAG also provided written comments on a medicine indicated for the management of moderate to severe acute pain in adult patients in a medically supervised environment.

95. In November, the EAG considered and advised on:

- a medicine indicated for the treatment and prevention of blood clots
- a medicine intended for the treatment of fungal infections in adults
- a medicine intended to reduce pain
- a medicine used to prevent and treat fungal infections (thrush) of the mouth, throat or gut and prevent oral thrush in those born of mothers with vaginal thrush
- a medicine indicated to reduce the symptoms of asthma and to help prevent asthma attacks

- a medicine indicated for the treatment of moderate to severe symptoms of benign prostatic hyperplasia (BPH), a non-cancerous growth of the prostate gland.

96. The EAG considered the company's response to questions and advised the Commission about a medicine proposed to relieve nerve pain.

97. In November, the EAG also provided written comments on:

- a European referral procedure (13-EMA Article 5(3) referral procedure) considering the quality aspects for Polymyxins (antibiotics such as Colistin which are used to treat bacterial infections)
- a draft monograph in Pharmeuropa proposing revision to the European Pharmacopoeia Chapter on methods of preparation of sterile products.

98. In December, the EAG considered and advised on:

- a medicine intended to treat thyroid cancer in adults when radioactive iodine treatment has not helped to stop the disease
- a medicine intended for the cutaneous treatment of genital and perianal warts
- a medicine intended to reduce the quantity of cystine crystals in the eye, in patients with cystinosis
- two alternative sterility test methods.

99. The EAG also heard a presentation and noted a paper on Rapid Microbiological Methods.

100. In December, the EAG also provided written comments on a medicine indicated for the treatment of pneumonia when known or suspected to be caused by certain bacteria.

Clinical Trials, Biologicals & Vaccines Expert Advisory Group (CTBVEAG)

101. The CTBVEAG met six times in 2014, convened three times via teleconference provided advice by written correspondence on five items.

102. In January, the EAG convened and made recommendations on:

- a medicine indicated to improve blood sugar control in adults with type 2 diabetes mellitus
- a medicine indicated for the treatment of advanced gastric cancer
- a medicine which is used to treat Multicentric Castleman's Disease (MCD). MCD causes non-cancerous growths (tumours) to develop in multiple lymph nodes in the body.

103. In March, the EAG convened and made recommendations on:

- a medicine used as part of a combination therapy for infants, children, adolescents and adults with particular forms of blood cancer
- a medicine used to treat a type of cancer that grows from abnormal nerve cells in the body.

The EAG also:

- discussed details of a proposal for a UK Early Access to Medicines Scheme (EAMS).
- was updated on the outcome of the advice provided for some applications since August 2013 via written comments
- discussed different possibilities on how to operate future meetings.

104. In April, the EAG convened and made recommendations on:

    - a medicine to treat urea cycle disorders. This is a specific inherited condition which is the lack of one of the liver enzymes that are needed to get rid of excess gas
    - a medicine to treat Non-Hodgkin lymphoma. This is an uncommon cancer that develops in the lymphatic system, which is a network of vessels and glands spread through the body.

105. In May, the EAG convened by teleconference and made recommendations on the requirements needed prior to consideration of the re-start of a clinical trial.

106. In July, the EAG convened and made recommendations on:

    - a medicine indicated to treat high-risk blood cancers and as additional treatment after stem cell transplantation
    - a medicine indicated to prevent human papilloma virus (HPV) infection. This is a group of viruses that affect the skin and moist membranes lining of the body in the cervix, anus, mouth and throat
    - the re-start of a clinical trial.

107. In September, the EAG provided written comments on:

    - a medicine indicated for the treatment of Alzheimer's disease
    - a clinical trial application regarding the treatment of Ebola virus.

108. In September, the Chair and epidemiologist member of the EAG convened by teleconference and made recommendations on a clinical trial application for the treatment of Ebola.

109. In September, the immunologist members of the EAG provided written comments on a treatment for acute angioedema attacks in adults with hereditary angioedema (HAE). Angioedema is the swelling of the deeper layers of the skin, caused by a build-up of fluid.

110. In October, the EAG convened and made recommendations on:

    - a vaccine indicated to prevent malaria and hepatitis B
    - a medicine for the treatment of haemophilia A, a bleeding disorder caused by lack of factor VIII activity due to antibody development
    - a medicine for the treatment of hypophosphatasia (HPP), a rare, inherited disease known for its impact on bones and teeth
    - a medicine for the treatment of unresectable or metastatic melanoma (a type of skin cancer).

111. In November, the EAG provided written comments on a clinical trial application for a medicine for the treatment of Ebola virus.

112. In December, the EAG convened by teleconference and advised on a vaccine to prevent Ebola disease.

Gastroenterology, Rheumatology, Immunology and Dermatology Expert Advisory Group (GRIDEAG)

113. The GRIDEAG did not meet in 2014, but provided advice by written correspondence on eight items.

114. In February, the EAG provided written comments on a medicine for the treatment of opioid-induced constipation.

115. In March, the EAG provided written comments on a medicine for the treatment of active psoriatic arthritis (PsA) in adult patients. PsA is the inflammation of the joints where joints become swollen, stiff, painful and difficult to move.

116. In April, the gastroenterologist members of the EAG provided written comments on a medicine for the prevention of nausea and vomiting caused by chemotherapy in adult patients.

117. In May, the dermatologist members of the EAG provided written comments on a medicine for the short term treatment of mild to moderate bacterial skin infections.

118. In June, the gastroenterologist and dermatologist members of the EAG provided written comments on a guideline on the demonstration of therapeutic equivalence for locally applied and locally acting products in the gastrointestinal tract.

119. In September, the dermatologist members of the EAG provided written comments on:

    - a medicine for the treatment of acute angioedema attacks in adults with hereditary angioedema (HAE). Angioedema is the swelling of the deeper layers of the skin, caused by a build-up of fluid.
    - a reclassification application for a medicine for the self-treatment of mild-moderate popular-pustular rosacea, a skin condition mainly affecting the face.

120. In December, the dermatologist members of the EAG provided written comments on a medicine for the treatment of moderate to severe plaque psoriasis (a skin condition that causes red, flaky, crusty patches of skin covered with silvery scales) in children 12 years of age.

Medicines for Women's Health Expert Advisory Group (MWHEAG)

121. The Medicines for Women's Health (MWH) EAG met at seven times during the year, with 3 face to face meetings and 4 teleconferences. Drs Sarah Atkinson and Katherine Darton retired and Professor Julietta Patnick demitted from the EAG during the year. Professor Jon Tobias was appointed to the Group as an expert in osteoporosis and Dr Jane Dickson was appointed to the Group as an expert in family planning.

122. The EAG considered the evidence and made recommendations on the following issues with marketed medicines:

- efficacy of levonorgestrel and ulipristal emergency contraception in women with high Body Mass Index
- the benefits and risks of use of bromocriptine for suppression of lactation
- information provided to patients on the effects of hormone replacement therapy on mammographic density
- RMPs for products containing co-cyprindiol (cyproterone acetate with ethinylestradiol)

123. The EAG considered and made recommendations on applications for marketed medicines for treatment of uterine fibroids, long-acting progestogen-only contraception, and the pharmacy availability of ulipristal-containing emergency contraception.

124. The EAG was informed about an application for a new medicinal product for treatment of bacterial vaginosis.

125. Members of the EAG considered and made recommendations on applications for a new product for hormone replacement therapy; benefits and risks of levonorgestrel-releasing intrauterine systems (LNG-IUS) and benefits and risks of use of NSAIDs during pregnancy.

Neurology, Pain and Psychiatry Expert Advisory Group (NPPEAG)

126. The NPPEAG met on one occasion in 2014, convened via teleconference on one occasion, and provided advice by written correspondence on six items.

127. In February, the pain experts provided written comments on a medicine proposed for use in the treatment of opioid-induced constipation.

128. In March, the neurology experts provided written comments on a medicine indicated for the treatment of Parkinson's disease, a degenerative neurological disorder.

129. In May, the psychiatry experts convened via teleconference and provided recommendations on:

- a medicine for use in the comprehensive treatment of attention deficit/hyperactivity disorder (ADHD) in adults
- a medicine indicated for ADHD in children and adolescents as part of a comprehensive treatment programme, if other medicinal and non-medicinal therapeutic measures are considered clinically inadequate.

130. In May, the neurology experts provided written comments on a paper on recommendations to minimise the cardiac risks of domperidone. This is a medicine used to relieve feelings of nausea or vomiting.

131. In August, the EAG convened and provided recommendations on:

- a medicine indicated for the treatment of narcolepsy with or without cataplexy. Narcolepsy is a chronic sleep disorder characterised by overwhelming daytime drowsiness and sudden attacks of sleep. It is often associated with cataplexy, which is a sudden loss of muscle tone causing temporary paralysis, usually triggered by strong emotions
- a medicine indicated for the treatment of Non-24-Hour Sleep-Wake Disorder in people who are totally blind. Non-24-hour sleep-wake disorder (N24) is a circadian rhythm sleep disorder in which an individual's biological clock fails to synchronize to a 24-hour day.

The EAG was updated on:

- Brand Prescribing of Antiepileptic Drugs
- European Guidelines on Pain Management

132. In October, the EAG provided written comments on:

- a medicine for the treatment of Multiple Sclerosis (MS),
- a medicine for use in the treatment of seizures in patients with epilepsy.

133. In December, the psychiatry experts provided written comments on a study conducted by the Food and Drug Administration (FDA) on intravenous iron containing products.

134. In December, the EAG provided written comments on a medicine indicated for the treatment of epilepsy, and used in treatment of bipolar disorder. The EAG provided advice on neurodevelopmental delay in children whose mothers used sodium valproate during pregnancy.

Oncology and Haematology Expert Advisory Group (OHEAG)

135. In 2014, the OHEAG met on two occasions and convened by teleconference on two occasions. The EAG also provided written comments on 11 items.

136. In January the EAG provided written comments on:

- a medicine indicated for the treatment of ovarian cancer
- a medicine for the treatment of non-small cell lung cancer.

137. In February, the haematologists provided written comments on a medicine to be used as part of a combination therapy for patients with acute B/T-cell lymphoblastic leukaemia (ALL) or B/T-cell lymphoblastic lymphomas (LBL), which are particular forms of blood cancer.

138. In March, the EAG convened and made recommendations on:

- two medicines indicated for the treatment of blood cancers in adults
- a medicine used to treat a type of cancer in children that grows from abnormal nerve cells in the body.

The EAG discussed details of a proposed UK Early Access to Medicines Scheme (EAMS) submission.

In addition, the EAG noted a procedural update on a benefit-risk review being undertaken in Europe in relation to the risk of serious vascular occlusive events associated with Iclusig (ponatinib), a medicine used in the treatment of certain leukaemias in adult patients.

The EAG was updated on the outcome of the advice provided for some applications since August 2013 via written comments.

The EAG also discussed different possibilities on how to operate future meetings.

139. In April, the EAG convened by teleconference and made recommendations on a benefit-risk review being undertaken in Europe in relation to the risk of serious vascular occlusive events associated with Iclusig (ponatinib), a medicine used in the treatment of Philadelphia positive leukaemias in adult patients.

140. In April, the EAG also provided written comments on:

- a medicine indicated for the prevention of nausea and vomiting caused by chemotherapy in adult patients
- a medicine to treat Non-Hodgkin lymphoma, an uncommon cancer that develops in the lymphatic system, which is a network of vessels and glands spread through the body
- a medicine for the treatment of prostate cancer.

141. In July, the EAG convened by teleconference and made recommendations on:

- a medicine indicated to treat non-small cell lung cancer (NSCLC) that is advanced or metastatic (i.e. has spread to other parts of the body) in adults
- a medicine indicated for the treatment of prostate cancer
- a medicine indicated for the treatment of multiple myeloma, a type of bone marrow cancer.

The EAG also noted a procedural update on a benefit-risk review being undertaken in Europe in relation to the risk of serious vascular occlusive events associated with Iclusig (ponatinib).

142. In August the EAG provided written comments on a medicine for the treatment of myelofibrosis, a rare form of blood cancer.

143. In September, the EAG convened and made recommendations on:

- a medicine used for the treatment of multiple myeloma, a type of bone marrow cancer, in adult patients
- a medicine for use in combination with other drugs to treat adults with metastatic carcinoma of the cervix
- a medicine for the treatment of pancreatic, lung and breast cancers in adults
- a medicine indicated for the palliative treatment of locally advanced or metastatic prostate cancer.

144. In October, the EAG provided written comments on:

- a medicine indicated for the treatment of advanced melanoma, a type of skin cancer
- a radiopharmaceutical product for diagnostic use
- a medicine for the treatment of bleeding in patients with acquired haemophilia A, a bleeding disorder caused by lack of factor VIII activity due to antibody development
- a medicine proposed for use in the treatment and control of growth of gastroenteropancreatic neuroendocrine tumours (advanced tumours of the intestine and pancreas that cannot be removed by surgery).

145. In December, the EAG provided written comments on:

- a medicine indicated to treat thyroid cancer in adults when radioactive iodine treatment has not helped to control the disease
- a medicine indicated for the treatment of breast cancer.

The EAG also advised on a product submitted under the Early Access to Medicines Scheme (EAMS).

Paediatric Medicines Expert Advisory Group (PMEAG)

146. The Paediatric Medicines Expert Advisory Group (PMEAG) advises 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. The EAG met 8 times in 2014 and provided advice through written correspondence for 9 papers.

Paediatric Investigation Plans (PIPs)

147. PMEAG and its individual members advise on PIPs. These are agreed through a European procedure with Member States acting as UK Rapporteur or Peer Reviewer. In 2014, the EAG discussed 9 PIPs where the UK is Rapporteur and 10 where UK has acted as Peer Reviewer. In addition, advice was also sought via written procedures for 3 PIPs for which UK was Peer Reviewer. The advice given covered a range of therapeutic areas. The EAG also provided comments for a PIP for which the UK was non-Rapporteur which concerned the development of a drug for treatment of cachexia in paediatric cancer patients. Members have also commented in writing on a number of procedures for which the deadlines fell between EAG meetings. The UK continues to make a strong contribution to decisions on the development of paediatric medicines at European level through the provision of delegates and UK experts, including PMEAG members, to the PDCO, its working-groups and *ad hoc* groups.

Advice on work-sharing procedures

148. The EAG considered 9 papers where the UK was Rapporteur for products being assessed under work-sharing procedures, coordinated at European level by Member States, which included studies completed before the Regulation came into force (Article 45 procedures). The EAG also considered 2 papers where the UK was Rapporteur for products being assessed under work-sharing procedures which included studies completed after the Regulation came into force (Article 46 procedures).

Advice related to marketing authorisation applications supported by paediatric data

149. The EAG reviewed 2 new products and 2 applications to add or extend paediatric use in an existing product. The products covered a range of indications including prevention of respiratory distress syndrome (RDS) in premature infants, reduction of elevated platelet counts in at-risk essential thrombocythaemia patients, treatment of moderate to severe plaque psoriasis and the treatment of mild to moderate atopic dermatitis.

Safe use of medicines in children

150. The EAG advised on paediatric use of codeine as an antitussive in cough and cold medicines, which was the subject of a European review under the new Pharmacovigilance Legislation. Furthermore the EAG provided advice regarding the risks associated with high content of sodium in paediatric medicines and the need for specific warnings in the product and patient information of paediatric medicines as part of the European assessment of a safety signal in adults and in children. The EAG considered the PRAC recommendations regarding the use of domperidone in the paediatric population as the result of a European review.

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

151. ***Regulatory guidance*** The EAG considered information regarding the Early Access to Medicines Scheme. The EAG was informed on the EU Commission consultation on the "Guideline on the format and content of applications for agreement or modification of a paediatric investigation plan and requests for waivers or deferrals and concerning the operation of the compliance check and on criteria for assessing significant studies". In addition, the EAG was informed on the public consultation of EMA's "Guideline on clinical investigation of medicinal products for the treatment of juvenile idiopathic arthritis". The EAG commented on EMA's "Draft Inventory of Drugs in Paediatric Oncology". The EAG also advised on the update of the paediatric pharmacovigilance reporting guideline.

152. ***Discontinuations*** In 2014, the EAG members gave advice on the discontinuation of 7 medicines for children, for a wide range of indications including medicines for respiratory conditions (such as asthma, bronchiolitis and cough), medicines for epilepsy and for migraine, a drug licensed for anaemia due to chronic renal disease, a drug for diabetes mellitus type 2 and a drug licensed for anaesthesia.

153. ***Advertising*** Members also raised concerns regarding the inappropriate advertising in a scientific publication of an agent intended for the treatment of bladder disorders.

154. ***Clinical trial protocols*** The EAG advised on an application for a paediatric clinical trial protocol and the appropriate dosing schedule of a monoclonal antibody in paediatric patients with a life-threatening blood disease.

Conclusion

155. During 2014, the Paediatric Medicines EAG again provided invaluable advice which supported the aim of the Paediatric Regulation to improve the number of medicines properly researched and authorised for use in children. It continued

to advise on PIPs, their modifications and, increasingly, on the subsequent marketing authorisation applications to extend paediatric use based on the studies in these plans. It also advised on updates to product information as a consequence of studies submitted through European work-sharing procedures. The EAG has continued to provide views across a wide range of therapeutic areas and issues such as discontinuation of paediatric medicines and the development of appropriate regulatory guidance. The EAG continues to participate in reviews of the safe use of medicines in children. This is increasing as a consequence of the new pharmacovigilance legislation.

Patient and Public Engagement Expert Advisory Group (PPEEAG)

156. The membership of the Commission's PPEEAG was appointed in 2012 following agreement of the terms of reference for this group by the Commission in 2011. Members are primarily lay people although a small number have a health professional background. The EAG is supported by two lay members from the Commission. The EAG is chaired by Mr Harry Cayton (Chief Executive of the Professional Standards Authority). Meetings are held quarterly.

157. The EAG work continued to progress within three work-streams which had been endorsed by CHM:

- Information improvement
- Internal influence
- External influence.

158. As part of the information improvement work-stream the EAG reviewed and advised on a number of pieces of case-work following CHM review of safety data. Patient information in a number of areas was optimised and the secretariat has instigated changes in the market place.

159. The introduction of a new drug-driving offence involved the EAG in advising on new medicines information which will support both healthcare professionals and patients in making informed decisions about medicine prescribing medicine taking.

160. The internal influence work-stream focussed on patient involvement in the regulatory decision-making process. The group finalised an interim report for consideration by the CHM which was endorsed. Work began in earnest to involve patients in national regulatory work through a national stakeholder platform for the reclassification of medicines. Further reports will be provided to CHM as the work progresses.

161. As part of the External Influence work-stream the EAG heard from colleagues in the Department for the Environment, Fisheries and Rural Affairs and provided advice on the patient perspective on pharmaceuticals in the environment as part of a wider cross government initiative.

162. The EAG also advised on the strategic road-map for the reporting of adverse drug reactions through the Yellow Card (YC) scheme as the 50th anniversary of YC was being celebrated. A strand of work entitle *"My Yellow Card – meeting the patient's needs"* was developed with input from the EAG.

Pharmacovigilance Expert Advisory Group (PEAG)

163. The Commission's Pharmacovigilance EAG membership includes expertise in pharmacovigilance, clinical pharmacology, toxicology, epidemiology, general practice, nursing, pharmacy and also includes lay representation.

164. The EAG met on 11 occasions during 2014, including once by teleconference, and provided advice by written procedure on a further occasion.

165. The EAG considered papers on the following drug safety issues:

- Renin-angiotensin system (RAS) agents – their use in combination and risk of cardiovascular and renal adverse effects
- Ivabradine – adverse cardiovascular outcomes
- Domperidone - QT-interval prolongation and sudden cardiac death (benefit-risk review)
- Ponatinib – vascular occlusive events (benefit-risk review)
- Codeine – treatment of cough and/or cold in children (benefit-risk review)
- Ibuprofen - arterial thrombotic risk with use of high doses (≥2400mg/day)
- Interaction between ibuprofen and aspirin leading to possible decreased cardioprotective effect of aspirin
- Dimethyl fumarate - risk of progressive multifocal leukoencephalopathy
- Hydroxyzine – QT interval prolongation
- Somatropin treatment for childhood short stature and risk of stroke in early adulthood
- Ferumoxytol (intravenous iron) - serious and fatal allergic reactions
- Paracetamol - serious skin disorders including Stevens-Johnson syndrome, toxic epidermal necrolysis and acute generalised exanthematous pustulosis
- Interferon beta - risk of thrombotic thrombocytopenic purpura, thrombotic microangiopathy and haemolytic uraemic syndrome
- Mycophenolate mofetil – bronchiectasis and hypogammaglobulinaemia

166. Where major regulatory action or restrictions on use were proposed, advice was also sought from the Commission on Human Medicines. The EAG's advice on the majority of these issues was subsequently taken forward for further discussion within the European medicines regulatory system.

167. The EAG gave advice on 17 Risk Management Plans (RMPs) including one for a new product being considered under the Early Access to Medicines Scheme (EAMS).

168. The EAG also advised on MHRA's vaccine surveillance strategies for new national vaccination programmes (rotavirus vaccine, shingles vaccine and intranasal 'flu vaccine) and pertussis vaccination in the third trimester of pregnancy.

169. The EAG considered papers which measured the impact of regulatory action taken previously for celecoxib, benzodiazepines and modafinil and provided advice on best practice for designing and reporting future outcome studies.

170. In addition to the monthly Yellow Card reporting statistics, the EAG considered proposed updates to the Yellow Card Scheme including revised guidance for reporting suspected adverse drug reactions in children and proposals to establish a single reporting system for all MHRA incident reporting schemes under the Yellow Card website (i.e. in addition, those for device failures, defective medicines, counterfeit medicines and blood products.

171. Summary reports based on the minutes of each meeting are published on the GOV.UK website. The safety advice given by the EAG on the majority of the issues listed above was communicated to healthcare professionals in the UK via the MHRA monthly bulletin, Drug Safety Update (https://www.gov.uk/drug-safety-update)

Alteplase Working Group

172. In May 2014, the Commission on Human Medicines (CHM) considered a thorough appraisal of evidence that had become available since the treatment-window for alteplase in stroke was extended in 2012, taking into consideration specific concerns that had been brought to its attention. Based on the evidence presented, CHM concluded that the data did not change the favourable balance of benefits and risks for alteplase, which remains an effective medicine for treating ischaemic stroke.

173. In order to be assured that all relevant sources of evidence have been taken into consideration, the CHM advised that an expert working group should be set-up. This group is reviewing information from a range of sources and will consider whether the evidence has implications for the favourable benefit to risk ratio of alteplase in the treatment of ischaemic stroke. It will further explore whether there is more we can do to improve the safe use of alteplase in the UK.

174. A working group has been convened, with experts in neurology, epidemiology, statistics, thrombosis, emergency medicine, stroke care, cardiology and lay participants and had its first meeting in November. A further one or two meetings will be planned for 2015. The expert working group will report its conclusions to the CHM and the outcome of the review will be made public after it is finalised during 2015. The proceedings are confidential whilst the review is ongoing.

Isotretinoin and Psychiatric Adverse Reactions Working Group

175. In 2014 a working group was set up by the CHM to evaluate the risk of psychiatric adverse reactions and their impact on the risk:benefit balance of isotretinoin.

176. The aims of the review were to:

- consider the evidence of a link between isotretinoin and psychiatric disorders
- decide whether the benefits of taking isotretinoin still outweigh the risk of adverse reactions (side effects) in most people
- consider whether regulatory action is required to minimise these risks
- make sure that the information available on isotretinoin effectively communicates the risks to healthcare professionals and the public.

177. The working group advised that the available study data were insufficient to establish a causal association but could not rule out an association between isotretinoin and psychiatric disorders. Given the evidence from case series and spontaneous case reports and the underlying risk of psychiatric disorders in this patient group, the current warnings about a risk of depression and suicidal behaviour in the Summary of Product Characteristics were considered appropriate.

178. The working group advised that the overall presentation of the current patient information leaflet for isotretinoin should be improved and that the most important side effects should be further emphasised. The working group concluded that education and awareness of the issues were key to patients and prescribers making informed decisions regarding treatment with isotretinoin and that this could be achieved through careful communications and improvements in the patient information leaflet.

179. The conclusions of the working group were presented to the Commission in September 2014. The Commission supported the conclusions and recommendations of the working group. The Commission noted that the full patient leaflet, not just the warnings regarding possible psychiatric disorders was being considered by the Patient and Public Engagement Expert Advisory Group and welcomed their input.

Nicotine Containing Products Working Group

180. The Nicotine Containing Products Working Group (NCP WG) met once in June 2014 and considered in the light of the scientific evidence available how novel nicotine containing products authorised as medicines should be supplied for use as smoking cessation aids.

181. The WG advised on the MHRA's assessment of all available data on:

- Current use of electronic cigarettes and the potential for these to act as a gateway to smoking for children and young people
- The appropriate legal classification for supply of those nicotine containing products which are the subject of a MA
- Safety of electronic cigarettes and the information which would be considered appropriate in a risk management plan for such products when the subject of a MA.

182. The working group advised that the available data raised concerns about the availability of NCP for over-the-counter access by children and young people under the age of 18 years and concluded that for this age group these products when authorised as medicines should be available only on prescription. The Commission subsequently endorsed the conclusions of the NCP WG.

183. The WG also advised on the level of data that would be required to support an application for a marketing authorisation to inform the guidance which the MHRA publishes for prospective applicants.

National Emergency Stockpile Quality Panel

184. The National Emergency Stockpile Panel which was formed in April 2010 continues to provide advice to the Emergency Preparedness Group of the Department of Health within the context of its UK Medicines Strategic Stockpile Expiry Contingency Protocol.

185. The Panel did not meet in 2014 nor did it provide any written comments. In future it is expected that the Panel will meet once a year.

Review of Non-Prescription Analgesics Working Group

186. In 2013 a working group was set up by the CHM in the light of evidence about the cardiovascular risks associated with diclofenac and ibuprofen, and following consideration by NICE of the risks and benefits of paracetamol and its role in the management of osteoarthritis.

187. The working group had met on 2 occasions in 2013 – in September and November to agree the terms of reference and consider papers on the following issues:

- An overview of non-prescription oral analgesics authorised in the UK
- Outcome of the consultation exercise MLX 382 on availability of diclofenac as a Pharmacy medicine.

188. The working group met on 2 more occasions in 2014 – in January and April – and considered papers on the following issues:

- Cardiovascular (arterial thrombotic) risks of ibuprofen. Assessment of new meta-analysis of clinical trial data and adequacy of current risk minimisation measures (SmPC contraindications and warnings).
- Paracetamol safety review
- Information on how the EAG's advice and recommendations regarding the arterial thrombotic risks of ibuprofen would be taken forward within the EU Medicines Regulatory Framework
- OTC availability of naproxen
- Cardiovascular (arterial thrombotic) risks of naproxen
- Consideration of Olsen studies and availability of diclofenac as a Pharmacy medicine
- Data on dose effect of NSAIDs and CV risk
- Risk management of codeine and dihydrocodeine containing analgesics
- Risk management of aspirin containing OTC analgesics
- Sodium-containing effervescent, dispersible and soluble medication and cardiovascular events.

189. The working group will advise the CHM of its conclusions in 2015 after which a report of the findings and recommendations of the group will be published.

Sodium Valproate Working Group

190. In 2014 a working group was set up by the CHM to evaluate the risk of developmental disorders and their impact on the risk:benefit balance of valproate use in women of child bearing potential.

191. The aims of the review were to:

- consider the evidence for an association between valproate exposure in pregnancy and neurodevelopmental effects and autistic spectrum disorder.
- consider the balance of risks and benefits of valproate in pregnancy, in women planning pregnancy and in women of childbearing potential in women with epilepsy and bipolar disorder.
- consider the place in clinical practice of valproate in its licensed indications.
- advise on appropriate measures to minimise risk associated with the use of valproate in pregnancy, taking into account use in unlicensed indications.

192. The working group advised that the available data were sufficient to support an association between adverse effects of sodium valproate on cognitive development in some children exposed in utero.

193. The working group concluded that sodium valproate has an important place in the treatment of some types of epilepsy and in the treatment of acute mania in bipolar disorder.

194. Given the data available it was considered that the benefit:risk in generalised epilepsy is positive but that it should not be used first line in female patients/women of childbearing potential, rather, its use should be reserved for when other treatments have failed. The Group considered that the lowest effective dose should be used by women of childbearing potential, in the absence of any alternative treatment.

195. Across all approved indications, women of childbearing potential should be treated with valproate only if other treatments are ineffective or are not tolerated, under specialist supervision and subject to regular review of the need for treatment.

- Women who received valproate should be given appropriate counselling.
- Women of childbearing potential who were established on valproate treatment should have a benefit-risk assessment performed in secondary care. Valproate should not be commenced for any reason in primary care.
- The benefits and risks of switching treatment should be assessed in women who become pregnant while receiving valproate.
- Children exposed to valproate in utero should be referred early for a neurological assessment.

196. Education and communication about the risks to the foetus of valproate exposure in utero should be provided to both patients and healthcare professionals on the conclusion of the European Article 31 referral. The wording of these materials should be agreed by regulators, Marketing Authorisation

Holders and patient groups. Professional bodies should be used as a means to communicate to healthcare professionals.

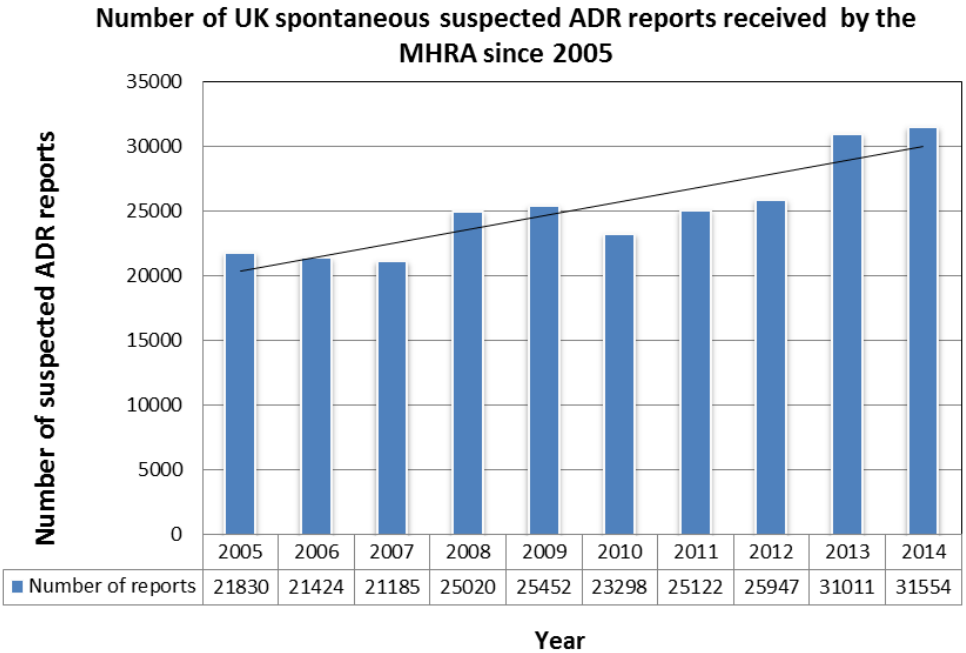
197. The conclusions of the working group meetings and outcome of the European review were presented to the Commission in December 2014. The Commission supported the conclusions and recommendations of the working group. The CHM endorsed the need for better information to be made available to patients on the risks of developmental disorders in children exposed to sodium valproate in utero, and the need for MHRA to send a letter to healthcare professionals and an article in Drug Safety Update on the strengthened risk minimisation measures. The Commission advised that communications on the regulatory outcome should be co-ordinated with communications from DH and NICE to ensure that consistent messages were being delivered to healthcare professionals and patients at the same time.

REPORTING OF SUSPECTED ADVERSE DRUG REACTIONS

198. Suspected Adverse Drug Reactions (ADRs) to medicinal products and vaccines are reported to the CHM and MHRA on a voluntary basis by healthcare professionals, coroners and patients through the Yellow Card Scheme. Reports are also submitted as a legal requirement by pharmaceutical companies holding Marketing Authorisations. Information collected through the Yellow Card Scheme is an 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 ADRs.

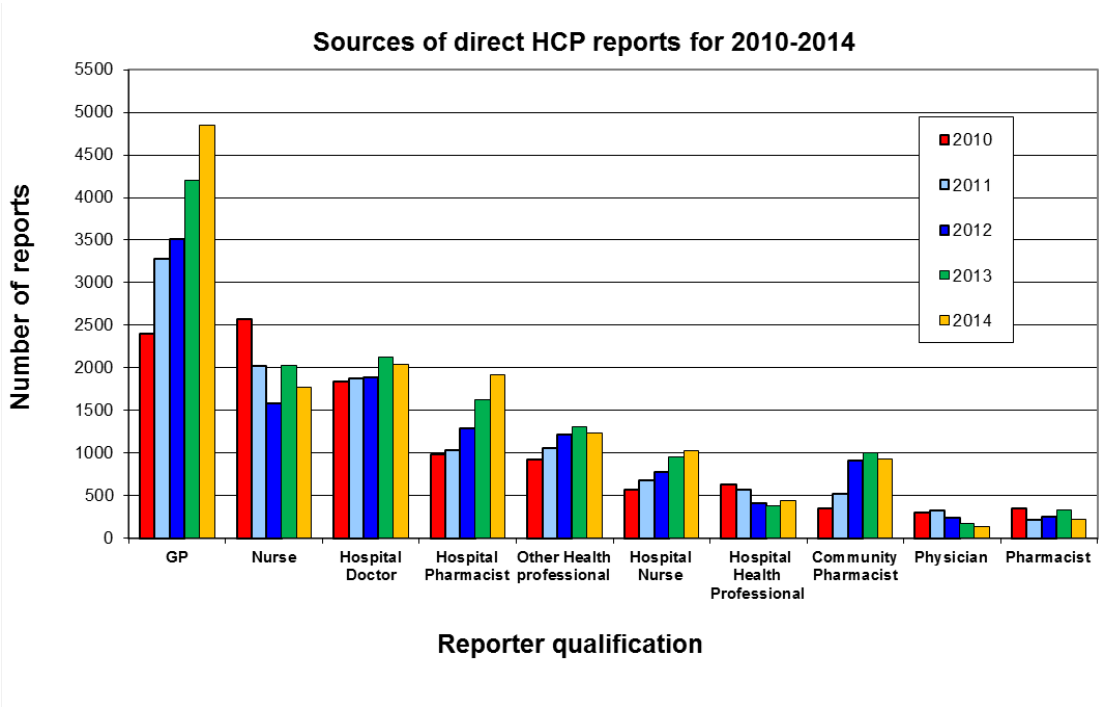
199. Figure 1 shows the total number of UK spontaneous Yellow Card reports received from pharmaceutical companies, healthcare professionals and patients over a ten year period between 1 January 2005 and 31 December 2014. The number of suspected ADR reports has increased by 9,724 reports (45%) over the ten year period. Overall the annual number of UK spontaneous ADR reports received since 2005 shows an increasing average trend as depicted by the line on the graph.

Figure 1 – Number of UK spontaneous suspected Adverse Drug Reaction reports received between 2005 and 2014



200. The total number of UK spontaneous suspected ADR reports increased by 2% (543 reports) in 2014 when compared to the previous year. The proportion of serious ADR reports remains unchanged at 86%. Of the total number of UK spontaneous suspected ADR reports received in 2014, 42% (13170) of reports were received from pharmaceutical industry, 45% (14542) directly from healthcare professionals and 12% (3805) from members of the public (patients, parents and carers). A breakdown of direct healthcare professional reports by reporter qualification between 2010 and 2014 is shown in Figure 2.

Figure 2 – Number of direct ADR reports received between 2010 and 2014 by reporter qualification



*Other health professionals include: dentists, optometrists, coroners, healthcare assistants, paramedics, chiropodists and other non-specified health professionals

201. Reports from GPs continue to form the highest proportion of direct reports received through the Yellow Card Scheme, showing the impact of the introduction of electronic reporting into the GP IT system SystmOne in 2010 (see below). A key focus of the Yellow Card strategy is to improve access and ease of reporting with GPs. There was a communications campaign in early 2013 to encourage reporting from GPs and pharmacists. In 2014, numbers of GP reports increased by 13% (654 reports) taking GP reporting to the highest level since the start of the Scheme. In total, GP reports accounted for 33% (4851 reports) of all direct healthcare professional Yellow Cards received by the MHRA in 2014.

202. In 2014, Yellow Cards completed by hospital doctors account for the second largest proportion of all direct healthcare professional reports accounting for 2,043 (14%). The MHRA are continuing to work with partners on the introduction of electronic Yellow Card reporting in secondary care (see below). The third largest contribution comes from hospital pharmacists (13% of direct healthcare professionals) and this is largely due the increased ease of reporting electronically (see below) – such reporting now accounts for over a third of all

direct hospital pharmacy reports. It is encouraging to note that the numbers of Yellow Cards received from hospital and community pharmacists have almost doubled between 2010 and 2014.

203. Patient reporting is an established part of the Yellow Card Scheme. Significant efforts to increase awareness of the Scheme through a specific communication campaign targeting parents and carers took place in 2014. Part of the campaign included development of a video which was posted on YouTube in April 2014 about Yellow Card reporting in the paediatric population. A social media campaign to promote this Yellow Card video received 24 retweets meaning an audience reach of around 349,000 people. In addition, Yellow Card information has been put into the Personal Child Health Record (the Red Book) given to parents of newborn children to help increase awareness of the Scheme. In 2014, the MHRA received the highest ever number of reports from patients, parents and carers with 3810 reports making up 12% of all direct reports.

204. Interactive e-learning modules for healthcare professionals on pharmacovigilance and the Yellow Card Scheme continued to be available in 2014. These included the BMJ learning module, interactive e-learning for nurses through the Nursing Times learning website and the CPPE module for pharmacists.

Yellow Cards as a professional quality indicator

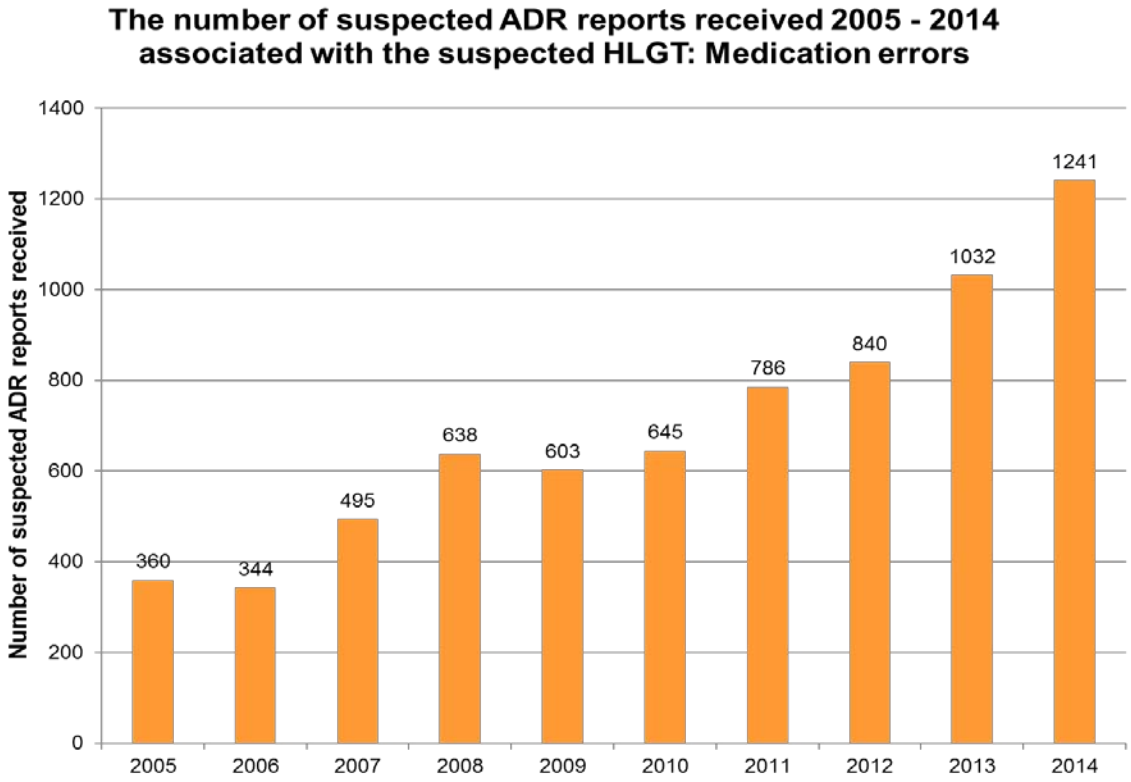
205. The New Medicines Service (NMS), launched in October 2011 is the fourth Advanced Service to be added to the NHS community pharmacy contract in England and the service has been extended to continue to run until 31st March 2015. It aims to provide early support to patients with long-term conditions to maximise benefits of newly prescribed medication and improve patient adherence. Successful implementation of the NMS is envisaged by the Pharmaceutical Services Negotiating Committee (PSNC) and NHS Employers to lead to an increase in the reporting of Yellow Cards, thereby supporting improved pharmacovigilance, the monitoring of drug safety and detection of new safety signals by the MHRA. Reports from community pharmacists have increased from 518 reports in 2011 to 928 reports in 2014 (44% increase over 3 years) since Yellow Card reporting was introduced as a quality indicator for successful implementation of the NMS for community pharmacy. This was also supported by previous communication campaigns targeted at community pharmacists.

A new National Medication Safety Network of Medication Safety Officers in England

206. In collaboration with NHS England, MHRA is working to simplify and increase medication error reporting, improve data quality, maximise learning and guide practice to minimise harm from medication errors by sharing incident data. The initiative facilitates implementation of new EU pharmacovigilance legislation, since the definition of ADR now includes medication error resulting in harm, and it reduces the need for duplicate data entry by frontline staff in the healthcare system. The initiative also aims to improve learning at local level, clarifying medication safety roles and identifying key safety contacts to allow better communication between local and national levels. The partnership has established a new National Medication Safety Network as a forum for discussing potential and recognised safety issues, identifying trends and actions to improve the safe use of medicines.

207. The total number of UK spontaneous suspected ADR reports associated with medication errors has increased by 17% (209 reports) in 2014 when compared to the previous year. Figure 3 shows the total number of UK spontaneous Yellow Card reports received associated with medication errors over a ten year period between 1 January 2005 and 31 December 2014.

Figure 3 – Number of UK spontaneous suspected Adverse Drug Reaction reports associated with medication errors received between 2005 and 2014



208. A Patient Safety Alert (PSA) was issued to the National Health Service (NHS) in England in March 2014 entitled: 'Improving Reporting and Learning on Medication Errors'. This was a joint publication between MHRA and NHS England[1]. The PSA was a Stage 3 Directive which requires organisations to act and confirm they have implemented the specific solutions or actions detailed therein to mitigate the risk of medication safety incidents, with emphasis on medication errors. It also means that a checklist of actions is required to be signed-off in a set timeframe tailored to the patient safety issue. As a result, the new network has over 350 registered Medication Safety Officers.

209. MHRA is working with the UK Devolved Administrations (Scotland, Northern Ireland and Wales) to share learnings from this initiative and to promote similar initiatives UK wide, alongside working with local risk management system suppliers to harmonise data collection from healthcare organisations to capture all relevant information required for national safety assessment and pharmacovigilance purposes.

[1] NHS England and MHRA. Patient Safety Alert; Stage 3 Directive. Improving medication error incident reporting and learning. 20th March 2014. Available: www.england.nhs.uk/2014/03/20/med-devices. Accessed 2nd February 2015

Signal detection

210. Signals of new and changing drug safety hazards are detected in a timely manner by the MHRA. Changes in the frequency of ADRs already known to be associated with drugs are also closely monitored through the signal detection process. The drug-event combinations from Yellow Card reports are assessed each week to identify potential safety signals. In 2014 there were a total of 70 validated signals – these are potential signals that have been identified by a statistical algorithm which subsequently require additional detailed investigation and review. These signals result in direct regulatory action such as updates to product information, whilst many more contribute to wider reviews alongside other sources of data. Each signal is prioritised[2] and assigned a time frame in which a national position should be reached. A breakdown of the signals and assigned priorities is provided in Table 1.

Table 1 - Number of signals assessed in 2014

	Signal Priority[2]			
	Top	**Increased**	**Standard**	**Not prioritised**
Number of signals	2	21	42	5

211. In 2014 ADR reports received from members of the public contributed towards 20 signals being detected, this includes seven signals where a member of the public's report stimulated regulatory action. Examples of signals taken forward include ustekinumab and exfoliative dermatitis (updated product information, risk management plan and Direct Healthcare Professional Communication) and updated product information for lanreotide to add hypersensitivity as a possible adverse effect.

Electronic Reporting

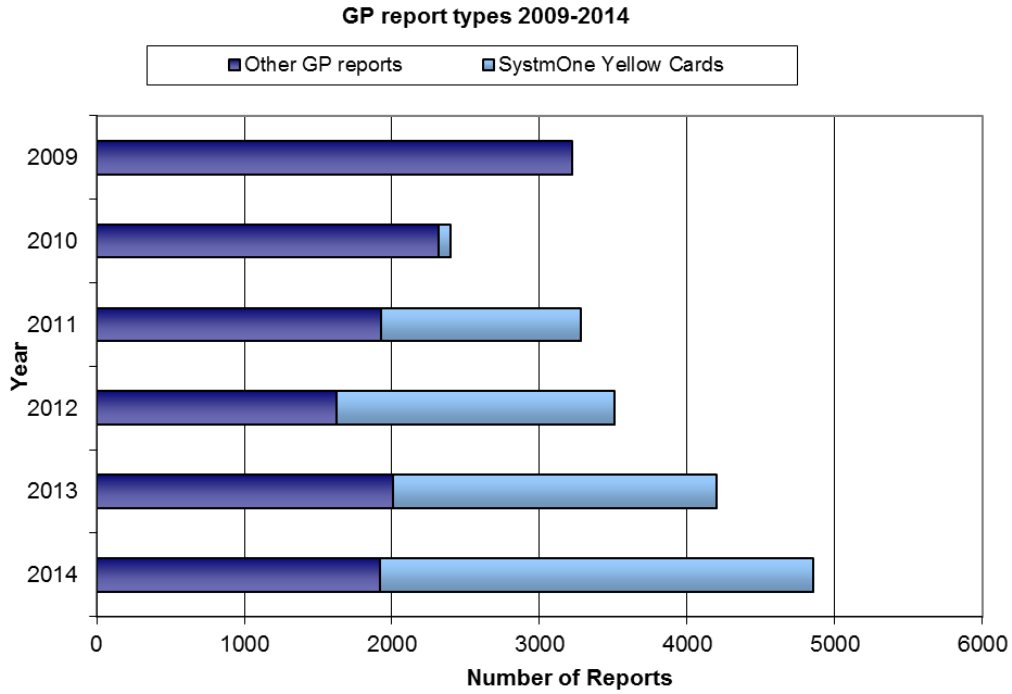
212. The Yellow Card strategy, which strengthens reporting of ADRs through the Yellow Card Scheme, has a strong focus on facilitating reporting i.e. making reporting convenient to access and easy to complete. Easier access to the Yellow Card Scheme can help to enable the earlier detection of any potential drug safety issues, allowing the MHRA to take prompt action to protect public health. As part of this strategy several projects are currently underway to facilitate electronic Yellow Card reporting through integration into clinical IT systems used by healthcare professionals.

213. Since November 2010, GPs have been able to report suspected ADR reports directly using the practice software SystmOne which is used in approximately 20% of GP practices across the UK. This was the first GP software to incorporate a Yellow Card reporting feature that enables GPs to quickly populate and securely send an electronic Yellow Card to the MHRA directly from their practice software. Figure 4 shows the impact on the number of reports received from GPs since the integration with SystmOne. In 2014, the MHRA received

[2] Top - action within 3 months, Increased - 6 months, Standard - 12 months, Not prioritised – priority not calculated (created for audit). Please note that these are maximum time frames; many signals will be handled within a shorter timeframe.

4057 electronic GP reports, accounting for 84% of all direct GP reporting. 2933 (60%) of these reports were received via the SystmOne practice software.

Figure 4 – Graph showing the impact on the number of Yellow Card reports received from GPs since the integration with clinical SystmOne software from 2009 to 2014



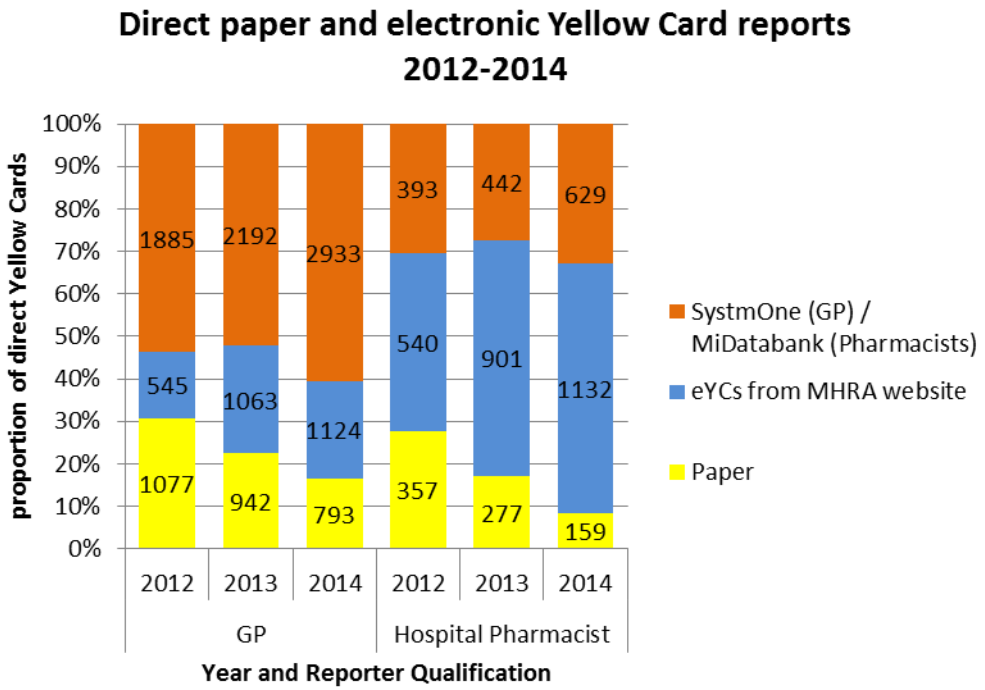
214. In 2012 the MHRA developed an NHS Information Standard for electronic Yellow Card reporting[3] and in 2014 work started on the integration of Yellow Card reporting into GP clinical IT systems in collaboration with NHS GP Systems of Choice with the support of the NHS Health and Social Care Information Centre. It is now mandatory for all GP systems in England to include the capability of reporting a Yellow Card and testing of these systems commenced in August 2014. These systems will be implemented across the UK in 2015 and aim to have a large impact by making Yellow Card reports easier and quicker to complete.

215. In collaboration with Southampton University Hospitals NHS Trust and the UK Medicines Information (UKMi) service, the MHRA have integrated automated production of Yellow Card reports using their MiDatabank software with medicines information pharmacists at over fifty NHS hospitals in the UK. In 2014, the MHRA received 629 reports through MiDatabank from hospital pharmacists, which accounts for 37% of all electronic hospital pharmacy reports and 33% of all direct pharmacist reports. In 2012, the CEO of the MHRA sent a letter to the NHS Chief Executives encouraging prioritisation of the installation of this software within NHS Trusts which was enhanced by workshops and awareness posters presented at UKMi conferences in 2012, 2013 and 2014.

[3] NHS Information Standards for electronic Yellow Card reporting:
ISB 1582 Electronic Yellow Card: www.isb.nhs.uk/library/standard/243 and www.isb.nhs.uk/documents/isb-1582

216. Work is continuing to increase the number of reports received via MiDatabank and SystmOne as part of the ongoing Yellow Card strategy. Figure 5 shows the impact on the number of reports received for GPs and Hospital Pharmacists from 2012 to 2014 following efforts to increase reporting through SystmOne and MiDatabank systems.

Figure 5 – Graph showing the breakdown of reporting methods (paper vs. electronic) received directly from GP and Hospital pharmacy sources between 2012 and 2014



217. A third system for direct Yellow Card reporting from the secondary care setting was also established towards the end of 2012 following collaboration between the MHRA, Newcastle upon Tyne NHS Foundation Trust and Cerner. Further work to develop the Cerner Millennium system was carried out in 2014 and plans are in place to launch this more widely across the UK in 2015.

218. Electronic reporting is also the most popular way of reporting for members of the public; in 2014, the MHRA received 3810 suspected ADR reports from patients, parent and carers, for which 84% were reported via the online Yellow Card reporting tool.

219. In September 2014, the MHRA embarked on leading a consortium of organisations including European medicines regulators, academics and the pharmaceutical industry in a three year project to develop new ways of gathering information on suspected adverse drug reactions (ADRs). The project, known as WEB-RADR[4], is in response to the rapid adoption of smartphones, apps, and social media as tools for communication information on medicines and health.

[4] http://web-radr.eu and http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON454333

220. The consortium will work to develop a mobile application (or 'app'), for healthcare professionals and the public to report suspected ADRs to national EU regulators. It will also investigate the potential for publicly available social media data for identifying potential drug safety issues. All social media data used within the project will be appropriately anonymised to protect data privacy.

221. This project is funded though the Innovative Medicines Initiative, a public private partnership between the European Commission and European Federation of Pharmaceutical Industries and Associations (EFPIA) with MHRA as the lead.

Updated Yellow Card forms to improve the reporting of ADRs in pregnancy

222. In 2014, the MHRA announced changes to its forms to increase and improve reporting of suspected ADRs to medicines used in pregnancy. Medicines should not be taken in pregnancy unless directed by a healthcare professional but is sometimes necessary when the benefit of a mother taking a medicine outweighs the potential risks to the baby from the drug and untreated illness. Changes to the online Yellow Card ADR form now allow important information to be captured. When entering data on a female 16 years or older, the reporter will be asked:

- If the woman is pregnant
- The dates of her last menstrual period if she is pregnant
- Expected date of delivery if she is pregnant.

223. Reporters are also encouraged to provide the following in the "additional information" fields of the Yellow Card:

- Information on previous pregnancies
- Dates and findings of ultrasonography
- If and when the woman started or stopped taking any other medicines and supplements during pregnancy (including folic acid).

224. Changes to the form allow MHRA to identify when a foetus was exposed to the medicine during gestation, enables better tracking of pregnancy outcome and more detailed information such as delivery complications, birth defects or developmental concerns. A Drug Safety Update article[5] was published to make healthcare professional aware of these changes. These changes will be mirrored in the paper Yellow Card for members of the public when next updated.

The 50th anniversary of the Yellow Card Scheme

225. To mark its 50th anniversary, promotion and education of the Yellow Card Scheme continued to be a priority in 2014/15. A series of events showcased the achievements of the Scheme in protecting public health and look to the future by developing a new Road Map with input from stakeholders. Themes under discussion include science and technology, better inclusion of ADR reporting in education programs and academic curricula, and more effective engagement with patients.

226. The first event in November 2014 was a strategic forum at which the Parliamentary Under Secretary of State for Life Sciences launched a new Yellow Card website which provides a single point of access to MHRA incident

[5] https://www.gov.uk/drug-safety-update/yellow-card-update-to-form

systems. Patients and healthcare professionals can now report any incidents or problems associated with medical devices, defective medicines and counterfeit healthcare products as well as suspected adverse drug reactions via this new single reporting portal.

227. The Chief Medical Officer delivered a keynote speech at a second event in December 2014 and a landmark scientific conference is planned in March 2015 The MHRA's Yellow Card Centres will be holding satellite events within their respective regions.

Yellow Card Centres

228. 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 in Wales, the West Midlands, Scotland, Northern & Yorkshire, and the North West. The YCCs undertake valuable work relating to a number of areas including academic research, the promotion and education of health professionals and patient organisations, on ADR reporting through the Yellow Card Scheme and communicating drug safety messages.

229. The Commission is grateful for the co-operation of those healthcare professionals and patients who submit reports of suspected ADRs and encourage the reporting of suspected ADRs to the Yellow Card Scheme.

MEMBERSHIP OF THE COMMISSION ON HUMAN MEDICINES (CHM)

Chair

Professor Stuart Ralston MB ChB MD FRCP FMedSci FRSE
Arthritis Research UK Professor of Rheumatology, University of Edinburgh, Western General Hospital, Edinburgh

Members

Professor Deborah Ashby[6] OBE BSc MSc PhD CStat Hon. MFPHM Hon. MRCR FMedSci
Professor of Medical Statistics and Clinical Trials Co-Director of Imperial Clinical Trials Unit, School of Public Health, Imperial College London

Mrs Eileen J Barrett[7] BSc PGCE CPE LPC
Lay Member. HR and Legal Director, Source BioScience, Nottingham

Mrs Alison Bowser[8]
Lay Representative. Patient and Public Involvement Officer, Research Design Service, Southampton University & National Institute for Health Research

Professor Janet H Darbyshire[9] CBE MB ChB FMedSci FRCP FFPH FRSS (Hon)
Emeritus Professor of Epidemiology, University College London

Dr J Colin Forfar[10] BSc (Hons) MBChB PhD MD MA FRCP FRCP (Edin)
Consultant Physician and Cardiologist, John Radcliffe Hospital, Oxford

Dr Jamie Fraser[11] BSc MB ChB MRCGP
GP Partner, Southside Surgery, Inverness

Professor Jonathan S Friedland[12] MA PhD FRCP FRCPE FRCPI FMedSci
Hammersmith Campus Director & Head of Section of Infectious Diseases & Immunity, Imperial College London; Hon Consultant in Infectious Diseases ICHT

Dr Richard Gilson[13] MD FRCP
Director, Centre for Sexual Health & HIV Research and Head, Research Department of Infection and Population Health, University College London

Professor Martin Gore[14] MBBS PhD FRCP
Medical Director and Consultant Medical Oncologist, The Royal Marsden NHS Foundation Trust and Professor of Cancer Medicine, Institute of Cancer Research

[6] End of appointment 31 December 2014
[7] Appointed 15 December 2014 – 14 December 2018
[8] End of appointment 31 December 2014
[9] End of appointment 31 December 2014
[10] Re-appointed 01 January 2014 – 31 December 2015
[11] Appointed 01 April 2014 – 31 March 2018
[12] Appointed 01 April 2014 – 31 March 2018
[13] Appointed 15 December 2014 – 14 December 2018
[14] Appointed 01 April 2014 – 31 March 2018

Ms Amanda Hoey[15]
Lay Member. Director, ConsumerHealth Consulting Ltd. Independent Health Policy and Strategy Consultant

Professor Malcolm R Macleod[16] BSc MBChB MRCP PhD FRCP (Edin)
Professor of Neurology and Translational Neurosciences, University of Edinburgh and Honorary Consultant Neurologist, NHS Forth Valley

Dr Rebecca Mann[17] BMBS FRCPCH
Consultant Paediatrician, Taunton and Somerset NHS Foundation Trust

Dr Sarah Meredith[18]
Deputy Director, MRC Clinical Trials Unit and Honorary Senior Lecturer, Department of Primary Care and Population Sciences, University College London

Dr Siraj Misbah MBBS (Hons) MSc FRCP FRCPath
Consultant Clinical Immunologist, Lead for Clinical Immunology, Oxford University Hospitals

Professor David G C Owens MD (Hons) FRCP FRCPsych
Professor of Clinical Psychiatry, Edinburgh University

Professor B Kevin Park[19] BSc PhD FMedSci FRCP (Hon) FBTS
Director of MRC Centre for Drug Safety Science, Professor of Pharmacology & Head of Institute of Translational Medicine, University of Liverpool

Professor Munir Pirmohamed[20] MB ChB (Hons) PhD FRCP FRCP (Edin) FMedSci
Professor of Clinical Pharmacology, University of Liverpool, NHS Chair of Pharmacogenetics and Director of the Wolfson Centre for Personalised Medicine

Professor Shirley Price[21] MSc PhD FBTS ERT FHEA FSB
Head of Academic Appeals and Academic Quality and Professor of Toxicology, University of Surrey

Carolyn, Lady Roberts RGN RHV MSc DUniv
Member of The Ethox Foundation - Oxford Centre for Ethics and Communication in Healthcare Practice. Health Visitor

Professor Kevin M G Taylor BPharm PhD MRPharmS
Chair of the British Pharmacopoeia Commission and Professor of Clinical Pharmaceutics, UCL School of Pharmacy, London

Dr Angela E Thomas[22] MB BS PhD FRCPE FRCPath FRCPCH
Consultant Paediatric Haematologist, Royal Hospital for Sick Children, Edinburgh

[15] End of appointment 31 December 2014
[16] Appointed 01 April 2014 – 31 March 2018
[17] Appointed 01 April 2014 – 31 March 2018
[18] Appointed 15 December 2014 – 14 December 2018
[19] Re-appointed 01 January 2014 – 31 December 2015
[20] Re-appointed 01 January 2014 – 31 December 2015
[21] Appointed 01 April 2014 – 31 March 2018
[22] Re-appointed 01 January 2014 – 31 December 2015

Professor Simon H L Thomas[23] BSc MBBS MD FRCP FRCP (Edin)
Professor of Clinical Pharmacology and Therapeutics, Newcastle University and Consultant Physician, Newcastle Hospitals NHS Foundation Trust

Dr Christopher Weir[24] BSc (Hons) PhD MSc FRSS C.Stat C. Sci
Reader in Medical Statistics, Centre for Population Health Sciences, University of Edinburgh

Professor Ian V D Weller[25] BSc MB BS MD FRCP (Hon) FRCP (Glas) **(Vice-Chair)**
Emeritus Professor of Sexually Transmitted Diseases, University College London Medical School

Invited Experts to Commission meetings:

Professor Colin Baigent FRCP FFPH
Deputy Director, Clinical Trial Service Unit & Epidemiological Studies Unit, Nuffield Department of Population Health, Oxford
(Attended September)

Dr Barbara A Bannister[26] MBE MSc FRCP
Honorary Consultant in Infectious Diseases, Royal Free London NHS Trust
(Attended January, February, March, April, June, July, September, October, November and December)

Mrs Eileen J Barrett BSc PGCE
Head of Legal and Employment, Source BioScience, Nottingham
(Attended April)

Professor Derek Calam OBE MA DPhil Hon DSc CChem FRSC FRSA Hon MRPharmS HonMTOPRA
Visiting Professor of Pharmaceutical Sciences at the University of Strathclyde
(Attended June and July)

Mr Harry Cayton CBE
Chief Executive, Professional Standards Authority for Health and Social Care, London
(Attended March)

Dr Steven Cunningham PhD FRCPCH FRCP
Consultant Respiratory Paediatrician, Royal Hospital for Sick Children, Edinburgh
(Attended January)

Dr Enrico Flossmann MRCP DPhil (Oxon)
Honorary Senior Lecturer in Neurology, Oxford University
(Attended May)

Dr Ailsa Gebbie MB ChB FRCOG FRCPE FFSRH
Consultant Gynaecologist and Deputy Director, Chalmers Centre, Edinburgh
(Attended July)

[23] Re-appointed 01 January 2014 – 31 December 2015
[24] Appointed 15 December 2014 – 14 December 2018
[25] End of appointment 31 December 2014
[26] Stepped down 31 December 2014

Professor Chris O'Callaghan
Professor of Respiratory & Paediatric Medicine, Head of Respiratory, Critical Care & Anaesthesia, Institute of Child Health, University College London
(Attended December)

Dr Rebecca Mann BMBS FRCPCH
Consultant Paediatrician, Taunton and Somerset NHS Foundation Trust
(Attended January, February and March)

Dr Patricia McGettigan MD FRCPI FRACP
Clinical Senior Lecturer in Clinical Pharmacology, Barts and the London School of Medicine and Dentistry
(Attended September)

Dr Sarah Meredith
Deputy Director, MRC Clinical Trials Unit and Honorary Senior Lecturer, Department of Primary Care and Population Sciences, University College London
(Attended July and September)

Dr Jai Patel MB ChB MRCP FRCR EBIR
Secretary to the British Society of Interventional Radiology and Consultant Vascular Radiologist, Leeds Teaching Hospitals NHS Trust
(Attended July)

Professor Shirley Price MSc PhD FBTS ERT FHEA FSB
Associate Dean of Learning and Teaching, Department of Biochemical and Physiological Sciences, Institute of Biosciences and Medicine, Faculty of Health and Medical Sciences, University of Surrey
(Attended January, February and March)

Professor John Warner OBE FMedSci FAAAAI FRCP FRCPCH
Professor of Paediatrics, Imperial College London and Consultant in Paediatric Allergy and Respiratory Disease, Imperial College Healthcare NHS Trust
(Attended January)

Dr Christopher Weir BSc (Hon) PhD MSc FRRS C.Stat C. Sci
Associate Director (Statistics), University of Edinburgh Medical School, Edinburgh
(Attended February, April, June, September and November)

Professor Anthony G Wilson MB BCH BAO DCH PhD FRCP
Professor of Rheumatology, University College Dublin
(Attended July)

Dr Geoffrey Wong MA MD (Res) MBBS MRCGP FHEA
GP Principal and Senior Lecturer in Primary Care, Queen Mary University of London
(Attended January, February and March)

Observers of Commission meetings:

Dr Keith Bragman MD FRCP FRCPath
President of the Faculty of Pharmaceutical Medicine
(Observed November)

Mr David Dipple
Lead Triennial Reviewer and Head of TR Programme Assurance, Department of Health (Attended December)

Mrs Joyce Epstein
Former Director of the Foundation for the Study of Infant Deaths (FSID)
(Observed February)

Mr Jamie Grant
Assistant Reviewer, Triennial Review Team, Department of Health (Attended December)

Dr Iain M MacIntyre MBChB PhD MRCP
Registrar in Clinical Pharmacology & Renal Medicine, Royal Infirmary of Edinburgh, Edinburgh
(Observed November)

Dr Sarah Meredith
Deputy Director, MRC Clinical Trials Unit and Honorary Senior Lecturer, Department of Primary Care and Population Sciences, University College London
(Observed March)

Dr Emma Morrison MB ChB BSc MRCP
Clinical Research Fellow, Centre for Cardiovascular Sciences, Queen's Medical Research Institute, University of Edinburgh
(Observed November)

Mr Nathaniel Nkrumah
Acting Head, Foreign Medicines Evaluation Registration Unit, Ghanaian Food and Drugs Authority (Attended December)

Mrs Mercy Owusu-Asante
Head, Drug Evaluation and Registration Department, Ghanaian Food and Drugs Authority (Attended December)

Professor David Webb MB BS MD DSc FRCP FRSE FMedSci
Christison Professor of Therapeutics and Clinical Pharmacology, University of Edinburgh and Royal Infirmary (and member of the Agency Board)
(Observed November)

The following Department of Health officials attended for specific agenda items:

Mrs Rebecca J Blessing
Section Head - Non-medical prescribing & general prescribing issues
(Attended November)

Mrs Jeannette Howe
Head of Pharmacy
(Attended January)

Ms Theresa Prendergast
Programme Manager
(Attended January)

The following Maritime and Coastguard Agency official attended for specific agenda items:

Mr Douglas MacDonald
Head of Aviation Operations, Maritime and Coastguard Agency
(Attended September)

The following NHS England officials attended for specific agenda items:

Mrs Helen Marriott
Allied Health Professions Medicines Project Lead
(Attended November)

Mrs Shelagh Morris OBE
Deputy Chief Allied Health Professions Officer
(Attended November)

MEMBERSHIP OF THE ANTI-INFECTIVES, HIV/AIDS AND HEPATOLOGY EXPERT ADVISORY GROUP

Remit

To advise the Commission on the safety and efficacy of medicines for use in infections including HIV, AIDS and hepatic diseases.

Acting Chair

Dr Barbara A Bannister[27] MBE MSc FRCP
Honorary Consultant in Infectious Diseases, Royal Free London NHS Trust

Members

Dr Sanjay Bhagani[28] BSc MB ChB FRCP
Consultant Physician and Honorary Senior Lecturer, Department of Infectious Diseases/HIV Medicine, Royal Free London Foundation Trust

Professor David Dockrell[29] MB BCh MD FRCPI FRCP (Glas) FACP
Professor of Infectious Diseases, Medical School, University of Sheffield

Dr Richard Hobson MB BS MRCP (UK) FRCPath PhD
Consultant Microbiologist and Honorary Senior Lecturer, Leeds Teaching Hospitals

Dr Susan Hopkins[30] MB ChB BAO (Hons) BA FRCPI
Consultant in Infectious Diseases and Microbiology, Royal Free Hampstead NHS Trust, Healthcare Epidemiologist, Health Protection Agency, Honorary Senior Lecturer, University College London

Dr Hermione Lyall BSc Hons MB ChB Hons MD FRCPCH
Consultant in Paediatric Infectious Diseases, St Mary's Hospital, Imperial College Healthcare NHS Trust, London

Dr Philip N Monk[31] MB ChB FFPH
Consultant in Health Protection, Public Health England, East Midlands Centre, Leicester

Professor Kevin Moore[32] BSc MB BS PhD FRCP
Professor of Hepatology, Royal Free Hospital, London

Professor Robert C Read[33] MBChB BMedSci MRCP MD FRCP
Professor of Infectious Diseases and Head of Academic Unit, Clinical Experimental Science, University of Southampton

[27] Stepped down 31 December 2014
[28] Re-appointed 14 January 2014 – 13 January 2018
[29] Re-appointed 14 January 2014 – 13 January 2018
[30] Re-appointed 13 March 2014 – 12 March 2016
[31] Re-appointed 14 January 2014 – 13 January 2018
[32] Re-appointed 14 January 2014 – 13 January 2018
[33] Re-appointed 14 January 2014 – 13 January 2018

Ms Hilary A Shenton[34] CPFA
Lay Representative. Retired Secretary to the School of Medicine, University of Sheffield

Professor Ian V D Weller[35] BSc MB BS MD FRCP (Hon) FRCP (Glas)
Emeritus Professor of Sexually Transmitted Diseases, University College London Medical School

[34] Re-appointed 13 March 2014 – 12 March 2016
[35] End of appointment 31 December 2014

MEMBERSHIP OF THE CARDIOVASCULAR, DIABETES, RENAL, RESPIRATORY AND ALLERGY EXPERT ADVISORY GROUP

Remit

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

Chair

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

Members

Professor Houman Ashrafian BA MA BM BCh MRCP DPhil
Associate Professor of Medicine, Head of Experimental Therapeutics, Honorary Consultant Cardiologist, Radcliffe Department of Medicine, University of Oxford

Dr Susan Benbow[36] MBChB MD FRCP
Consultant Physician in Diabetes and Endocrinology & Clinical Head of Medicine,
Diabetes Centre, Aintree University Hospital NHS Trust, Liverpool

Professor Peter M A Calverley[37] MB ChB JCHMT FRCP FRCPE FMedSci
Emeritus Professor of Medicine (Pulmonary and Rehabilitation Medicine), University of Liverpool

Professor Richard Donnelly MD PhD FRCP FRACP
Professor in Medicine and Head, School of Graduate-Entry Medicine, University of Nottingham

Dr Iolo J Doull MRCP DM FRCPCH
Consultant Respiratory Paediatrician, Respiratory/Cystic Fibrosis Unit, Children's Hospital for Wales, Cardiff

Dr John Firth BA BM ChB DM FRCP
Consultant Physician and Nephrologist, Addenbrooke's Hospital, Cambridge

Dr Andrew Grace MB PhD FRCP FACC FESC
Consultant Cardiologist, Papworth and Addenbrooke's Hospitals Cambridge & Research Group Head, Department of Biochemistry, University of Cambridge

Professor Wasim Hanif[38] MBBS MD FRCP
Professor of Diabetes & Endocrinology, Consultant Physician and Clinical Director of Diabetes, University Hospital Birmingham

[36] Resigned 22 January 2014
[37] Resigned 06 March 2014
[38] Appointed 15 May 2014 – 14 May 2016

Professor Richard IG Holt MA MB BChir PhD FRCP FHEA
Professor in Diabetes & Endocrinology, Human Development and Health Academic Unit, Faculty of Medicines, University of Southampton; Honorary Consultant Physician, University Hospital, Southampton NHS Foundation Trust

Dr Philip W Ind BA Cantab MB BChir MA Cantab FRCP
Consultant Physician and Honorary Senior Lecturer in Respiratory Medicine, Imperial School of Medicine, Hammersmith Hospital

Professor Alan G Jardine BSc MD FRCP
Professor of Renal Medicine, University of Glasgow

Professor Ann Millar MBChB MD FRCP **(Vice Chair)**
Professor in Respiratory Medicine, Bristol University & Honorary Consultant, North Bristol NHS Trust

Dr Hilary Pinnock MB ChB (Hons) MRCGP MD
Reader, Asthma UK Centre for Applied Research, Allergy and Respiratory Research Group, University of Edinburgh; General Practitioner, Whitstable Medical Practice

Dr Pallav L Shah MD MBBS FRCP
Consultant Physician, Royal Brompton Hospital and Chelsea & Westminster Hospital, Reader in Respiratory Medicine, Imperial College

Dr Caroline Vaughan PhD
Lay Representative of MHRA EAGS. Trustee and Director of Contact a Family and FamilyLine

Mr Phil Willan MSc
Lay Representative. Member of MHRA Pharmacovigilance EAG, Cardiovascular, Diabetes, Renal, Respiratory and Allergy EAG, Patient and Public Engagement EAG, Lay Members Forum; Member of the Royal College of Physicians' (RCP) Patient and Carer Network; Member of the RCP Joint Speciality Committee (JSC) for Renal Medicine, Healthcare Associated Infections Working Group, Specialist Advisory Committee for Renal Medicine, JSC for Allergy and Immunology, Faculty of Forensic and Legal Medicine, Federation CPD Policy Committee, Equality and Diversity Monitoring Committee and Patient Safety Committee. Member of the NHS England Clinical Reference Group for Renal Transplantation

MEMBERSHIP OF THE CHEMISTRY, PHARMACY AND STANDARDS EXPERT ADVISORY GROUP

Remit

To advise the Commission 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

Professor Kevin M G Taylor BPharm PhD FRPharmS
Chair of the British Pharmacopoeia Commission and Professor of Clinical Pharmaceutics, UCL School of Pharmacy, London

Members

Professor Michael E Aulton BPharm PhD FRPharmS FAAPS FSP
Emeritus Professor, De Montfort University, Leicester

Professor Graham Buckton BPharm PhD DSc FRPharmS FRSC
Professor of Pharmaceutics, UCL School of Pharmacy

Professor Derek H Calam[39] OBE MA DPhil Hon DSc CChem FRSC FRSA Hon MRPharmS Hon MTOPRA
Visiting Professor of Pharmaceutical Sciences at the University of Strathclyde

Professor Brian J Clark MSc PhD CChem FRSC
Professor of Pharmaceutical and Biomedical Analysis, Bradford University

Professor Ruth Duncan PhD
Professor Emerita in Cell Biology and Drug Delivery, Cardiff University and Visiting Professor at the University of Greenwich

Professor Gillian M Eccleston BSc PhD CChem FRSC FRPharmS **(Vice Chair)**
Professor of Pharmaceutics, Strathclyde University

Mr V'lain G Fenton-May BPharm MIPharm FRPharmS
Pharmaceutical Microbiologist

Professor Geoffrey W Hanlon BSc PhD MRPharmS
Emeritus Professor of Pharmaceutical Microbiology, School of Pharmacy & Bio-Molecular Sciences, University of Brighton

Dr Gillian M Hawksworth MBE PhD FFRPS FRPharmS (Hon) DSc
Academic Community Pharmacist, Senior Lecturer at University of Huddersfield & Past President of the RPSGB

[39] Re-appointed 31 October 2014 – 30 October 2015

Miss Carol E Knott MRPharmS MBA MIHM
Lay Representative. Director of Windcliff Management Ltd

Mr Robert Lowe BPharmS MRPharmS
Practising Hospital Pharmacist, NHS Eastern Region

Professor Christopher Marriott[40] PhD DSc Hon DSc FRPharmS CChem FRSC FRSM **(Vice Chair)**
Emeritus Professor of Pharmaceutics, King's College, London

Professor Yvonne Perrie BSc Hons MRPharmS FAPS FSB PhD
Head of Pharmacy, Aston University

Ms Hilary A Shenton[41] CPFA
Lay Representative. Retired Secretary to the School of Medicine, University of Sheffield

Professor Michael D Threadgill PGCE MA PhD DSc FRSC CChem
Professor in Medicinal Chemistry, Department of Pharmacy and Pharmacology, University of Bath

Professor Peter York PhD BSc DSc FRPharmS CChem FRSC FAAPS
Emeritus Professor of Pharmaceutics, Bradford University

[40] Became Vice-Chair 15 July 2014
[41] Re-appointed 14 February 2014 – 13 February 2016

MEMBERSHIP OF THE CLINICAL TRIALS, BIOLOGICALS & VACCINES EXPERT ADVISORY GROUP

Remit

To advise the Commission on:

- First time in human (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 CHM may wish to have oversight
- Whether a product's mechanism of action is novel and comes within the scope of the EAG
- 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
- 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 Thomas MB BS PhD FRCPE FRCPath FRCPCH
Consultant Paediatric Haematologist, Royal Hospital for Sick Children, Edinburgh

Members

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

Professor Janet H Darbyshire[42] CBE MB ChB FMedSci FRCP FFPH FRSS (Hon) **(Vice Chair)**
Emeritus Professor of Epidemiology, University College London

[42] End of appointment 31 December 2014

Professor Andrew J T George MA PhD DSc FRCPath FHEA FRSA FSB
Vice Principal (Education and International), Brunel University, London

Dr Elwyn Griffiths BSc PhD DSc CChem FRSC
Consultant in Biologicals and Vaccines, World Health Organization; Formerly Director General, Biologics and Genetic Therapies Directorate, Health Canada, Ottawa, Canada

Dr Helen J Lachmann MD FRCP **(Vice Chair)**
Reader and Honorary Consultant in Amyloidosis and Renal Medicine, University College London

Professor Christopher Mason[43] MBBS PhD FRCS FRCSI
Professor of Regenerative Medicine Bioprocessing, University College London

Professor Elizabeth Miller OBE BSc MBBS FRCPath FFPHM FMedSci
Consultant Epidemiologist, Immunisation Department, Centre for Infections, Health Protection Agency

Dr Siraj Misbah MBBS (Hons) MSc FRCP FRCPath
Consultant Clinical Immunologist, Lead for Clinical Immunology, Oxford University Hospitals

Professor Clive W Mulholland[44] BSc PhD CSci FIBMS SFHEA FRSA
Deputy Vice Chancellor, University of South Wales – Lay Representative

Professor B Kevin Park BSc PhD FMedSci FRCP (Hon) FBTS
Director of MRC Centre for Drug Safety Science, Professor of Pharmacology & Head of Institute of Translational Medicine, University of Liverpool

Professor Andrew Pollard[45] PhD FRCPCH
Chair of the Joint Committee on Vaccination and Immunisation; Professor of Paediatric Infection and Immunity, University of Oxford

Dr Stephen Poole PhD
Consultant: Biological Medicines and Vaccines

Professor Robert C Read[46] MBChB BMedSci MRCP MD FRCP
Professor of Infectious Diseases and Head of Academic Unit, Clinical Experimental Science, University of Southampton

Dr Peter F Searle[47] BA PhD
Senior Lecturer, School of Cancer Sciences, University of Birmingham

Professor Kevin Shakesheff[48] BSc PhD FRPharmS
Head of School of Pharmacy and Professor of Drug Delivery and Tissue Engineering, University of Nottingham

[43] End of appointment 14 May 2014
[44] End of appointment 13 January 2014
[45] Appointed 17 July 2014 – 16 July 2018
[46] End of appointment 13 January 2014
[47] Re-appointed 15 May 2014 – 14 May 2016
[48] End of appointment 14 May 2014

Mrs Margaret V Shotter[49] BSc MSc
Lay Member

Professor Owen Thomas[50] BSc PhD AMIChemE
Director of Biochemical Engineering, School of Chemical Engineering, University of Birmingham

Mrs Madeleine Wang BA (Hons)
Lay Representative. Patient Advocate

Dr Christopher Weir[51] BSc (Hons) PhD MSc FRSS C.Stat C. Sci
Reader in Medical Statistics, Centre for Population Health Sciences, University of Edinburgh

Invited Experts

Professor John D Isaacs[52] BSc (Hon) MB BS PhD FRCP
Director of the Institute of Cellular Medicine & Professor of Clinical Rheumatology, Medical School, Newcastle University

[49] Resigned 13 January 2014
[50] End of appointment 16 July 2014
[51] Re-appointed 15 December 2014 – 14 December 2018
[52] Stepped down 31 December 2014

MEMBERSHIP OF THE GASTROENTEROLOGY, RHEUMATOLOGY, IMMUNOLOGY & DERMATOLOGY EXPERT ADVISORY GROUP

Remit

To advise the Commission on the safety and efficacy of medicines for use in gastroenterological, rheumatological, immunological and dermatological diseases.

Chair

Professor Anthony G Wilson[53] MB BCH BAO DCH PhD FRCP
Professor of Rheumatology, Medical School, University of Sheffield

Members

Dr Ian Barrison BSc MB FRCP FEBGH
President European Board of Gastroenterology and Hepatology; Associate Dean, Postgraduate Medicine, School of Life and Medical Sciences, University of Hertfordshire

Professor Deborah Bax[54] MB ChB MD FRCP (London & Edinburgh)
Consultant Physician in Rheumatology, Hallamshire Hospital, Sheffield; Honorary Professor in Rheumatology, University of Sheffield

Mr David Chandler[55]
Lay Representative. Chief Executive, Psoriasis and Psoriatic Arthritis Alliance, Hertfordshire

Professor David Gawkrodger[56] DSc MD FRCP FRCPE
Professor Emeritus in Dermatology, University of Sheffield
Emeritus Consultant Dermatologist, Sheffield Teaching Hospitals NHS Foundation Trust **(Vice Chair)**

Dr Clive Grattan[57] BA MA MB BChir FRCP MD ILT
Consultant Dermatologist, Norfolk and Norwich University NHS Trust

Dr Richard Groves[58] MB BS MRCP FRCP
Consultant Dermatologist, St John's Institute of Dermatology, Guy's and St Thomas Hospital

Professor John D Isaacs[59] BSc (Hon) MB BS PhD FRCP
Director of the Institute of Cellular Medicine & Professor of Clinical Rheumatology, Medical School, Newcastle University

[53] Re-appointed 14 October 2014 – 13 October 2018
[54] End of appointment 13 October 2014
[55] Re-appointed 17 October 2014 – 16 October 2017
[56] End of appointment 13 October 2014
[57] End of appointment 13 October 2014
[58] Re-appointed 14 October 2014 – 13 October 2017
[59] End of appointment 13 October 2014

Dr John C Mansfield[60] MA MBBS MD FRCP
Consultant Physician and Senior Lecturer in Gastroenterology, Royal Victoria Infirmary and Newcastle University

Professor Kevin Moore[61] BSc MB BS PhD FRCP
Professor of Hepatology, Royal Free Hospital, London

Dr Frances Williams BSc MBBS MRCP PhD CCST FRCP (Edin)
Reader in Genetic Epidemiology and Hon Consultant Rheumatologist, King's College London

Professor Patricia Mang Ming Woo[62] CBE FRCP FRCPCH FMedSci
Professor of Paediatric Rheumatology and Honorary Consultant, UCL

[60] End of appointment 13 October 2014
[61] Re-appointed 14 October 2014 – 13 October 2016
[62] End of appointment 13 October 2014

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 Ailsa Gebbie MB ChB FRCOG FRCPE FFSRH
Consultant Gynaecologist and Deputy Director, Chalmers Centre, Edinburgh

Members

Professor Juliet Compston OBE MD FRCP FRCPath FMedSci
Professor of Bone Medicine & Honorary Consultant Physician, School of Clinical Medicine, Cambridge University

Dr Katherine Darton[63] BA BSc PhD LGSM
Lay member

Dr E Jane Dickson[64] MB BChir FSRH
Consultant in Sexual and Reproductive Healthcare Contraception, Sexual Health and Community Gynaecology, Oxleas NHS Foundation Trust

Professor Philip Hannaford MB ChB DRCOG DCH MD FRCGP FFSRH FFPH
Professor of Epidemiology, University of Aberdeen

Dr Sally Hope FRCP FRCGP DRCOG
Honorary Research Fellow in Woman's Health, Department of Primary Health Care, University of Oxford and Clinical Assistant in Osteoporosis at the Nuffield Orthopaedic Hospital, Oxford

Professor Mary Lumsden BSc MB BS MD FRCOG **(Vice Chair)**
Professor of Medical Education & Gynaecology, University of Glasgow

Professor Julietta Patnick[65] CBE
Director, NHS Cancer Screening Programmes, Sheffield & Directorate of Health and Wellbeing, Public Health England

Professor Siobhan Quenby MBBS BSc MD FRCOG
Professor of Obstetrics, Warwick University

Mrs Margaret V Shotter BSc MSc
Lay Member

[63] End of appointment 13 January 2014
[64] Appointed 17 April 2014 – 16 April 2018
[65] Resigned 17 February 2014

Professor Jonathan H Tobias[66] BA (Cantab) MBBS PhD (London) FRCP MD (London)
Professor of Rheumatology, University of Bristol; Honorary Consultant Rheumatologist, North Bristol Trust

Commission on Human Medicines Observer:

Carolyn, Lady Roberts RGN RHV MSc DUniv
Member of The Ethox Foundation - Oxford Centre for Ethics and Communication in Healthcare Practice. Health Visitor

[66] Appointed 13 March 2014 – 12 March 2018

MEMBERSHIP OF THE NEUROLOGY, PAIN & PSYCHIATRY EXPERT ADVISORY GROUP

Remit

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

Chair

Professor David G C Owens MD (Hons) FRCP FRCPsych
Professor of Clinical Psychiatry, Edinburgh University

Members

Dr Jonathan Cavanagh[67] MB ChB MPhil MD FRCPsych
Senior Lecturer in Psychiatry, Glasgow University and Honorary Consultant Psychiatrist, NHS Greater Glasgow and Clyde

Dr Beverley Jane Collett[68] 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, Department of Clinical and Experimental Epilepsy, UCL Institute of Neurology; Clinical Director, Queen Square Division, UCLH NHS Foundation Trust

Dr Nicholas Fletcher[69] BSc MBBS MD FRCP
Consultant Neurologist, Walton Centre for Neurology & Neurosurgery, Liverpool

Mr Michael J Harnor MSc MEd
Retired University Academic; Current Trustee/Director of Neurological Charities

Dr Anthony L Johnson BSc PhD CStat
Honorary Senior Research Associate, MRC Clinical Trials Unit at UCL, London

Professor Malcolm R Macleod BSc MBChB MRCP PhD FRCP (Edin)
Professor of Neurology and Translational Neurosciences, University of Edinburgh and Honorary Consultant Neurologist, NHS Forth Valley

Professor John T O'Brien BA MA BMBCh DM FRCPsych
Professor of Old Age Psychiatry, University of Cambridge

Professor Martin Rossor[70] BChir MA MB MD FRCP FMedSci
Professor of Neurology, Institute of Neurology, London

Professor Peter A G Sandercock MA DM FRCPE FMedSci
Professor of Medical Neurology and Honorary Consultant Neurologist, University of Edinburgh

[67] End of appointment 13 October 2014
[68] Resigned 15 October 2014
[69] Resigned 20 October 2014
[70] Re-appointed 14 January 2014 – 13 January 2016; Resigned 23 January 2014

Dr Catherine F Stannard[71] MB ChB FRCA FFPMRCA
Pain Clinic Macmillan Centre, Frenchay Hospital, Bristol

Professor Eric A Taylor MA MB FRCP FRCPsych (Hon) FMedSci
Emeritus Professor of Child & Adolescent Psychiatry, King's College London Institute of Psychiatry

Dr Christopher Weir[72] BSc (Hons) PhD MSc FRSS C.Stat C.Sci
Reader in Medical Statistics, Centre for Population Health Sciences, University of Edinburgh

Dr John B Winer[73] MB BS MRCP MSc (Immuno) MD FRCP
Consultant Neurologist, Queen Elizabeth Hospital, Birmingham

[71] Re-appointed 09 December 2014 – 08 December 2016
[72] Re-appointed 09 December 2014 – 08 December 2016
[73] Re-appointed 13 March 2014 – 12 March 2016

MEMBERSHIP OF THE ONCOLOGY AND HAEMATOLOGY EXPERT ADVISORY GROUP

Remit

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

Chair

(Acting) Dr Angela E Thomas[74] MB BS PhD FRCPE FRCPath FRCPCH
Consultant Paediatric Haematologist, Royal Hospital for Sick Children, Edinburgh

Professor Martin Gore[75] MBBS PhD FRCP
Medical Director and Consultant Medical Oncologist, The Royal Marsden NHS Foundation Trust and Professor of Cancer Medicine, Institute of Cancer Research

Members

Mrs Eileen J Barrett[76] BSc PGCE CPE LPC
Lay Member. HR and Legal Director, Source BioScience, Nottingham

Professor Mark D Bower MA MB BChir PhD FRCP FRCPath
Consultant Medical Oncologist, Chelsea & Westminster Hospital, London

Professor Stephen Devereux[77] PhD FRCP FRCPath
Consultant Haematologist, Kings College Hospital

Dr Chris Gallagher BSc PhD FRCP
Consultant Medical Oncologist, St Bartholomew's Hospital, Barts and the London NHS Trust

Professor Charlie Gourley BSc (Hons) MB ChB PhD MRCP FRCP
Professor and Honorary Consultant in Medical Oncology, University of Edinburgh Cancer Research Centre

Professor John Gribben[78] BSc (Hons) MBChB MD FRCPath DSc FRCP FMedSci
Professor of Medical Oncology, Director of Experimental Cancer, Medicine Centre Barts and the London Cancer Centre

Professor Barry Hancock[79] OBE MBChB DCH MD FRCP FRCR
Emeritus Professor of Oncology, University of Sheffield

[74] Stepped down as Chair 31 August 2014
[75] Appointed as Chair 01 September 2014 – 31 March 2018
[76] Re-appointed 18 June 2014 – 17 June 2016
[77] Re-appointed 18 July 2014 – 17 July 2017
[78] Resigned 01 February 2014
[79] End of appointment 17 June 2014

Professor Peter Hillmen[80] MB ChB PhD FRCPath
Consultant Haematologist, St James's University Hospital, Leeds

Dr Angela E Thomas[81] MB BS PhD FRCPE FRCPath FRCPCH **(Vice Chair)**
Consultant Paediatric Haematologist, Royal Hospital for Sick Children, Edinburgh

Invited Expert

Professor A Hilary Calvert MB BChir MSc MD FRCP FMedSci
Director of Cancer Drug Discovery and Development, UCL Cancer Institute

[80] End of appointment 10 November 2014
[81] Continued as Vice-Chair 01 September 2014 – 31 December 2015

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

Dr Rebecca Mann[82] BMBS FRCPCH
Consultant Paediatrician, Taunton and Somerset NHS Foundation Trust

Members

Dr Eileen M Baildam MB ChB DRCOG DCH RCP FRCP FRCPCH
Consultant Paediatric Rheumatologist and Honorary Senior Lecturer, Alder Hey Foundation NHS Trust and University of Liverpool

Dr Helen Burdett[83] MB ChB MRCP FRCA
Consultant Anaesthetist, Tunbridge Wells Hospital

Dr Steven Cunningham MBChB PhD FRCPCH FRCP **(Vice Chair)**
Consultant and Honorary Reader in Paediatric Respiratory Medicine, Royal Hospital for Sick Children, Edinburgh

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

Dr Meriel Jenney[84] MBChB MRCP MD FRCPCH
Consultant Paediatric Oncologist/Assistant Medical Director (Cancer Services), Children's Hospital for Wales

Professor Nigel Klein BSc MBBS MRCP PhD FRCPCH
Consultant, Great Ormond Street Hospital for Children NHS Trust; Professor of Infectious Diseases and Microbiology, Institute of Child Health, UCL

Ms Fiona Lynch BSc (Hons) MSc RCN
Paediatric Intensive Care Unit Nurse Consultant, Evelina Children's Hospital

Dr Rubin Minhas[85] MB ChB MBA
GP Principle

Professor Marie-Louise Newell MB MSc PhD FMedSci
Professor of Global Health, Academic Unit of Human Development and Health, Faculty of Medicine, University of Southampton

[82] Acting Chair from 01 January 2014 – 31 March 2014, then appointed as Chair 01 April 2014 – 31 March 2018
[83] Appointed 18 September 2014 – 17 September 2018
[84] Appointed 16 January 2014 – 15 January 2018
[85] Appointed 18 July 2014 – 17 July 2016

Professor Anthony Nunn[86] BPharm FRPharmS Hon FRCPCH
Honorary Fellow, Department of Women's and Children's Health, University of Liverpool; Industry Professor, School of Pharmacy and Biomedical Sciences, Liverpool John Moores University, Alder Hey Children's Hospital, Liverpool

Ms Sara Payne BA CPE LPC
Lay Representative. Solicitor

Professor Shirley Price[87] MSc PhD FBTS ERT FHEA FSB
Head of Academic Appeals and Academic Quality and Professor of Toxicology, University of Surrey

Dr Jane Tizard[88] MBBS FRCP FRCPCH
Consultant Paediatric Nephrologist, Bristol Royal Hospital for Children

Dr Beverly Tsai-Goodman[89] MD FRCP PG Cert Med Ed
Consultant Paediatric and Fetal Cardiologist, Bristol Children's Hospital and Deputy Dean for South Bristol Academy, University of Bristol Medical School

Dr Catherine L C Tuleu[90] PhD Cert Ed MRPharmS
Reader in the Department of Pharmaceutics, Director of the Centre for Paediatric Pharmacy Research, UCL School of Pharmacy

Professor Heather M Wallace[91] PhD FRCPath FRSC FSB FBPharmacolS FBTS European Registered Toxicologist
Professor of Biochemical Pharmacology and Toxicology, Division of Applied Medicine, University of Aberdeen

Mrs Madeleine Wang[92] BA (Hons)
Lay Representative. Patient Advocate

Dr Mark Whiting BNursing MSc PhD
Consultant Nurse, Children's Community and Specialist Nursing, Peace Children's Centre, Hertfordshire Community NHS Trust

Dr Morris Zwi[93] MB BCh FRCPsych
Consultant Child & Adolescent Psychiatrist, Richmond Royal Hospital

[86] Re-appointed 12 November 2014 – 11 November 2017
[87] End of appointment 11 November 2014
[88] Re-appointed 12 November 2014 – 11 November 2016
[89] Appointed 17 July 2014 – 16 July 2018
[90] Re-appointed 14 January 2014 – 13 January 2018
[91] Re-appointed 12 November 2014 – 11 November 2018
[92] Re-appointed 12 November 2014 – 11 November 2016
[93] Re-appointed 12 November 2014 – 11 November 2018

MEMBERSHIP OF THE PATIENT AND PUBLIC ENGAGEMENT EXPERT ADVISORY GROUP

Remit

To advise the Commission on:

- The development of effective communications for patients, the public and carers to help them make informed choices about medicines and to use medicines safely.
- How to improve communication between patients and health professionals and between the MHRA and the public on the safe use of medicines.
- Ways to promote the availability and accessibility of high quality information about individual medicines available in the UK.
- Ways to encourage reporting of adverse drug reactions (ADRs) by patients and the public. Recognising the importance of the patient experience, to advise on building links between patient concerns as experienced in direct ADR reports and the information provided to patients.
- Facilitating targeted patient involvement on relevant regulatory issues, where patient/public involvement has not otherwise been achieved by working with specific patient organisations.
- Providing a patient perspective on strategic issues such as the upcoming European legislation on Patient Information.

Chair

Mr Harry Cayton CBE
Lay Member. Chief Executive, Professional Standards Authority for Health and Social Care, London

Members

Ms Hellen Adom BA MA
Lay Member. Outreach Assistant, NHS Sickle Cell & Thalassaemia Screening Programme, London

Mr David Chandler
Lay Member. Chief Executive, Psoriasis and Psoriatic Arthritis Alliance, Hertfordshire

Mr John Chapman LL.B (Lon)
Lay Member. Patient/Carer Member

Mrs Joyce Epstein
Lay Member. Former Director of the Foundation for the Study of Infant Deaths (FSID)

Dr Nicola Jane Gray PhD MRPharmS FHEA FSAHM (US)
Lay Member. Independent Pharmacist Researcher, Manchester

Mrs Farrah Pradhan
Lay Member. Invited Reviews Coordinator at the Royal College of Obstetricians and Gynaecologists

Mrs June Rogers MBE RN RSCN BA (Hons) MSc
Lay Member. PromoCon Paediatric Advisor, Disabled Living

Dr Bella Starling PhD BSc Hons Dip
Lay Member. Director of Public Programmes, Nowgen, a Centre for Genetics in Healthcare

Mr Paddy Storrie MA (Oxon) NPQH
Lay Member. Deputy Headmaster, St. George's School, Hertfordshire and Lay Member, N.I.C.E Technology Appraisals Committee

Mr Phil Willan MSc **(Vice-Chair)**
Lay Member. Member of MHRA Pharmacovigilance EAG, Cardiovascular, Diabetes, Renal, Respiratory and Allergy EAG, Patient and Public Engagement EAG, Lay Members Forum; Member of the Royal College of Physicians' (RCP) Patient and Carer Network; Member of the RCP Joint Speciality Committee (JSC) for Renal Medicine, Healthcare Associated Infections Working Group, Specialist Advisory Committee for Renal Medicine, JSC for Allergy and Immunology, Faculty of Forensic and Legal Medicine, Federation CPD Policy Committee, Equality and Diversity Monitoring Committee and Patient Safety Committee. Member of the NHS England Clinical Reference Group for Renal Transplantation

External Experts

Professor D K Theo Raynor BPharm (Hons) PhD MRPharmS
Professor of Pharmacy Practice, University of Leeds

Mrs Anne Joshua BPharm (Hons) MSc Pharm Dip MRPharmS
NHS 111 Pharmacy Lead, NHS England

Professor Angus Mackay OBE MA PhD (Cantab) MB ChB BSc (Pharmacol) FRCP (Edin) FRCPsych TPsych
Professor of Psychological Medicine, University of Glasgow

Invited Observers

Mrs Alison Bowser
Lay Representative. Patient and Public Involvement Officer, Research Design Service, Southampton University & National Institute for Health Research

Ms Amanda Hoey
Lay Representative. Director, ConsumerHealth Consulting Ltd. Independent Health Policy and Strategy Consultant

Carolyn, Lady Roberts RGN RHV MSc DUniv
Member of The Ethox Foundation - Oxford Centre for Ethics and Communication in Healthcare Practice. Health Visitor

MEMBERSHIP OF THE PHARMACOVIGILANCE EXPERT ADVISORY GROUP

Remit

To advise the Commission 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[94] MB ChB (Hons) PhD FRCP FRCP (Edin) FMedSci
Professor of Clinical Pharmacology, University of Liverpool, NHS Chair of Pharmacogenetics and Director of the Wolfson Centre for Personalised Medicine

Members

Dr Robert C G Bracchi BSc MB BCh MD FRCGP
General Practitioner and Honorary Senior Lecturer, Cardiff University

Dr Jamie Coleman ChB MA (Med Ed) FRCP FB Pharmacol.S
Senior Lecturer in Clinical Pharmacology, University of Hospitals Birmingham NHS Foundation Trust & Queen Elizabeth Hospital Birmingham

Dr William Dixon MRCP PhD
MRC Clinician Scientist and Honorary Consultant Rheumatologist, The University of Manchester

Dr Ian J Douglas BSc MSc PhD
Senior Lecturer in Pharmacoepidemiology, London School of Hygiene & Tropical Medicine

Professor Alison B Ewing BSc MSc MIPharmM FFRRPS FRPharmS
Clinical Director of Pharmacy, Royal Liverpool and Broadgreen University Hospital NHS Trust; Professor of Pharmacy Innovation, Liverpool John Moores University

Ms Amanda Lee RGN RM RNP MSc (NURS) BSc (Hons) Dip HEd PG Cert ANNP
PhD Student & Academic Lecturer Health Professional Studies, University of Hull

[94] Re-appointed 01 January 2014 – 31 December 2015

Professor Glyn Lewis BA MSc MB BS MRCPsych PhD
Professor of Psychiatric Epidemiology, University College London

Professor Simon R J Maxwell MD PhD FRCP FRCPE FBPharmacolS FHEA
Professor of Student Learning/Clinical Pharmacology, Western General Hospital, Edinburgh & University of Edinburgh

Dr Karen Miller BSc MBBS DRCOG DCH DFFP FRCGP
GP Partner, Adelaide Medical Centre, London

Dr Nicholas J Plant BSc PhD
Reader in Molecular Toxicology, University of Surrey

Professor Alan Silman MRCP MSc MFCM MD FFPHM FRCP FMedSci
Former Medical Director of the Arthritis Research Campaign

Dr Ruben Thanacoody MD FRCP FRCP (Edin)
Consultant Physician, Royal Victoria Infirmary; Honorary Clinical Senior Lecturer, Institute of Cellular Medicine, Newcastle University

Dr Caroline Vaughan PhD
Lay Representative of MHRA EAGS. Trustee and Director of Contact a Family and FamilyLine

Professor Patrick Waller[95] BMedSci MD MPH FRCP Ed. FFPM FB Pharmacol.S
Honorary Professor, Faculty of Epidemiology and Public Health, London School of Hygiene & Tropical Medicine

Mr Phil Willan MSc
Lay Representative. Member of MHRA Pharmacovigilance EAG, Cardiovascular, Diabetes, Renal, Respiratory and Allergy EAG, Patient and Public Engagement EAG, Lay Members Forum; Member of the Royal College of Physicians' (RCP) Patient and Carer Network; Member of the RCP Joint Speciality Committee (JSC) for Renal Medicine, Healthcare Associated Infections Working Group, Specialist Advisory Committee for Renal Medicine, JSC for Allergy and Immunology, Faculty of Forensic and Legal Medicine, Federation CPD Policy Committee, Equality and Diversity Monitoring Committee and Patient Safety Committee. Member of the NHS England Clinical Reference Group for Renal Transplantation

[95] Resigned 31 December 2014

THE COMMISSION'S WORKING GROUPS:

MEMBERSHIP OF THE ALTEPLASE WORKING GROUP

Chair

Professor Ian V D Weller BSc MB BS MD FRCP (Hon) FRCP (Glas)
Emeritus Professor of Sexually Transmitted Diseases, University College London Medical School

Members

Professor Deborah Ashby OBE BSc MSc PhD CStat Hon. MFPHM Hon. MRCR FMedSci
Professor of Medical Statistics and Clinical Trials Co-Director of Imperial Clinical Trials Unit, School of Public Health, Imperial College London

Professor Colin Baigent FRCP FFPH
Deputy Director, Clinical Trial Service Unit & Epidemiological Studies Unit, University of Oxford

Dr Dennis Briley FRCP
Consultant Neurologist, Stoke Mandeville Hospital and Oxford University Hospitals NHS Trust

Dr Jeremy Dwight MD FRCP
Consultant Cardiologist, Oxford University Hospitals NHS Trust

Professor Stephen Evans BA MSc CStat FRCP (Edin) FISPE Hon. FRCP (Lon)
Professor of Pharmacoepidemiology, London School of Hygiene and Tropical Medicine

Dr Jeff Keep MBBS FRCS (Eng) FCEM
Consultant in Emergency Medicine and Major Trauma, King's College Hospital NHS Foundation Trust, London

Professor Peter Langhorne BSc MB ChB PhD FRCP (Glas)
Professor of Stroke Care, Glasgow University and Honorary Consultant Physician, NHS Greater Glasgow and Clyde

Dr Clifford Mann FRCP FCEM
President of the College of Emergency Medicine and Consultant in Emergency Medicine, Taunton and Somerset NHS Foundation Trust

Professor Keith Muir MB ChB MSc MD FRCP
SINAPSE Professor of Clinical Imaging & Consultant Neurologist, Institute of Neuroscience & Psychology, University of Glasgow, Southern General Hospital Glasgow

Dr Martin Punter MB ChB MRCP PhD CCT
Consultant Neurologist, Greater Manchester Neurosciences Centre, Salford Royal NHS Foundation Trust; Honorary Lecturer, The University of Manchester

Dr Liam Smeeth MB ChB FRCGP FFPH FRCP MSc PhD
Head of the Department of Non-Communicable Disease Epidemiology and Professor of Clinical Epidemiology, London School of Hygiene and Tropical Medicine

Dr David Werring FRCP PhD
Reader in Clinical Neurology, University College London and Consultant Neurologist, National Hospital for Neurology and Neurosurgery, Queen Square

Mr Phil Willan MSc
Lay Representative. Member of MHRA Pharmacovigilance EAG, Cardiovascular, Diabetes, Renal, Respiratory and Allergy EAG, Patient and Public Engagement EAG, Lay Members Forum; Member of the Royal College of Physicians' (RCP) Patient and Carer Network; Member of the RCP Joint Speciality Committee (JSC) for Renal Medicine, Healthcare Associated Infections Working Group, Specialist Advisory Committee for Renal Medicine, JSC for Allergy and Immunology, Faculty of Forensic and Legal Medicine, Federation CPD Policy Committee, Equality and Diversity Monitoring Committee and Patient Safety Committee. Member of the NHS England Clinical Reference Group for Renal Transplantation

Dr Peter Wilmshurst
Consultant Cardiologist, University Hospital of North Midlands

Dr H Bart van der Worp MD PhD
Neurologist, University Medical Centre, Utrecht

Invited External Experts:

Dr David Collas BSc MB BS FRCP
Consultant Stroke Physician, West Hertfordshire Hospitals NHS Trust

Mr Joe Korner
Director of External Affairs, Stroke Association

Professor Mike Laffan
Professor of Haemostasis & Thrombosis, Imperial College London and Director of Hammersmith Hospital Haemophilia Centre

Visiting External Experts:

Professor Jonathan Emberson PhD
Associate Professor, Clinical Trial Service Unit and Epidemiological Studies Unit, University of Oxford

Professor Gary A Ford CBE FMedSci
Chief Executive Officer, Oxford Academic Health Science Network, Consultant Physician, Oxford University Hospitals NHS Trust, Visiting Professor of Clinical Pharmacology, University of Oxford

Dr Roger Shinton MD FRCP
Retired Consultant Physician, Birmingham Heartlands Hospital

MEMBERSHIP OF THE ISOTRETINOIN WORKING GROUP

Chair

Professor Munir Pirmohamed MB ChB (Hons) PhD FRCP FRCP (Edin) FMedSci
Professor of Clinical Pharmacology, University of Liverpool, NHS Chair of Pharmacogenetics and Director of the Wolfson Centre for Personalised Medicine

Members

Dr Anthony Bewley BA (Hons) FRCP
Consultant Dermatologist, Barts and the London NHS Trust, Whipps Cross University Hospital NHS Trust, London

Mrs Alison Bowser
Lay Representative. Patient and Public Involvement Officer, Research Design Service, Southampton University & National Institute for Health Research

Dr David Coghill MB ChB MD FRCPsych
Reader in Child and Adolescent Psychiatry, University of Dundee

Dr Katherine Darton BA BSc PhD LGSM
Lay Member

Professor I Nicol Ferrier BSc MB ChB MD FRCP FRCPsych
Professor of Psychiatry and Honorary Consultant Psychiatrist, University of Newcastle

Professor David Gawkrodger DSc MD FRCP FRCPE
Professor Emeritus in Dermatology, University of Sheffield; Emeritus Consultant Dermatologist, Sheffield Teaching Hospitals NHS Foundation Trust

Professor Ian Goodyer MA MD FRCPCH FRCPsych FMedSci FRCP PhD
Professor of Child & Adolescent Psychiatry, University of Cambridge

Dr Clive Grattan BA MA MB BChir FRCP MD ILT
Consultant Dermatologist, Norfolk and Norwich University NHS Trust

Professor David Gunnell MB ChB MRCGP PhD MSc FFPHM
Professor of Epidemiology, University of Bristol

Dr Stephen Kownacki
Executive Chairman, Primary Care Dermatology Society (PCDS)

Dr Alison Layton MB ChB FRCP
Consultant Dermatologist, Harrogate and District NHS Foundation Trust

Professor David G C Owens MD (Hons) FRCP FRCPsych
Professor of Clinical Psychiatry, Edinburgh University

Dr Anshoo Sahota BSc (Hons) MBBS FRCP
Consultant Dermatologist, Whipps Cross University Hospital and the Royal London Hospital; Honorary Secretary, British Association of Dermatologists

MEMBERSHIP OF THE NATIONAL EMERGENCY STOCKPILE QUALITY PANEL

Chair

Professor Stuart Ralston MB ChB MD FRCP FMedSci FRSE
Arthritis Research UK Professor of Rheumatology, University of Edinburgh, Western General Hospital, Edinburgh

Members

Dr Barbara A Bannister MBE MSc FRCP **(Vice Chair)**
Consultant in Infectious and Tropical Diseases, Royal Free Hospital, London

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

Professor Janet H Darbyshire CBE MB ChB FMedSci FRCP FFPH FRSS (Hon)
Emeritus Professor of Epidemiology, University College London

Professor B Kevin Park BSc PhD FMedSci FRCP (Hon) FBTS
Director of MRC Centre for Drug Safety Science, Professor of Pharmacology & Head of Institute of Translational Medicine, University of Liverpool

Professor Munir Pirmohamed MB ChB (Hons) PhD FRCP FRCP (Edin) FMedSci
Professor of Clinical Pharmacology, University of Liverpool, NHS Chair of Pharmacogenetics and Director of the Wolfson Centre for Personalised Medicine

Dr Angela E Thomas MB BS PhD FRCP FRCPath FRCPCH
Consultant Paediatric Haematologist, Royal Hospital for Sick Children, Edinburgh

MEMBERSHIP OF THE NICOTINE CONTAINING PRODUCTS WORKING GROUP

Chair

Professor Ian V D Weller BSc MB BS MD FRCP (Hon) FRCP (Glas)
Emeritus Professor of Sexually Transmitted Diseases, University College London Medical School

Members

Ms Deborah Arnott MBA FRCP (Hon)
Chief Executive, Action on Smoking & Health

Professor Deborah Ashby OBE BSc MSc PhD CStat Hon. MFPHM Hon. MRCR FMedSci
Professor of Medical Statistics and Clinical Trials Co-Director of Imperial Clinical Trials Unit, School of Public Health, Imperial College London

Professor Paul Aveyard PhD MRCP MRCGP FFPH
Professor of Behavioural Medicine, University of Oxford

Professor John R Britton MB BS MD FRCP FFPHM
Professor of Epidemiology and Director, UK Centre for Tobacco Control Studies, Head of Division of Epidemiology and Public Health, University of Nottingham

Professor Brian J Clark MSc PhD CChem FRSC
Professor of Pharmaceutical and Biomedical Analysis, Bradford University

Professor Henry Dargie MB ChB FRCP FESC FRSE
Consultant Cardiologist, University of Glasgow

Professor Peter J Helms MB BS PhD FRCP FRCPE FRCPCH
Emeritus Professor of Child Health, University of Aberdeen

Ms Amanda Hoey
Lay Member. Director, ConsumerHealth Consulting Ltd. Independent Health Policy and Strategy Consultant

Professor Martin Jarvis
Emeritus Professor of Health Psychology, Department of Epidemiology & Public Health, University College London

Dr Mike Knapton MA (cantab) MBBChir FRCGP
Associate Medical Director (Prevention, Survival and Support), British Heart Foundation

Dr Rebecca Mann BMBS FRCPCH
Consultant Paediatrician, Taunton and Somerset NHS Foundation Trust

Professor Christopher Marriott PhD DSc Hon DSc FRPharmS CChem FRSC FRSM
Emeritus Professor of Pharmaceutics, King's College, London

Professor Marcus Munafò MA (Oxon) MSc PhD (Soton)
Professor of Biological Psychology, University of Bristol

Dr Nicholas J Plant BSc PhD
Reader in Molecular Toxicology, University of Surrey

Dr Rosalind Ranson MB BS MA MRCGP
General Practitioner, Woodside Health Centre, London

Carolyn, Lady Roberts RGN RHV MSc DUniv
Member of The Ethox Foundation - Oxford Centre for Ethics and Communication in Healthcare Practice. Health Visitor

Professor Liam Smeeth MBChB FRCGP FFPH FRCP MSc PhD
Head of the Department of Non-Communicable Disease Epidemiology and Professor of Clinical Epidemiology, London School of Hygiene and Tropical Medicine

Guest Presenter

Dr Jamie Brown PhD CPsychol
SSA Senior Research Fellow, University College London

Department of Health Observer

Mr Andrew Black
Tobacco & Public Health

Public Health England Observer

Ms Jo Locker
Tobacco Control Manager, Alcohol Tobacco and Drugs Division

MEMBERSHIP OF THE REVIEW OF NON-PRESCRIPTION ANALGESICS WORKING GROUP

Chair

Professor Stuart Ralston MB ChB MD FRCP FMedSci FRSE
Arthritis Research UK Professor of Rheumatology, University of Edinburgh, Western General Hospital, Edinburgh

Members

Mrs Alison Bowser
Patient and Public Involvement Officer, Research Design Service, Southampton University

Dr William Dixon MRCP PhD
MRC Clinician Scientist and Honorary Consultant Rheumatologist, The University of Manchester

Dr Ian J Douglas BSc MSc PhD
Senior Lecturer in Pharmacoepidemiology, London School of Hygiene & Tropical Medicine

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

Dr Gillian M Hawksworth MBE PhD FRPharmS (Hon) DSc FCPP (Hon)
Academic Community Pharmacist, Visiting Professor of Pharmacy at Huddersfield University & Past President of the RPSGB

Dr Karen Miller BSc MBBS DRCOG DCH DFFP MRCGP
GP Partner, Adelaide Medical Centre, London

Professor Munir Pirmohamed MB ChB (Hons) PhD FRCP FRCP(E)
Professor of Clinical Pharmacology, University of Liverpool, NHS Chair of Pharmacogenetics and Director of the Wolfson Centre for Personalised Medicine

Carolyn, Lady Roberts RGN RHV MSc
Member of The Ethox Foundation-Oxford Centre for Ethics and Communication in Healthcare Practice. Health visitor

Professor Kevin M G Taylor BPharm PhD MRPharmS
Chair of the British Pharmacopoeia Commission and Professor of Clinical Pharmaceutics, UCL School of Pharmacy, London

Invited External Experts:

Professor Colin Baigent FFPH FRCP
Professor of Epidemiology and Honorary Consultant in Cardiovascular Epidemiology

Dr Rebecca Mann BM BS FRCPCH
Consultant Paediatrician, Taunton and Somerset NHS Foundation Trust

Invited Observers:

Ms Gul Root
Department of Health

Professor Neal Maskrey
National Institute for Health and Care Excellence

Mr Jonathan Underhill
National Institute for Health and Care Excellence

MEMBERSHIP OF THE SODIUM VALPROATE WORKING GROUP

Chair

Professor Munir Pirmohamed MB ChB (Hons) PhD FRCP FRCP (Edin) FMedSci
Professor of Clinical Pharmacology, University of Liverpool, NHS Chair of Pharmacogenetics and Director of the Wolfson Centre for Personalised Medicine

Members

Mrs Alison Bowser
Lay Representative. Patient and Public Involvement Officer, Research Design Service, Southampton University & National Institute for Health Research

Professor David Coghill MB ChB MD FRCPsych
Reader in Child and Adolescent Psychiatry

Ms Nicole Crosby-McKenna
Senior Policy and Campaigns Officer, Epilepsy Action

Mr Sultan (Sid) Dajani MRPharmS Dip.CommPharm Independent Prescriber BPharm ACPP
Community Pharmacist and owner of Wainwrights Chemist, Bishopstoke, Hampshire

Dr Katherine Darton BA BSc PhD LGSM
Lay Member

Dr Brendan Davies
Consultant Neurologist & Clinical Lead, North Midlands Regional Headache Clinical University Hospital of North Staffordshire

Dr Christopher Derry MD FRCP
Consultant Neurologist, Western General Hospital, Edinburgh

Professor Helen Dolk DrPH
Professor of Epidemiology & Health Services Research, University of Ulster

Professor Guy Goodwin FMedSci
W.A. Handley Professor of Psychiatry, University Department of Psychiatry, University of Oxford

Mr Michael Harnor MSc MEd
Retired University Academic; Current Trustee/Director of Neurological Charities

Dr Richard Hamish McAllister-Williams BSc MB ChB PhD MRCPsych MD FRCPsych
Reader in Clinical Psychopharmacology, University of Newcastle

Dr Karen Miller BSc MBBS DRCOG DCH DFFP FRCGP
GP Partner, Adelaide Medical Centre, London

Carolyn, Lady Roberts RGN RHV MSc DUniv
Member of The Ethox Foundation - Oxford Centre for Ethics and Communication in Healthcare Practice. Health Visitor

Dr Paramala J Santosh MBBS Dip NB (Psych) MD PhD FRCPsych
Visiting Reader, Developmental Neuropsychiatry & Psychopharmacology and Head and Consultant Child & Adolescent Psychiatrist, Kings College London

Dr Judy Shakespeare GP RCGP
Clinical Champion in Perinatal Mental Health, representing the RCGP

Professor Eric Taylor MA MB FRCP FRCPsych (Hon) FMedSci
Emeritus Professor of Child & Adolescent Psychiatry, King's College London Institute of Psychiatry

Dr Trudy Thomas
Clinical Lecturer, Medway School of Pharmacy

Professor Patrick Waller BMedSci MD MPH FRCP Ed. FFPM FB Pharmacol.S
Honorary Professor, Faculty of Epidemiology and Public Health, London School of Hygiene & Tropical Medicine

Dr John Winer MB BS MRCP MSc (Immuno) MD FRCP
Consultant Neurologist, Queen Elizabeth Hospital, Birmingham

Dr Laura Yates MBChB DRCOG MRCPCH PhD
Consultant in clinical Genetics, Institute of Genetic Medicine, International Centre for Life, Newcastle-upon-Tyne

Invited Observers:

Dr Rebeca Bromley ClinPsyD PhD
NIHR Research Fellow, Genetic Medicine, Institute of Human Development, St Mary's Hospital

MEMBERSHIP OF THE EXTERNAL EXPERT ADVISORY PANEL

Anaesthesia

Dr Andrew Bowhay MBBS FRCA MA
Consultant Paediatric Anaesthesia, Liverpool University

Dr Thomas Clutton-Brock FRCP FRCA FFICM
Senior Lecturer, Anaesthesia & Intensive Care Medicine, Queen Elizabeth Hospital

Dr Patricia Richardson[96] BM MRCP FRCA
Consultant in Burns Anaesthesia and Intensive Care, Broomfield Hospital, Chelmsford, Essex

Dr Jonathan Ross[97] MBChB FRCA FFICM
Consultant Cardiothoracic Anaesthetist, Sheffield Teaching Hospitals NHS Foundation Trust and Honorary Clinical Senior Lecturer, Anaesthesia, University of Sheffield

Dr Lindsey 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

Dermatology

Dr Clive Grattan BA MA MB BChir FRCP MD ILT
Consultant Dermatologist, Norfolk and Norwich University NHS Trust

Diabetology/Endocrinology

Professor D John Betteridge BSc PhD MD FRCP FAHA
Professor of Endocrinology and Metabolism, University College London, London

Professor Peter Clayton MD MRCP FRCPCH
Professor of Child Health & Paediatric Endocrinology and Director, Institute of Human Development, University of Manchester; Honorary Consultant, Royal Manchester Children's Hospital

Professor Paul Stewart MB ChB MD FRCP FMedSci
Dean & Professor of Medicine, University of Leeds

[96] Stepped down from Panel 08 December 2014
[97] Stepped down from Panel 31 December 2014

Gastroenterology

Dr Harriet Mitchison[98] MBBS MA MD FRCP
Consultant Gastroenterologist, District General Hospital, Sunderland

Geriatric Medicine

Professor Peter Crome MD PhD DSc FRCP FFPM FBPharmacolS
Professor Emeritus, Keele University; Honorary Professor, University College London

Gynaecology/Family Planning/Well Woman/Obstetrics

Professor Alistair R W Williams MD FRCPath
Professor of Gynaecological Pathology, University of Edinburgh

Haematology

Professor Gordon Cook MB ChB PhD FRCP (Glas) FRCPath FRCPI
Consultant Haematologist and Myeloma Lead, St James's Institute of Oncology, Leeds Teaching Hospitals Trust

Liver/Lipidology

Professor Gilbert Thompson MD FRCP
Emeritus Professor of Clinical Lipidology, Division of Investigative Science, Imperial College School of Medicine, London

Medicine (general)

Professor Jayne Franklyn[99] MD PhD FRCP FMedSci
William Withering Professor of Medicine; Head, School of Clinical and Experimental Medicine; College of Medical and Dental Sciences

Professor Paul Stewart MB ChB MD FRCP FMedSci
Dean & Professor of Medicine, University of Leeds

Neurology

Professor Colin Kennedy MD FRCP FRCPCH
Professor in Neurology and Paediatrics, University of Southampton

Dr Robin Grant MBChB MD FRCP (Glas) FRCP (Edin)
Consultant NHS Neurologist and Part-Time Senior Lecturer, Centre for Neuro-Oncology, Western General Hospital, Edinburgh

Nurse

Professor Karen Luker BNurs PhD FMedSci
Head of School of Nursing, Midwifery & Social Work

[98] Stepped down from Panel 09 December 2014
[99] Stepped down from panel 21 February 2014

Oncology

Professor Hugh MacDougall[100] MBChB DMRT FRCS FRCR FRCPE
Dean of the Faculty of Medicine and Head of the School of Medicine, School of Medicine, University of St Andrews

Palliative Medicine/Pain Management

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 Bowhay MBBS FRCA MA
Consultant Paediatric Anaesthesia, Liverpool University

Professor Peter Clayton MD MRCP FRCPCH
Professor of Child Health & Paediatric Endocrinology; Director, NIHR Greater Manchester, Lancashire & South Cumbria Medicines for Children Research

Professor Nedim Hadzic MD MSc FRCPCH
Professor of Paediatric Hepatology, King's College Hospital

Dr Nigel Hoggard MBBChir MD MRCP FRCR
Consultant Neuroradiologist/Clinical Senior Lecturer, Royal Hallamshire Hospital

Professor Colin Kennedy MD FRCP FRCPCH
Professor in Neurology and Paediatrics, University of Southampton

Professor Shakeel Qureshi MB ChB FRCP
Consultant Paediatric Cardiologist, Guy's Hospital, London

Professor Alan Smyth MA MBBS MRCP MD FRCPCH
Professor of Child Health & Head of Division of Child Health, Obstetrics & Gynaecology (COG), University of Nottingham

Dr David Tuthill[101] MB BCh FRCPCH
Consultant Paediatrician, Children's Hospital for Wales, Cardiff

Dr Christopher Wren[102] MB ChB
Consultant Paediatric Cardiologist, Department of Paediatric Cardiology, Freeman Hospital

Pathologists/Histopathology/Biology/Immunobiology

Professor Alistair R W Williams MD FRCPath
Professor of Gynaecological Pathology, University of Edinburgh

Professor Sir Nicholas Wright MA MD PhD DSc FRCPath
Deputy Principal, Hammersmith Hospital London

[100] Stepped down from panel 31 August 2014
[101] Joined panel 17 November 2014
[102] Stepped down from Panel 31 December 2014

Pharmacokinetics

Professor Leon Aarons BSc (Hons) MSc PhD
Professor of Pharmacometrics, Manchester Pharmacy School, Manchester University

Professor Amin Rostami PharmD PhD FCP FAAPS FJSSX
Professor of Systems Pharmacology, Manchester Pharmacy School, University of Manchester

Dr Alison Thomson BSc MSc PhD
Senior Lecturer, Strathclyde Institute of Pharmacy & Biomedical Sciences, University of Strathclyde and Area Pharmacy Specialist, Western Infirmary Glasgow

Radiology/Nuclear Medicine

Professor Paul Griffiths MBChB PhD FRCR
Professor of Radiology & Head of Dept of Academic Unit of Radiology, University of Sheffield, Royal Hallamshire Hospital, Sheffield

Professor Jonathan Hill FRCP FRCR
Consultant in Radiology & Nuclear Medicine, Lancashire Teaching Hospitals and Hon Professor of Radionuclide Radiology University of Salford

Dr Nigel Hoggard MBBChir MD MRCP FRCR
Consultant Neuroradiologist/Clinical Senior Lecturer, Royal Hallamshire Hospital

Mr Paul Maltby[103] CSci MIPEM MRPharmS
Principal Radiopharmacist, Merseyside & Cheshire, Royal Liverpool University Hospital

Professor Michael O'Doherty[104] BA MBBS MRCP MSc MD FRCP
Consultant in Nuclear Medicine, Guy's & St Thomas Hospital, London

Dr Andrew Scarsbrook BM BS B Med Sci FRCR
Consultant Radiologist & Nuclear Medicine Physician, St James's University Hospital, Leeds

Renal Medicine/Nephrology

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

[103] Stepped down from Panel 30 November 2014
[104] Stepped down from Panel 31 December 2014

Respiratory Medicine

Professor Alan Smyth MA MBBS MRCP MD FRCPCH
Professor of Child Health & Head of Division of Child Health, Obstetrics & Gynaecology (COG), University of Nottingham

Rheumatology

Professor David Isenberg MD FRCP
Academic Director of Rheumnatology, University College London

Professor Roger Sturrock B.D. MD FRCP
Emeritus Professor of Rheumatology and Hon. Senior Research Fellow, Centre For Rheumatic Diseases

Urology

Professor Christopher Chapple BSc MD FRCS (Urol) FEBU
Consultant Urological Surgeon, Royal Hallamshire Hospital; Honorary Professor of Urology, University of Sheffield; Visiting Professor of Urology, Sheffield Hallam University; Secretary General, European Association of Urology

Professor Freddie Hamdy MB ChB LRCP-LRCS (Ed) LRCPS (Glas) FRCS (Ed) MD (Shef) FRCS (Ed) (Urol) FMed Sci
Consultant Urological Surgeon at Oxford Radcliffe Hospitals NHS Trust, Nuffield Professor of Surgery and Professor of Urology

Professor Robert Pickard MD FRCS (Urol)
Professor of Urology, Institute of Cellular Medicine, Newcastle University

MEMBERSHIP OF THE OPHTHALMIC EXTERNAL EXPERT PANEL

Members

Dr Sajjad Ahmad FRCOphth PhD
Consultant Ophthalmic Surgeon and Senior Clinical Lecturer, St Paul's Eye Unit (Royal Liverpool University Hospital)

Mr Bruce Allan MD FRCS FRCOphth
Consultant Ophthalmic Surgeon, Moorfields Eye Hospital, London

Mr Ejaz Ansari BSc (Hons) MBBCh FRCOphth MD
Consultant Ophthalmic Surgeon, Maidstone and Tunbridge Wells NHS Trust

Professor Paul N Bishop B Med Sci (Hons) BM BS DO FRCS FRCOphth PhD
Professor of Ophthalmology & Matrix Biology; Head of Centre for Ophthalmology and Vision Research, Institute of Human Development, University of Manchester; Consultant Ophthalmologist, Manchester Royal Eye Hospital, CMFT

Professor Charles Claoué MA (Cantab) MD DO FRCS FRCOphth FEBO MAE
Consultant Ophthalmic Surgeon - 119 Harley Street, London W1G 6AU; Consultant Ophthalmic Surgeon & Hospital Hero - Queen's Hospital, BHR University Hospitals NHS Trust

Professor Baljean Dhillon BMed Sci BM BS FRCP (Glas) FRCS (Edin) FRCOphth
Princess Alexandra Eye Pavillion, Edinburgh

Ms Cecilia H Fenerty MD FRCOphth
Consultant Ophthalmologist, Royal Eye Hospital, Manchester

Mr Philip G Hykin FRCS FRCOphth
Consultant Ophthalmic Surgeon, Moorfields Eye Hospital, London

Mr Teifion Emlyn James MBBS DO FRCP FRCS FBCLA FRCOphth
Consultant Ophthalmic Surgeon and Director, Regional Uveitis Service, Calderdale Royal Hospital; Managing Director, The EyeBag Company Ltd

Professor Sir Peng T Khaw PhD FRCP FRCS FRCOphth CBiol FSB FRCPath FMedSci
Professor of Glaucoma and Ocular Healing, and Consultant Ophthalmic Surgeon

Mr Anthony King MD MMedSci FRCOphth
Consultant Ophthalmologist, Department of Ophthalmology, Queens Medical Centre, Nottingham

Mr Martin McKibbin MB BS FRCOphth
Consultant Ophthalmologist, St James University Hospital, Leeds

Professor Sunil Shah MB BS FRCOphth FRCSE FBCLA
Professor of Ophthalmology & Consultant Ophthalmic Surgeon, England Foundation Trust, Birmingham and Midland Eye Centre and the Midlands Eye Institute

COMMISSION ON HUMAN MEDICINES/EXPERT ADVISORY GROUPS SECRETARIAT

Commission on Human Medicines (CHM)

Dr K Prasad
Principal Assessor, Licensing

Ms S Morgan
Principal Assessor, Pharmacovigilance

Ms S Singh
Secretary

Ms E Paik
Assistant Secretary **(until 20th April 2014)**

Ms E Agca
Assistant Secretary **(from 21st April 2014)**

Chemistry, Pharmacy and Standards Expert Advisory Group (CPSEAG)

Dr L A Anderson
Principal Assessor

Ms E Agca
Secretary

Clinical Trials, Biologicals & Vaccines Expert Advisory Group (CTBVEAG)

Dr J Bonnerjea
Principal Assessor, Licensing (Biologicals)

Dr Elaine Godfrey **(until 18th May 2014)**
Principal Assessor, Licensing (Clinical Trials)

Dr Martin O'Kane **(from 19th May 2014)**
Principal Assessor, Licensing (Clinical Trials)

Dr P Bryan
Principal Assessor, VRMM

Ms E Paik
Secretary

Pharmacovigilance Expert Advisory Group

Ms C Davies
Principal Assessor

Ms E Paik
Assistant Secretary **(until 20th April 2014)**

Ms E Agca
Assistant Secretary **(from 21st April 2014)**

GLOSSARY

ABHI: Association of British Healthcare Industries

ABPI: Association of the British Pharmaceutical Industry

ABRHP: Advisory Board on the Registration of Homeopathic Products

ADHD: Attention Deficit Hyperactivity Disorder

ADR: Adverse Drug Reaction

AI: Adverse Incident

AIMDD: Active Implantable Medical Devices Directive

AITS: Adverse Incident Tracking System

ANDPB: Advisory Non-Departmental Public Body

AR: Assessment Report

ARB: Arms Length Body

ARM: Application to Reclassify a Medicine

ASMF: Active Substance Manufacturer

ASPR: Anonymised Single Patient Report

ART: Assisted Reproductive Technology

ATC: Anatomical, Therapeutic, Chemical

AT: Assistive Technology

ATE: Arterial Thromboembolic Events

BAN: British Approved Names.

BCPNN: Bayesian Confidence Propagation Neural Network

BGMA: British Generic Manufacturers Association

BHMA: British Herbal Medicines Association

BIR: British Institute of Radiology

Black triangle status: Assigned to new drugs and vaccines that are being intensively monitored by the MHRA to confirm the risk/benefit profile of the product

BMA: British Medical Association

BNF: British National Formulary

Borderline products: Products close to the boundary between medicines that need a licence and products (such as nutritional supplements, cosmetics) that do not.

BP: British Pharmacopoeia

BPC: British Pharmacopoeia Commission

BPR: Buckingham Palace Road. MHRA Headquarters in Victoria, London

BROMI: Better Regulation of Over-the-counter Medicines Initiative

BSE: Bovine Spongiform Encephalopathy

BSI: British Standards Institution

BVEAG: Biologicals and Vaccines Expert Advisory Group

CA: Competent Authority

CAS: Central Alerting Service

CAPLA/CANDA: Computer Assisted Product Licence Application/Computer Assisted New Drug Application

CCG: Clinical Commissioning Group

CD: Controlled Drug

CDR&REAG: Cardiovascular, Diabetes, Renal Respiratory and Allergy Medicines Expert Advisory Group

CDF: Competence Development Framework

CDRH: The Centre for Devices and Radiological Health

CE(O): Chief Executive (Officer)

CE MARK: European mark of approval for medical devices.

CEN: Comité Européen de Normalisation (European Committee for Standardisation)

CENELEC: Comité Européen de Normalisation Electrotechnique (European Committee for Electrotechnical Standardisation)

Centralised application / Centralised procedure: Relating to the EU licensing system resulting in a single European MA and direct access to a single community market

CFC: Chlorofluorocarbons

CHM: Commission on Human Medicines

CHMP: Committee for Medicinal Products for Human Use

CI: Confidence Interval

CIOMS: Council for International Organisations of Medical Sciences

CJD: Creutzfeldt-Jakob Disease

CLIN: Clinical Devices division of the MHRA

CMD(h): Co-ordination group for Mutual recognition and Decentralised procedures (human)

CMS: Concerned Member State

COMMS: Communications division of the MHRA

COPD: Chronic Obstructive Pulmonary Disease

CP: Chinese Pharmacopoeia

CPD: Continuing Professional Development

CPRD: Clinical Practice Research Datalink

CPSEAG: Chemistry, Pharmacy and Standards Expert Advisory Group

CQC: Care Quality Commission

CR: Computed Radiology

CSD: Committee on the Safety of Devices

CT: Computed tomography

CTA: Clinical Trial Authorisation

CTD: Clinical Trials Directive

CTD: Common Technical Document

CTEAG: Clinical Trials Expert Advisory Group

CVMP: Committee for Veterinary Medicinal Products

DA: Designating Authority

DAE: Discontinuation due to Asthma-related Event

DAP: Drug Analysis Print

DB: Device Bulletin

DCP: De-Centralised Procedure

DDL: Dear Doctor Letter

DDPS: Detailed Description of Pharmacovigilance System

DDX: Doctors and Dentist exemptions

DRGIEAG: Dermatology, Rheumatology, Gastroenterology and Immunology Expert Advisory Group

DG: Directorate General [of the European Commission]

DHPC: Direct Healthcare Professional Communication - also known as Dear Doctor letter

DH: Department of Health

DIRC: Departmental Industrial Relations Council

DMF: Drug Master File

DMRC: Defective Medicines Report Centre

DR: Digital Radiology

DSMB: Data and Safety and Monitoring Board

DSRU: Drug Safety Research Unit

DSU: Drug Safety Update

DTS: Device Technology & Safety division of the MHRA

E2B: Data elements for individual case safety reports.

EAG: Expert Advisory Group

EBGM: Empirical Bayes Geometric Mean

EC: *see EU*

ECG: Electrocardiogram

ECPHIN: European Community Pharmaceutical Information Network

eCTD: Electronic Common Technical Document

EDQM: European Directorate for the Quality of Medicines & Healthcare

EEA: European Economic Area - member States of the EU together with Iceland, Lichtenstein and Norway.

EFTA: European Free Trade Association

EFPIA: European Federation of Pharmaceutical Industries Associations

EFQM: European Foundation for Quality Management

EHTPA: European Herbal and Traditional Medicine Practitioners Association

EMACOLEX: A group of European lawyers from health departments and regulatory agencies.

EMA: European Medicines Agency

EP: European Pharmacopoeia

EPAR: European Public Assessment Report for medicines

EPID: Extended (also Expanded) Public Information Document

EQA: European Quality Award (see also EFQM)

ERA: European Regulatory Affairs

ETSI: European Telecommunications Standards Institute

EU: European Union

EUDRA: European Union Drug Regulatory Authorities

EudraCT: The clinical trial application and database hosted by the EMA.

EudraGMP: The community database containing information on all pharmaceutical manufacturers.

EUDRALEX: Web server for the on-line dissemination of community guidelines, notice to applicants and pharmaceutical legislation.

EUDRALINK: As EudraNet II can only be accessed and used by the national competent authorities, the EudraLink secure communication service has been developed to allow secure information exchange between the pharmaceutical industry, research institutes and pharmaceutical experts via the public internet.

EUDRAMAIL: A dedicated secure e-mail system based on functional mailboxes, which allows working groups to exchange messages relevant to their specific group.

EUDRANET: A European human and veterinary pharmaceuticals telecommunication network allowing scientific experts, those working on pharmaceutical business processes and policy makers to have a secure and well structured electronic environment to ‘meet’, exchange information and work together on a pan-European scale.

EUDRANET II: A managed virtual private IP network (IP VPN) based on encrypted tunnels over the public internet.

EUDRAPHARM: The central European database providing core data on all centrally

authorised medicinal products, including maximum residual limits for veterinary medicinal products and nationally authorised products from Member States ready to supply data as part of a pilot exercise.

EUDRAPORTAL: The central entry point for all the Eudra applications.

EUDRATRACK: A tracking and communication system for mutual recognition and
decentralised applications for Member States.

EudraVigilance: A data processing network and management system for reporting and evaluating suspected adverse reactions during development and following the marketing authorisation of medicinal products in the European Economic Area (EEA).

EURD list: The list of European Union reference dates and frequency of submission of
PSURs.

EVMPD: EudraVigilance Medicinal Product Dictionary

EWP: Efficacy Working Party

FARAW: Fairness & Respect at Work

FDA: Food and Drug Administration

FIN: Finance division of the MHRA

FOI: Freedom Of Information

FTCM: Federation of Traditional Chinese Medicines

FVAR: Final Variation Assessment Report

GBS Guillain-Barre Syndrome

GCP: Good Clinical Practice

GDP: Good Distribution Practice

GHTF: Global Harmonisation Task Force

GLP: Good Laboratory Practice

GLPMA: Good Laboratory Practice Monitoring Authority

GMDN: Global Medical Device Nomenclature

GMO: Genetically Modified Organism

GMP: Good Manufacturing Practice

GMPLA: Good Manufacturing Practice Licensing Authority

GVP: Good pharmacovigilance Practices - *see also GPvP*

GP: General Practitioner

GPRD: General Practice Research Database

GPvP: Good Pharmacovigilance Practice

GRIDEAG: Gastroenterology, Rheumatology, Immunology & Dermatology Expert Advisory Group

GSI: Government Secure Intranet

GSL: General Sales List

GxP: General abbreviation for Good Practice standards.

HCPC: Health and Care Professions Council

Herbal highs: Products that mimic, or claim to mimic, the effects of controlled drugs

HFMA: Health Food Manufacturers' Association

HLGT: High Level Group Term - part of the Medical Dictionary for Drug Regulatory Affairs (MedDRA) terminology

HLT: High Level Term - part of the Medical Dictionary for Drug Regulatory Affairs (MedDRA) terminology

HMAC: Herbal Medicines Advisory Committee

HMPC: European committee on Herbal Medicinal Products

HMR: Human Medicines Regulations

HPV Human Papillomavirus

HRT: Hormone Replacement Therapy

HSE: Health & Safety Executive

HTA: Human Tissue Authority/Act

I&AC: Imaging and Acute Care

IB: Investigator's Brochure - compilation of clinical and non-clinical data on the investigational product

ICES: Integrating Community Equipment Services

ICH: International Conference on Harmonisation

ICNIRP: International Commission on Non-Ionising Radiation Protection

ICS: Inhaled Corticosteroids

ICSR: Individual Case Safety Report

ICT: Information and Communications Technology

IEC: International Electrotechnical Commission

IEPS: Inspections, Enforcement and Standards Division of the MHRA

IM: Intramuscular

IMD: Information Management Division of the MHRA

IMP: Investigational Medicinal Products

ImPACT: Imaging Performance Assessment of CT scanners

IMS: Information Management Strategy

INN: International Non-proprietary Name

INR: International Normalised Ratio

IP: International and Parliamentary function

IP: Intra-peritoneal or Intra-pleural

IPEM: Institute of Physics and Engineering in Medicine

IPU: Information Processing Unit

IRAS: Integrated Research Application System

IRC: Industrial Relations Council

IRG: Independent Review Group on silicone gel breast implants

IR(ME)R: Ionising Radiation (Medical Exposure) Regulations

IRR: Ionising Radiation Regulations

IVDMDD: In Vitro Diagnostic Medical Device Directive

ISAC: Independent Scientific Advisory Committee [for MHRA database Research]

ISBN: International Standard Book Number

ISO 9000: A series of international standards for quality systems.

ITT: Intention To Treat

ITU: Intensive Therapy (care) Unit

IU: International Unit (or UI)

IU(C)D: IntraUterine (Contraceptive) Device

IVD: In Vitro Diagnostic Medical Device

IT: Information Technology

IV: Intravenous

LA: Licensing Authority

LABA: Long Acting β2 Agonist

LFT: Liver Function Test

LGC: Laboratory at Teddington - formerly the Laboratory of the Government Chemist, now an independent chemical analysis laboratory.

LibCat: The MHRA library catalogue providing access to the holdings of the MHRA and the Department of Health.

LLT: Low Level Term - part of the Medical Dictionary for Drug Regulatory Affairs (MedDRA) terminology.

LOCF: Last Observation Carried Forward

MA: Marketing Authorisation

MAA: Marketing Authorisation Application

MAC: Microbiology Advisory Committee

MAH: Marketing Authorisation Holder

MDA: Medical Devices Agency - merged with the Medicines Control Agency in 2003 to become the MHRA

MDA: Medical Device Alert

MDD: Medical Devices Directive

MDR: Medical Device Reporting or Medical Device Regulations (SI 2002/618 and 2003/1697)

MDLO: Medical Device Liaison Officer

MEDDRA: Medical Dictionary for Drug Regulatory Affairs

MedDRA: Medical Dictionary for Regulatory Activities

MGPS: Multi-item Gamma Poisson Shrinker

MEDS: Management of Electronic Document Strategy

MHRA: Medicines and Healthcare products Regulatory Agency

MISG: Ministerial Industry Strategy Group

ML: Manufacturer's Licence

MLWP: The Working Party on Community Monographs and Community List

MLX: Consultative letters sent out by the MHRA to interested parties when considering proposals to amend orders and regulations made under the Medicines Act

MORE: Manufacture's On-line Reporting Environment

MR: Mutual Recognition

MRA: Mutual Recognition Agreement

MRI: Magnetic Resonance Imaging

MS: Member State [of the European Union (EU)]

MTL: Medicines Testing Laboratory - formerly the Laboratory of the Government Chemist at Teddington, Middlesex.

MTS: Medicines Testing Scheme

Mutual Recognition: Part of the EU licensing system aimed at facilitating access to a single market using the principle of mutual recognition

MWHEAG: Medicines for Women's Health Expert Advisory Group

NAHS: National Association of Health Stores

NAO: National Audit Office

NAS: New Active Substance

NB: Notified Body

NBOG: Notified Body Operations Group

NCAS: National Clinical Assessment Service

NCE: New Chemical Entity

NEL: No Effect Level - now replaced by NOAEL or NOEL

NHS: National Health Service

NIBSC: National Institute for Biological Standards and Control

NICE: National Institute for Health and Care Excellence

NIGB: National Information Governance Board [for Health and Social Care]

HIHR: National Institute for Health Research

NOAEL: No Observed Adverse Effect Level

NOEL: No Observed Effect Level

NOP: Non-Orthodox Practitioner

NOS: Not Otherwise Specified

NPPEAG: Neurology, Pain and Psychiatry Expert Advisory Group

NRLS: National Reporting and Learning System

NRPB: National Radiological Protection Board

NUI: Non-Urgent request for Information

OH: Occupational Health

OHEAG: Oncology and Haematology Expert Advisory Group

OG: Open Government

OGD: Other Government Department

OIS: The Department of Health's IT system.

Orange guide: Alternative title for the 'Rules and Guidance for Pharmaceutical Manufacturers and Distributors'

Orphan drug: A drug for a rare disease

OTC: Over-The-Counter [product]

P (Medicine): Pharmacy medicine

P-value: The probability (ranging from 0 to 1) that the result in a study could have occurred by chance.

P&CC: Patient and Client Council [for Assistive Technology (AT)]

PA: Persons Appointed

PACS: Picture Archiving and Communications Systems

PACSnet: Picture Archiving and Communications Systems National Evaluation Team

PAGB: Proprietary Association of Great Britain

PAR: Public Assessment Report

Parallel import: A pharmaceutical product therapeutically equivalent to an

existing licensed UK product and licensed in the UK in accordance with the rules of the parallel import scheme

PCT: Primary Care Trust

PCS: Public and Commercial Services Union

PDA: Performance and Development Agreement

PDCO: European Paediatric Committee

PDP: Personal Development Plan

PEAG: Pharmacovigilance Expert Advisory Group

PEG: Paediatric Expert Group

PEM: Prescription Event Monitoring

PET: Positron Emission Tomography

PET/CT: Positron Emission Tomography (PET) and Computerised Tomography (CT)

PGD: Patient Group Directions

Pharmacopoeia: A compendium of standards for pharmaceutical or chemical substances.

Ph. Eur.: European Pharmacopoeia

PhVWP: Pharmacovigilance Working Party

PHE: Public Health England

PI: Principal Investigator

PIC: Pharmaceutical Inspection Convention

PICS: Pharmaceutical Inspection Co-operation Scheme

PIEAG: Patient Information Expert Advisory Group

PIL: Patient Information Leaflet

PIP: Paediatric Investigation Plan

PIQ: Patient Information Quality

PK: Pharmacokinetic(s)

PL: Product Licence

PLAT: Product Licensing Assessment Teams

PL(PI): Product Licence (Parallel Import)

PLR: Product Licence of Right

PMDD: Premenstrual Dysphoric Disorder

PMEAG: Paediatric Medicines Expert Advisory Group

PMH: Past medical history

PMS: Post-Marketing Surveillance

PO: Private Office

POM: Prescription Only Medicines

POM TO P: The means by which a Prescription Only Medicine can become a Pharmacy Medicine (i.e. available only from a pharmacist); also known as ‘de-pomming’.

PPEEAG: Patient and Public Engagement Expert Advisory Group

PPI: Patient Pack Initiative

PPI: Proton Pump Inhibitor

PQ: Parliamentary Question

PRAC: Pharmacovigilance Risk Assessment Committee [of the EMA]

PRR: Proportional Reporting Ratio

PRR: Proportioned Reporting Ratio

PSE WG: Pseudoephedrine Working Group

PSG: Professional Skills for Government

PSUR: Periodic Safety Update Report

PT: Preferred Term - part of the Medical Dictionary for Drug Regulatory Affairs (MedDRA) terminology

PUMA: Paediatric Use Marketing Authorisation

PUWER: Provision and Use of Work Equipment Regulations

PV: Pharmacovigilance

PVAR: Preliminary Variation Assessment Report

QA: Quality Assurance

QC: Quality Control

QOS: Quality Overall Summary

QP: Qualified Person

QWP: Quality Working Party

RamaXL: A subscription service that gives subscribers easy access to nonconfidential
information on all medicinal products authorised in the UK, together with the ability to track their own applications as they progress through the assessment process.

RCGP: Royal College of General Practitioners

RCHM: Register of Chinese Herbal Medicines

RCR: Royal College of Radiologists

RCT: Randomised (controlled) Clinical Trial

RFI: Request for Further Information

rINN: Recommended International Non-proprietary Name

RMP: Risk Management Plan

RMS: Reference Member State

ROR: Reporting Odds Ratio

RPPS: Regulatory Pharmacovigilance Prioritisation System

RP: Responsible Person

RPSGB: Royal Pharmaceutical Society of Great Britain

RMS: Records Management System

RSC: Royal Society of Chemistry

RSI: Request for Supplementary Information

RSM: Royal Society of Medicine

Rx: Abbreviation for a medical prescription

SABS: Safety Alert Broadcast System

SAE: Serious Adverse Effect

SAG: Scientific Advisory Group [of the EMA]

SAMM: Safety Assessment of Marketed Medicines - guidelines that apply to the conduct of all company sponsored studies designed to evaluate drug safety

SCOP: Pharmacovigilance Sub-Committee of the Committee on Safety of Medicines [Replaced by PEAG of the CHM]

SD: Standard Deviation

SEAC: Spongiform Encephalopathy Advisory Committee

Section 4 Committees: Committees established under the Medicines Act to promote advice on the safety, quality or efficacy of medicines and the collection and investigation of information concerning adverse drug reactions.

Section 44 Letters: Letters issued under the 1968 Medicines Act to seek additional information. For instance, S 21(1) or S 28(3) letters allow the provisional conclusions of the Committee on Safety of Medicines to be conveyed to a company.

SI: Statutory Instrument

SLA: Service Level Agreement

SMF: Site Master File

SMQ: Standardised MedDRA query - part of the Medical Dictionary for Drug Regulatory Affairs (MedDRA) terminology

SmPC: Summary of Product Characteristics - *see SPC*

SOC: System Organ Class - part of the Medical Dictionary for Drug Regulatory Affairs (MedDRA) terminology

SOL: Department of Health Solicitor's Branch.

SOP: Standard Operating Procedure

SPC: (see also SmPC) Summary of Product Characteristics

SPC: Special Precautions and Contra-indications

SPECT: Single Photon Emission Computed Tomography

SSRI: Selective Serotonin Reuptake Inhibitor

SUSAR: Suspected Unexpected Serious Adverse Reaction

SWP: Safety Working Party

Syn (Synonym): A botanical name that is commonly used but is not botanically accepted as the correct term for a species

TAG: Technical Advisory Group

TCM: Traditional Chinese Medicine

TGA: Therapeutic Goods Administration (Australia)

THM: Traditional herbal medicine

THMPD: Traditional Herbal Medicinal Products Directive

THMRS: Traditional Herbal Medicines Registration Scheme

THR: Traditional Herbal Registration

TO: Treat Officially - description used for all letters sent to the Secretary of State or ministers to be answered by officials.

TOPRA: The Organisation for Professionals in Regulatory Affairs

TOTO: Top Of The Office

TS: Tuberous Sclerosis

TSE: Transmissible Spongiform Encephalopathy

UKPAR: United Kingdom Public Assessment Report for Medicines

UKRC: United Kingdom Radiological Conference

USAN: United States Adopted Names - a list of drug names officially recognised in the US.

USP: United States Pharmacopoeia

UTI: Urinary Tract Infection

vAIC: Virtual Adverse Incident Centre

vCJD Variant Creutzfeldt-Jakob Disease

VMD: Veterinary Medicines Directorate

VRMM: Vigilance and Risk Management of Medicines division of the MHRA

VTE: Venous Thromboembolism

WHMP: Western Herbal Medicine Practitioner

WL: Wholesale dealer’s Licence

YCC: Yellow Card Centre

BRITISH PHARMACOPOEIA COMMISSION ANNUAL REPORT FOR 2014

INTRODUCTION

1. The British Pharmacopoeia Commission, appointed under Part 2 of the Human Medicines Regulations 2012, is responsible under regulation 317(4) of the 2012 Regulations for preparing new editions of the British Pharmacopoeia and the British Pharmacopoeia (Veterinary) 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 regulation 318(2) of the 2012 Regulations 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 members of the British Pharmacopoeia Commission during 2014, showing their terms of appointment, is shown in **Appendix I**. Following the retirement of Mr V'Iain Fenton-May at the end of 2013, the Commission appointed Professor Alastair Davidson as the Vice-Chair with effect from 1st January 2014 in accordance with Rule 2 of the Rules Governing the Proceedings of the British Pharmacopoeia Commission.

3. A list of members of the supporting Expert Advisory Groups, Panels of Experts and Working Parties for 2014 is given in **Appendix II**. In order to support a BP/MHRA project to investigate the application of the Quality by Design concept to analytical methods and the pharmacopoeia, a new Working Party on Analytical Quality by Design was established and its first meeting was held in September. A full review of membership was undertaken during the year and the terms of office for all newly appointed and re-appointed members will run from 1st January 2015 to 31st December 2018.

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 in that, with the exception of the Chair, members may continue to hold personal interests in the pharmaceutical industry. Members of the Expert Advisory Groups, Panels of Experts and Working Parties are also required to comply with the Code of Practice. Explanatory Notes clarifying how interests are recorded are included in the British Pharmacopoeia and British Pharmacopoeia (Veterinary).

MEETINGS

5. The British Pharmacopoeia Commission met three times during 2014. Fourteen meetings of the Expert Advisory Groups, Panels of Experts and Working Parties were also held during the year. The Panel of Experts on Microbiology and the Panel of Experts on Veterinary Immunological Products both met for the first time during the year in order to discuss issues relevant to the UK. These meetings were held at the Medicines and Healthcare Products Regulatory Agency, 151, Buckingham Palace Road, London SW1W 9SZ.

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 British Pharmacopoeia website (http://www.pharmacopoeia.com).

TRIENNIAL REVIEW

7. In accordance with Cabinet Office Requirements to review Non-Departmental Public Bodies every three years, the British Pharmacopoeia Commission (BPC) will be the subject of a Triennial Review during 2015. The review will examine (1) whether there is a continuing need for the functions performed by the BPC and (2) the governance and performance of the BPC. Three members of the Department of Health Triennial Review Team attended the December meeting of the BP Commission as part of the review process.

SECRETARIAT

8. The British Pharmacopoeia Secretariat is based at the headquarters of the Medicines and Healthcare Products Regulatory Agency (London). A list of members of the Secretariat is shown in **Appendix III**.

LABORATORY

9. The British Pharmacopoeia Laboratory is based at the Laboratory of the Government Chemist (LGC) (Teddington). The Laboratory is managed under a collaboration agreement with LGC. The Laboratory Management Board is shown in **Appendix III**.

COSTS

10. For each meeting that they attend, members of the British Pharmacopoeia Commission are entitled to claim a taxable attendance fee of £325 (Chair's fee, £500). Members of the Expert Advisory Groups, Panels of Experts and Working Parties are entitled to claim a taxable attendance fee of £200 per meeting attended (Chair's fee, £325). Travel and subsistence is also payable within MHRA guidelines.

PROGRESS AND PUBLICATIONS

British Pharmacopoeia 2014

11. Following publication of the British Pharmacopoeia 2014 two electronic updates were issued providing users with the text of the 8th edition of the European Pharmacopoeia together with that of Supplement 8.1, followed by Supplement 8.2.

British Pharmacopoeia 2015

12. The British Pharmacopoeia 2015 was published in August 2014. This new edition is now available as a package containing the five volumes of the British Pharmacopoeia 2015, the one volume of the British Pharmacopoeia (Veterinary) 2015 and access to the electronic versions of both publications (online and single-user USB format). Publication of the 2015 edition marked 150 years since publication of the first edition of the British Pharmacopoeia in 1864. This celebratory edition, which was issued with a complimentary 150th Anniversary USB containing a digital facsimile of the BP 1864, includes the new branding which has been included across the range of BP publications.

13. This new edition contains almost 3500 monographs for substances and articles used in the practice of medicine and over 400 infrared reference spectra, together with the customary appendices and supporting material. The effective date of the British Pharmacopoeia 2015 is 1st January 2015.

14. All monographs published within the 8th Edition of the European Pharmacopoeia, as amended by Supplements 8.1 and 8.2, are included either in this edition of the British Pharmacopoeia or, where appropriate, in the associated edition of the British Pharmacopoeia (Veterinary). Following the signing of a collaboration agreement between the British Pharmacopoeia Commission and the European Directorate for the Quality of Medicines and HealthCare in 2013, the text of the European Pharmacopoeia was provided by electronic transfer. This simplified the incorporation of the text within the publications and reduced the associated proof-reading for the BP Secretariat. 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.

15. The British Pharmacopoeia 2015 contains 39 new monographs of national origin which were not published in previous editions. These include one new monograph for a Traditional Herbal Medicine (Sesame Seed) and eight new monographs for unlicensed formulations. Eight new infrared reference spectra have been added to this edition.

16. The General Notices were updated to reflect that the provisions of the European Pharmacopoeia General Monograph for Pharmaceutical Preparations apply to all dosage forms, whether or not an individual monograph is included in the British Pharmacopoeia.

17. The recommendations of the former Working Party on Inhaled Products are currently under review. Once the review has been completed, any changes to

affected monographs will be included in a future edition of the British Pharmacopoeia.

18. One new Appendix was added to harmonise with the European Pharmacopoeia (V R: Detection and Measurement of Radioactivity). Following editorial changes to the national monographs for Pancreatin, Pancreatin Granules and Gastro-resistant Pancreatin Tablets, the Assay for the determination of Pancreatin content has been moved to a new Appendix (XIV I: Assay of Pancreatin).

19. One new Supplementary Chapter was added to harmonise with the European Pharmacopoeia (Chapter VII B: Names of Herbal Drugs used in Traditional Chinese Medicine).

British Pharmacopoeia (Veterinary) 2015

20. The British Pharmacopoeia (Veterinary) 2015 was published as a companion volume to the British Pharmacopoeia 2015 in August 2014. This new edition contains monographs, infrared reference spectra and a number of appendices relating to materials used solely in veterinary medicine. The effective date of the British Pharmacopoeia (Veterinary) 2015 is 1st January 2015.

21. The General Notices were updated to reflect that the provisions of the European Pharmacopoeia General Monograph for Pharmaceutical Preparations apply to all dosage forms, whether or not an individual monograph is included in the British Pharmacopoeia (Veterinary).

22. Efforts are being made to ensure that the British Pharmacopoeia (Veterinary) continues to provide authoritative quality standards for veterinary medicines in the UK and worldwide.

British Approved Names

23. Supplement No. 3 to British Approved Names 2012 was published in August 2014, adding 34 new names not previously published.

BP Online

24. Access to the online version of the publications (www.pharmacopoeia.co.uk) was provided as a component of the British Pharmacopoeia 2015 package. The CD-ROM format, which has been available since publication of the 1993 edition, was replaced by provision of a single-user USB format.

25. A maximum of three BP monographs can be supplied electronically to users on request, together with the necessary supporting information including the Introduction, General Notices, Appendices and Supplementary Chapters.

Prices and Availability

26. Details of the prices and availability of the above-mentioned publications are shown in **Appendix IV**.

Future Publications

27. By the end of 2014 work was progressing on the preparation of the next editions of the British Pharmacopoeia and British Pharmacopoeia (Veterinary). These will be published during 2015 and will have an effective date of 1st January 2016.

28. An electronic update to the British Pharmacopoeia 2015 was issued in early 2015 providing users with the text of Supplement 8.3 to the 8th Edition of the European Pharmacopoeia which came into effect on 1st January 2015. Further updates will be issued to coincide with the implementation of Supplements 8.4 and 8.5 on 1st April and 1st July 2015 respectively. These updates will only be available via the online BP. The texts will subsequently be included in the BP 2016 publications.

OTHER PHARMACOPOEIAL MATTERS

BP Website

29. A project is underway to redevelop both the British Pharmacopoeia website (www.pharmacopoeia.com) and the website providing the online BP (www.pharmacopoeia.co.uk). The project will result in one new consolidated website, which will replace the two existing websites whilst maintaining the functionality of both. The redeveloped website will offer an improved user experience and incorporates feedback from current users of both sites.

30. The site has continued to make information available to both the public and users and provide greater transparency in the monograph development and revision process. The information made available includes the provision of draft new and revised monographs for comment.

Unlicensed Medicines

31. Monographs that only apply to unlicensed medicines are identified as such in the British Pharmacopoeia by the inclusion of a statement indicating that the medicines are not currently licensed in the United Kingdom.

32. 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.

33. 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. In addition to monographs for widely-used preparations, steps are being taken to identify other areas within the field of unlicensed medicines where the provision of information in the British Pharmacopoeia would be valuable.

Traditional Herbal Medicines

34. 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.

Quality by Design

35. The application of Quality by Design approaches to pharmacopoeial methods is intended to improve the robustness of methods and monographs and to facilitate the adoption of innovative analytical technologies. As part of the joint BP/MHRA project, discussions have been held with both the European Pharmacopoeia and the United States Pharmacopeia with a view to continuing to share information as these concepts evolve.

Liaison with Other Organisations

36. The BP has been developing links with several academic institutions and is currently involved in projects with 8 universities. Lectures have been given to pharmacy and chemistry students on “Use of the British Pharmacopoeia”, “Pharmaceutical Analysis” and “Nomenclature of Medicines and Prescription Errors Due to Names”.

37. A collaborative inter-laboratory study was undertaken between the BP Laboratory and the laboratory of the Therapeutic Goods Administration (Australia) in connection with elaboration of the draft monographs for Montelukast finished products. This study ensured that the test procedures in the monographs were robust and rugged and ensured that a key regional stakeholder was fully engaged in the monograph development process.

38. The BP has been working closely with the pharmaceutical industry to ensure that the publication meets the needs of the users. A number of BP staff attended a meeting of the European Federation of Pharmaceutical Industries and Associations (EFPIA) in July to discuss common areas of interest.

39. A meeting between representatives from the Veterinary Medicines Directorate (VMD) and the BP took place in December. The BP and VMD continue to collaborate closely on the development of monographs for veterinary medicines and on a range of regulatory and policy issues relating to veterinary medicines.

BP Reference Materials

40. 20 new BP Reference Materials were established to support the British Pharmacopoeia and British Pharmacopoeia (Veterinary) publications, 37 were replaced and 138 were re-tested to ascertain their continued stability.

41. The demand for these reference materials remained high throughout the year. 20,920 vials were sold within the UK and to countries worldwide, representing a 24% increase in sales from the previous year.

Nomenclature

42. The BP continued to provide advice and comments to the World Health Organization (WHO) Committee on International Nonproprietary Names (INN). Recommended INN (rINN) for products licensed in the UK are subsequently adopted as British Approved Names. UK Experts attended two meetings during the year and contributed to the evaluation of INN requests and the development

of WHO policies on drug nomenclature. Two rINN Lists (71 and 72) were published by WHO during the year.

43. The BP Secretariat is also responsible for assessing proposed invented names for medicines in the UK and providing the UK input to the EMA Naming Review Group. During the year 1086 proposed invented names were assessed on behalf of the MHRA and 610 on behalf of the EMA.

MHRA/NIBSC Merger

44. As a consequence of the merger, the Secretariat has been working with colleagues from NIBSC in the areas of Herbal and Biological Medicines and it is anticipated that work in these areas will continue and increase in the future.

45. A meeting was held between representatives from the BP and NIBSC to discuss issues relating to the control of biological medicines, including the possibility of developing monographs at an earlier stage in the lifecycle of a product and the support for future monographs. The feasibility of the BP providing secondary biological reference standards is currently being examined.

46. A number of informal meetings took place to progress the BP/NIBSC project on herbal medicines. Work also progressed on the development of micrographs to aid the identification of herbal drugs.

150th Anniversary of the British Pharmacopoeia

47. In January the British Pharmacopoeia celebrated 150 years since publication of the first edition in 1864. A number of technical meetings took place in April during which this landmark achievement was celebrated: the annual meeting of National Pharmacopoeial Authority Secretaries (organised by the European Directorate for the Quality of Medicines and HealthCare, hosted by the MHRA); the Third International Meeting of World Pharmacopoeias (organised by the World Health Organization, hosted by the MHRA); conference on “The Quality of Medicines – Future Evolution”.

48. A number of bilateral meetings were held during this time in order to progress international collaboration activities with countries including China, India, Indonesia, Kazakhstan, Russia and the United States of America and with WHO.

49. A commemorative reception was held at the House of Lords which included speeches from Earl Howe (Parliamentary Under Secretary of State for Quality), Ms Helen Gordon (Chief Executive, Royal Pharmaceutical Society) and Sir Gordon Duff (Chair of the MHRA). This event was attended by many current and former members of the British Pharmacopoeia Commission and staff, together with many national and international colleagues, and provided an opportunity to reflect on the history and successes of the British Pharmacopoeia and the challenges ahead.

European Pharmacopoeia

50. The third and fourth Supplements to the 8th edition of the European Pharmacopoeia (Supplements 8.3 and 8.4) were published in July 2014 and October 2014 respectively. Supplement 8.3 came into effect on 1st January 2015

and Supplement 8.4 will come into effect on 1st April 2015. The fifth Supplement (8.5) was published in January 2015 and will come into effect on 1st July 2015.The text of these publications will be included in the next editions of the British Pharmacopoeia or British Pharmacopoeia (Veterinary), as appropriate.

51. The UK continued to play a highly active role in support of the work of the European Pharmacopoeia Commission and its expert groups, providing Chairs to three Groups of Experts and seven Working Parties and experts to all of the principal Expert Groups and Working Parties.

52. 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 Pharmeuropa and provides technical data in support of the elaboration of new monographs and revision of existing monographs.

53. 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 British Pharmacopoeia Commission.

54. 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 2014, is included in **Appendix V**.

50th Anniversary of the European Pharmacopoeia

55. The first edition of the European Pharmacopoeia was published in 1964 and the European Directorate for the Quality of Medicines and HealthCare (EDQM) celebrated this anniversary by hosting an international conference at its offices in Strasbourg during October (EDQM: 50 Years of Leadership in the Quality of Medicines – Paving the way for the future). This event was attended by a number of BP staff and members of the British Pharmacopoeia Commission and included a number of Workshops on areas such as Biologicals, Finished Product Monographs, Herbals, Impurities, Pharmacopoeial Harmonisation and Quality by Design.

International Liaison and Collaboration

56. Liaison was maintained on a wide range of topics relating to pharmacopoeial matters and nomenclature with various international organisations and bodies including the World Health Organization (WHO), the Australian Therapeutic Goods Administration Laboratories, the Canadian Health and Food Protection Branch, the United States Pharmacopeia (USP) and the United States Adopted Names (USAN) Council. This collaboration has been enhanced with the appointment of a number of overseas representatives to the British Pharmacopoeia Commission's Expert Advisory Groups and Panels of Experts.

57. BP Staff attended the Third and Fourth International Meetings of World Pharmacopoeias which were organised by the World Health Organization. The Third Meeting was held in London (April) and the Fourth Meeting was held in Strasbourg (October). The meetings focussed on the continuing development of the guidelines on "Good Pharmacopoeial Practices". Good progress was made with the draft guidelines although there were a number of issues to overcome in light of differences in medicines legislation amongst the participating countries.

58. Throughout the year BP Secretariat staff have provided feedback to WHO on draft monographs for the International Pharmacopoeia, which has been greatly appreciated. Many of the standards included in the International Pharmacopoeia, and the policies employed, are consistent with those in the British Pharmacopoeia.

59. The BP participated in the 49th Meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations held in October 2014.

60. During December a member of staff from WHO spent several days with the BP in order to gain an understanding of BP procedures and how these could be applied to the work of the International Pharmacopoeia. He also attended a meeting of one of the Expert Advisory Groups.

61. The project on informal prospective harmonisation with the United States Pharmacopeia (USP) has now expanded to include collaboration and sharing of information on chemical medicines, biological medicines, unlicensed medicines and herbal and complementary medicines. Three informally harmonised Montelukast finished product monographs were published in the British Pharmacopoeia 2015.

62. BP staff attended a number of USP Workshops on “DNA Methods for the Quality Control of Botanical Products” and “Lifecycle Approach to Validation of Analytical Procedures with Related Statistical Tools”. Reports on MHRA activities relating to Quality by Design and on European Regulatory activities in this field were presented at the latter Workshop.

63. In order to support The Stationery Office, publisher of the BP and BP (Vet), BP staff attended the American Association of Pharmaceutical Scientists Annual Meeting and Exposition and provided presentations on the work of the BP and International Collaboration. This meeting was also attended by representatives from LGC, a partner in the establishment of British Pharmacopoeia Chemical Reference Substances.

64. During April, Memoranda of Understanding were signed between the British Pharmacopoeia and Kazakhstan and between the British Pharmacopoeia and WHO. These agreements allow BP monographs to be cited in the State Pharmacopoeia of the Republic of Kazakhstan and for the collaboration between the BP and the International Pharmacopoeia to continue.

65. A Memorandum of Understanding between the MHRA and the Chinese Food and Drug Administration was signed in June. This agreement will enable the BP and the Chinese Pharmacopoeia to collaborate in the areas of Traditional Herbal Medicines, medicinal products and biological materials. Along with representatives from the MHRA, the BP attended the 7th Annual Joint Chinese Pharmacopoeia – United States Pharmacopeia Science and Standards Symposium held in China during November. Discussions were held with the Secretary General of the Chinese Pharmacopoeia to consider ways to progress areas of collaboration.

ACKNOWLEDGEMENTS

66. The British Pharmacopoeia Commission wishes to record its immense gratitude to the staff of the British Pharmacopoeia and Laboratory Services Group of the Medicines and Healthcare Products Regulatory Agency concerned with the business of the Commission and its Expert Advisory Groups, Panels of Experts and Working Parties. Significant input to the work of the British Pharmacopoeia Commission continued to be received from members of staff from the Licensing Division, the Vigilance & Risk Management of Medicines Division, the Inspection, Enforcement & Standards Division and the Information Centre of the Agency. Members of staff of the Communications Division worked closely with the BP Secretariat to prepare for the activities related to the celebrations for the 150th anniversary of the BP and continue to work with the Secretariat to find ways to promote the BP brand. Significant input has also been received from the BP and MHRA Laboratories, from the Department of Health, from the National Institute for Biological Standards and Control and from the Veterinary Medicines Directorate.

67. 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. In particular the Commission wishes to acknowledge the contribution of those members who have now retired from the Expert Advisory Groups, Panels of Experts and Working Parties of the British Pharmacopoeia Commission.

68. The Commission wishes to acknowledge the advice of the publishing team at The Stationery Office in the production of the British Pharmacopoeia 2015 and the British Pharmacopoeia (Veterinary) 2015.

69. The Commission also wishes to acknowledge the staff at the Medicinal Plant Names Services at the Royal Botanical Gardens, Kew, who provided advice on the Latin scientific names cited in the new national monographs for Traditional Herbal Medicines.

MEMBERSHIP OF THE BRITISH PHARMACOPOEIA COMMISSION

Chair

Professor Kevin M G Taylor BPharm PhD FRPharmS
Professor of Clinical Pharmaceutics, UCL School of Pharmacy

Members

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

Mr Barry Capon CBE MA DL (Lay Representative)
Former Non-Executive Director, Norfolk and Suffolk NHS Foundation Trust

Dr Graham D Cook BPharm PhD MRPharmS
Senior Director, Process Knowledge/Quality by Design, Pfizer

Mr Andrew Coulson BVetMed MSc MRCVS
Member of the Royal College of Veterinary Surgeons; Former Superintending Inspector, Science & Research Group, The Home Office

Professor Alastair Davidson BSc PhD FRPharmS **(Vice Chair)**
Visiting Professor of Pharmaceutical Sciences, University of Strathclyde

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

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

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

Dr Gerard Lee BPharm PhD FRPharmS MRSC CChem
Former Group Manager, British Pharmacopoeia and Laboratory Services, MHRA; former Secretary & Scientific Director, British Pharmacopoeia Commission

Dr Brian R Matthews BPharm PhD FRPharmS FTOPRA MRI
Consultant on Pharmaceutical and Medical Device Regulatory Affairs; former Senior Director, EC Registration, Alcon Laboratories

Professor John Miller MSc PhD MRSC CChem
Visiting Professor, Strathclyde Institute of Pharmacy and Biomedical Sciences; former Head of the EDQM Laboratory

Dr Ronald Torano BSc PhD MRSC CChem
Pharmacopoeial Intelligence and Advisory Specialist, GlaxoSmithKline

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

Mrs Josephine Turnbull LLB (Lay Representative)
Former Chair of Tees, Esk and Wear Valley NHS Foundation Trust

Dr Paul Varley BSc PhD
Vice President of Biopharmaceutical Development, Medimmune Limited

Professor Elizabeth Williamson BPharm PhD MRPharmS
Former Professor of Pharmacy, University of Reading

Secretary and Scientific Director

Dr Samantha Atkinson BSc MSc PhD MRSC Group Manager, BP & Laboratory Services, MHRA
Visiting Fellow, Reading University

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

EXPERT ADVISORY GROUPS

ABS: Antibiotics	R L Horder (**Chair**), G D Cook (**Vice-Chair**), P Ellis, V Jaitely, A Livingstone, W Mann, J Miller, N Thomas, B White, I R Williams
BIO: Biological and Biotechnological Products	L Tsang (**Chair**), P Varley (**Vice-Chair**), A F Bristow, D H Calam, J Cook, L Findlay, S Gill, E Griffiths, B Patel, A M Pickett, T Pronce, I Rees, D Sesardic, P Sheppard, W J Tarbit, A H Thomas, R Thorpe (*Corresponding members* A O Onadipe, J N A Tettey)
HCM: Herbal and Complementary Medicines	E Williamson (**Chair**), L A Anderson (**Vice-Chair**), T Chapman, A Charvill, K Helliwell, P Hylands, C Leon, A C Moffat, M Pires, M Rowan, K Strohfeldt-Venables, J Sumal, P Viner, C Wright, K Zhao (*Corresponding members* SS Handa, A Krauss, Z-T Wang)
MC1: Medicinal Chemicals	A G Davidson (**Chair**), D Cairns (**Vice-Chair**), M Ahmed, J C Berridge, M Broughton, A J Caws, P Fleming, V Loh, W J Lough, D J Malpas
MC2: Medicinal Chemicals	G Cook (**Chair**), C T Goddard (**Vice-Chair**), M Cole, A Gibson, J Lim, J Miller, P Murray, J Qiu, A Ruggiero, M Turgoose (*Corresponding members* M Brits, W Sherwin)
MC3: Medicinal Chemicals	V Fenton-May (**Chair**), E Williamson (**Vice-Chair**), M Almond, S Arkle, C T Goddard, P Hampshire, W K L Pugh, B Rackstraw, R Torano, M Tubby, I R Williams
NOM: Nomenclature	J K Aronson (**Chair**), L Tsang (**Vice-Chair**), M Ahmed, S Clarke[1], D Mehta, G P Moss, R Thorpe (*Corresponding members* R G Balocco Mattavelli, E M Cortés Montejano, J S Robertson)
PCY: Pharmacy	R L Horder (**Chair**), B R Matthews (**Vice-Chair**), M Aulton, E Baker, N Broad[1], G Davison, G Eccleston, D Elder, R A Lowe, J MacDonald, J F McGuire
ULM: Unlicensed Medicines	V Fenton-May (**Chair**), M G Lee (**Vice-Chair**), S Branch, A Charvill, W Goddard, S Jones, M A Oldcorne, N J Precious[1], J Rothwell, M Santillo, J Smith, P Weir

PANELS OF EXPERTS

BLP: Blood Products	K Chidwick, A R Hubbard, P Varley
IGC: Inorganic and General Chemicals	C T Goddard (**Chair**), M Almond, A C Cartwright, P Henrys, D Malpas, C Mroz, D Riches
MIC: Microbiology	V Fenton-May (**Chair**), S Denyer, D P Hargreaves, B R Matthews, P Newby
RAD: Radioactive Materials	J Ballinger, J Brain, D Graham, S R Hesslewood, G Inwards, P Maltby, R D Pickett, R Smith, S Waters
VET: Veterinary Medicines	E Williamson (**Chair**), P Lees (**Vice-Chair**), A Cairns, S Cockbill, A Coulson, D Evans, E Flahive, B Ward
VIP: Veterinary Immunological Products	A-M Brady, K Redhead, J Salt, P W Wells

WORKING PARTIES

AQbD: Analytical Quality by Design (*established in July*)	G Cook (**Chair**), S Brown, S Ellison, M Hanna-Brown, S Jones, D Makohon, P Nethercote, E Razzano (*Corresponding membe*r K Barnett)
CX: Excipients	C Mroz (**Vice-Chair**), E Anno, R Cawthorne, B R Matthews, M I Robertson, K Slevin

[1] Resigned during the year.

MEMBERS OF THE BRITISH PHARMACOPOEIA COMMISSION STAFF

SECRETARY AND SCIENTIFIC DIRECTOR

Dr S Atkinson

SECRETARIAT

Mrs M Vallender (*Editor-in-Chief)*
Mr S Young (*Head of Analytical Science*)
Mrs M Barrett
Ms H Corns
Mr P Crowley
Mr A Evans
Ms J Francomb
Mr A Gibb
Dr P Holland
Ms G Li-Ship
Dr R A Pask-Hughes
Ms C Pitt
Mr J Pound
Ms N Salmon
Dr F J Swanson
Mr M Whaley

NIBSC BASED STAFF

Dr C Howard
Ms C Lockie-Williams

LABORATORY MANAGEMENT BOARD

Dr S Atkinson (*Secretary and Scientific Director*, BP)
Mrs M Vallender (*Editor-in-Chief,* BP)
Mr S Young (*Head of Analytical Science*, BP)
Dr K Courtney (*BP Laboratory Team Leader*, LGC)
Dr D Griffiths (*Managing Director, Laboratory and Managed Services,* LGC)
Mr D Holcombe (*MHRA Laboratory Manager,* LGC)
Mr S Wood (*Head of Regulatory and Legislative Service*s, LGC)

ADMINISTRATIVE

Miss N Begum
Mr B Delahunty
Ms H Jagpal
Mr W Jeffries
Miss J Paine

BRITISH PHARMACOPOEIA COMMISSION PUBLICATIONS

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

British Pharmacopoeia 2015 package

Consisting of:-

British Pharmacopoeia 2015

British Pharmacopoeia (Veterinary) 2015

Online Access (single-user licence, allowing access to three in-year electronic updates)

USB format (single-user licence)

(Subscription price £1000; £875 for print and online versions 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 2012: Supplement No. 3

(Price £20)

EUROPEAN PHARMACOPOEIA COMMISSION

UNITED KINGDOM DELEGATION DURING 2014:

Main: S Atkinson, A G Davidson, K Taylor
Alternates: R L Horder, M Vallender

MEMBERS OF GROUPS OF EXPERTS FROM THE UNITED KINGDOM DURING 2014:

Group 1	Biological Methods and Statistical Analysis	V Fenton-May (***Chair***), S Denyer (*Specialist*)[1], G Marco (*Specialist*)[1]
Group 6	Biological Substances	C Burns
Group 6B	Human Blood and Blood Products	A R Hubbard
Group 7	Antibiotics	A Gibson, V Jaitely (*Specialist*)
Group 9	Inorganic and Organic Chemistry	C T Goddard
Group 9G	Medicinal Gases	M G Lee (***Chair***), P Henrys
Group 10A	Organic Chemistry (Synthetic Products)	D J Malpas (*Specialist*)
Group 10B	Organic Chemistry (Synthetic Products)	S Arkle
Group 10C	Organic Chemistry (Synthetic Products)	J McKendrick
Group 10D	Organic Chemistry (Synthetic Products)	C T Goddard
Group 11	Organic Chemistry (Natural Products)	M Tubby
Group 12	Dosage Forms and Methods	R Horder (***Chair***)
Group 13H	Fatty Oils and Derivatives	R Cawthorne, M Evans (*Specialist*)
Group 14	Radioactive Compounds	R D Pickett
Group 15	Sera and Vaccines	S Schepelmann (*Specialist*), D Sesardic (*Specialist*), P Stickings
Group 15V	Veterinary Sera and Vaccines	A-M Brady
Group 16	Plastic Containers for Pharmaceutical Use	K Allen[1]
Group P4	Procedure 4	S Young

[1]Resigned during the year.

MEMBERS OF WORKING PARTIES FROM THE UNITED KINGDOM DURING 2014:

Alkyl Mesilates	J Midgley (***Chair***)
Allergens	A Cook
Bacterial Endotoxins Test	L Findlay
Carbohydrates	J Michaud (***Chair***)
Cell Therapy Products	M O'Kane
Chromatographic Separation Techniques	S Young
Chairs of Chemical Groups	M G Lee
Dialysis Solutions	M G Lee (***Chair***)
Extracts	K Helliwell (***Chair***), L Anderson, M Pires
Functionality-related Characteristics	C Mroz
Gene Therapy Products	E Pollitt
Glass Containers	L Yoest
Glycan Mapping	C T Yuen
Heavy Metals	A Evans
Homoeopathic Manufacturing Methods	R A Pask-Hughes, J Sumal
Homoeopathic Raw Materials and Stocks	R A Pask-Hughes, J Sumal
Host-cell Proteins	A Kippen
Inhalanda	K Taylor
Monoclonal Antibodies	R Thorpe (***Chair***), P Varley
Monocyte Activation Test	L Findlay
Nuclear Magnetic Resonance Spectroscopy	C Jones
Pharmaceutical Preparations	V Fenton-May (***Chair***), M G Lee
Procedure 4 for Biologicals	K Chidwick, M Wadhwa
Process Analytical Technology	N Broad, I Lynch
Propellants	T Purewal

Raw Materials for the Preparation of Cellular and Gene Therapy Products	L Bisset
Rules of Procedure	S Atkinson
Special Revision Programme	A Evans
Standard Terms	M Ahmed
Statistics	R Gaines Das
Traditional Chinese Medicines	M Whaley
Vibrational Spectroscopy and Analytical Data Modelling	N Broad
Water for Pharmaceutical Use	M G Lee (***Chair***), A Hopkins

CODE OF PRACTICE FOR CHAIRMEN AND MEMBERS OF THE COMMISSION ON HUMAN MEDICINES, CERTAIN 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:

- Commission on Human Medicines (CHM)
- The following committees ("the Committees"):

  Herbal Medicines Advisory Committee (HMAC);

  The Advisory Board on the Registration of Homeopathic Products (ABRHP)

- The Expert Advisory Groups (EAGs) established by the CHM and/or the Committees.

2.2 This Code of Practice does not apply to the British Pharmacopoeia Commission (BPC), which 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 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 the Committees

4.4 The chairman and members of the CHM, HMAC and ABRHP 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 HMAC and ABRHP, 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, HMAC and ABRHP (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, ABRHP 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, ABRHP 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 permissible for members of CHM, HMAC, ABRHP 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 the 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 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, the 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 the 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:

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Stuart Ralston (Chair)	None	None	Amgen	Blososumab - Investigator on trial	Yes	None
			Merck	Odanacatib - DSMB member	Yes	
			Novartis	Zoledronic acid - DSMB chair	Yes	
			Lilly	Teriparatide - research grant	Yes	
Professor Deborah Ashby	None	None	GlaxoSmithKline	Methodological Collaboration	Yes	None
			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	
			AstraZeneca A/S	Methodological Collaboration	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Novo Nordisk A/S	Methodological Collaboration	Yes	
			Takeda	Methodological Collaboration	Yes	
			Lundbeck A/S	Methodological Collaboration	Yes	
			Eli Lilly	Methodological Collaboration	Yes	
			Genetech	Methodological Collaboration	Yes	
			LA-SER	Methodological Collaboration	Yes	
Mrs Eileen J Barrett	None	None	None	None	None	None
Mrs Alison Bowser	None	None	None	None	No	None
Professor Janet H Darbyshire	None	None	None	None	No	None
Dr J Colin Forfar	None	None	None	None	No	None
Dr Jamie Fraser	None	None	None	None	No	None
Professor Jonathan Friedland	None	None	None	None	No	None
Dr Richard Gilson	None	None	Sanofi Pasteur/MSD	Gardasil/Gardasil 9 - advisory board	Yes	
			ViV	Antiretroviral therapies - participating site in clinical trials	Yes	
			Pfizer	Maraviroc - Investigator, initiated research grant	Yes	
			Gilead Sciences	Antiretroviral therapies - participating site in clinical trials, local PI in trials	Yes	
Professor Martin Gore	None	None	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Ms Amanda Hoey	None	None	None	None	No	I am an independent consultant. I have a contract with the BMJ to provide health care policy analysis and strategy advice. The BMJ has advertising and sponsorship contracts with the pharmaceutical industry which follow a strict code of practice, including separation between the editorial and pharma ad sales teams. I do not work directly on projects or journals that receive pharma advertising or sponsorship. An immediate family member is an Executive Director of BMJ. They lead the Clinical Improvement Division which develops clinical decision support and education products to help doctors improve care and outcomes for patients.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						These include BMJ Learning, BMJ Quality, BMJ Masterclasses, BMJ Best Practice and BMJ Informatica. Some of these products are licensed by pharmaceutical companies who make the content freely accessible to clinicians internationally. Others receive pharmaceutical company sponsorship (e.g. the International Forum on Quality and Safety in Healthcare and BMJ masterclasses). The BMJ retains full editorial control over all its content and how it is used.
Professor Malcolm R Macleod	None	None	None	None	No	None
Dr Rebecca Mann	None	None	None	None	No	None
Dr Sarah Meredith	None	None	Abbott	Lopinavir, Ritonavir - grant & product donated for a trial	Yes	None
			Amgen	Neupogen/GM-CSF - product donated for a trial/grant	Yes	
			Astellas	Enzalutamide - grant & product donated for a trial	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			AstraZeneca	Cediranib/AZD 8931 - grant & product donated for a trial/product donated for a trial	Yes	
			Bayer	Sorafenib - grant & product donated for a trial	Yes	
			Bayer	Aspirin/Moxifloxacin - product donated for a trial	Yes	
			Boehringer Ingelhein, Bristol-Myers Squibb	Efavirenz, atripla - grant & product donated for a trial	Yes	
			Boehringer Ingelhein, Bristol-Myers Squibb	Anazanavir - product donated for a trial	Yes	
			Cipla	Albendazole, Azithromycin, Cotrimoxazole/Isoniazid/ Pyridoxine, Fluconazole, Efavirenz, Nevirapine, Lapimune minitabs - products donated for a trial	Yes	
			Gilead Sciences	Tenofovir, Emitricitabine, Atripla - grant & product donated for a trial	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Gilead Sciences	Emtricitabine (Truvada), Efavirenz, Tenofovir (Viread) - product donated for a trial	Yes	
			Gilead, Tibotec, a division of Janssen-Cilag Ltd, Roche	Truvada, Tenofovir - grant & product donated for a trial	Yes	
			GlaxoSmithKline	Lapatinib, Abacavir, Zidovudine, Lamivudine - grant & product donated for a trial	Yes	
			GlaxoSmithKline	Combivir, Kivexa - product donated for a trial	Yes	
			GlaxoSmithKline	HIV Conserve Vaccine - product donated for a trial/grant & product donated for a trial	Yes	
			Janssen	Abiraterone - grant & product donated for a trial	Yes	
			Janssen-Cilag	Darunavir, Ritonavir - grant & product donated for a trial	Yes	
			Lilly	Gemcitabine - product donated for a trial	Yes	
			Merck	Topotecan, Pegylated Interferon, Doxoirubicin, Efavirenz - products donated for a trial	Yes	
			Merck	Temozolomide - grant	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Merck	Raltegravir, Virinostat - grant & product donated for a trial	Yes	
			Merck Serono	Cetuximab - grant & product donated for a trial	Yes	
			Novartis	Zoledronic Acid - grant & product donated for a trial	Yes	
			Roche	Bevacizumab - grant & product donated for a trial	Yes	
			Roche	Capecitabine - product donated for a trial	Yes	
			Sanofi-Aventis	Docetaxel - grant & product donated for a trial	Yes	
			Sanofi Pasteur	NYVAC C - product donated for a trial	Yes	
			Tibotec	Darunavir - product donated for a trial	Yes	
			Virco	Resistance-tests - product donated for a trial	Yes	
			WHO/GDF	Clofazimine - product donated for a trial	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Siraj Misbah	None	None	CSL Behring	UK National Co-ordinator for multicenter,open-label extension study of IgPro20 in maintenance treatment of chronic inflammatory demyleinating polyneuropathy (CIDP) in patients completing study IgPro20_3003	Yes	20% SCIg – IgPro20 Hizentra. Honorarium will be paid into departmental funds
Professor David G C Owens	None	None	None	None	No	None
Professor B Kevin Park	None	None	Janssen Pharmaceutica N.V.	Project grant on the role of the Nrf2 system in DILI	Yes	None
			AstraZeneca	Joint supervision on AZ sponsored BBSRC CASE studentship	Yes	
			GlaxoSmithKline	Supervisor on GSK funded PhD studentship	Yes	
			Pfizer	Pfizer award for innovative science	No	
			Merck	Donation for the Centre for Drug Safety Science	Yes	
			Merck	Project grant on translational biomarkers for DILI	Yes	
			Amgen	Project grant on Keap1-Nrf2 system	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Munir Pirmohamed	None	None	GlaxoSmithKline	NP, NS Support of the MRC Clinical Pharmacology Training Scheme	Yes	None
			Astra Zeneca	NP, NS Support of the MRC Clinical Pharmacology Training Scheme	Yes	
			Pfizer	Bosutinib - Research grant to investigate mechanisms of diarrhoea associated with bosutinib	Yes	
Professor Shirley Price	None	None	None	None	No	None
Carolyn, Lady Roberts	None	None	None	None	No	Member of Council, University of Hull
Professor Kevin M G Taylor	None	None	AstraZeneca	Research project and contribution to EPSRC Doctoral Training Centre in my department	Yes	None
			Boots	Contribution to EPSRC Doctoral Training Centre in my department	Yes	
			Pfizer	Contribution to EPSRC Doctoral Training Centre in my department	Yes	
			GlaxoSmithKline	Contribution to EPSRC Doctoral Training Centre in my department	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Quadrant	Contribution to EPSRC Doctoral Training Centre in my department	Yes	
Dr Angela E Thomas	None	None	Baxter	Sponsor for a conference on haemophilia run by the Journal of Internal Medicine	No	None of the support listed has been direct but through unconditional educational grants given to the organising body. I have not received any honoraria. I attended the Haemostasis Academy dinner which was arranged for all participants and teachers on the course
			Bayer	Sponsor for a conference on haemophilia run by the Journal of Internal Medicine	No	
			CSL Behring	Sponsor for a conference on haemophilia run by the Journal of Internal Medicine	No	
			Octapharma	Sponsor for a conference on haemophilia run by the Journal of Internal Medicine	No	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			SOBI	Sponsor for a conference on haemophilia run by the Journal of Internal Medicine	No	
			Novo Nordisk	Sponsor for a conference on haemophilia run by the Journal of Internal Medicine. Also a supporter of the Haemophilia Academy Edinburgh October 2014 at which I was a speaker	No	
Professor Simon H L Thomas	None	None	None	None	No	None
Dr Christopher Weir	Reneuron Ltd	DSMB membership fees (until 14/12/14)	GE Healthcare	Responsiveness monitor - Co-funding of a research project on which I am a co-investigator	No	None
	Celgene	DSMB membership fees (Nov 2014 until 14/12/14)				
Professor Ian V D Weller	None	None	None	None	No	None

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Barbara Bannister (Acting Chair)	None	None	None	None	No	None
Dr Sanjay Bhagani	Abbvie	Fees for ad hoc advisory boards	Boehriger Ingelheim	Faldaprevir - Site PI, phase 3 StartVerso4 study		An immediate family member is an employee of Abbvie Ltd.
	Bristol-Myers Squibb	Lecture fees, ad hoc advisory boards and travel/accommodation for attendance at International Conference	Janssen	Telaprevir - Site PI, phase 3 studies 3008/3005		
	Gilead	Lecture fees and fees for attendance at ad hoc advisory board meetings	Gilead	Site PI, phase 3 Photon-2 study. Site PI, Gilead Sofosbuvir Registry		
	Janssen	Fees for developing an Educational Program, lecture fees and ad hoc advisory board meetings	Bristol-Myers Squibb	Peg-IFN-lamda Daclatasvir - UK CI, phase 3 Dimension Study		
Professor David Dockrell	Bristol-Myers Squibb	Antiretrovirals - Consultancy fee, used to support travel to meetings	ViiV	Antiretrovirals and anti-hepatitis - Provide support for lunchtime educational meetings in my clinical department	Yes	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	GlaxoSmithKline	Nrf2 agonists in development for COPD - Grant funding for a PhD and a second joint project with lab consumables looking at basis of susceptibility of lung infection in patients with COPD. One study also involves testing some Nrf2 agonist compounds developed by GSK in our assays. I also provide some consultancy on their labs assays involving macrophages and models of infection	Gilead	Antiretrovirals and anti-hepatitis - Provide support for lunchtime educational meetings in my clinical department	Yes	
	ViiV	Antiretroviral (Dolutegravir) - Chaired an educational meeting for HIV doctors. I received a fee also used to help meeting attendance	Bristol-Myers Squibb	Antiretrovirals and anti-hepatitis - Provide support for lunchtime educational meetings in my clinical department	Yes	
			Janssen-Cillag	Antiretrovirals and anti-hepatitis - Provide support for lunchtime educational meetings in my clinical department	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Merck, Sharp and Dohme	Antiretrovirals and anti-hepatitis - Provide support for lunchtime educational meetings in my clinical department	Yes	
			Abbott	Antiretrovirals and anti-hepatitis - Provide support for lunchtime educational meetings in my clinical department	Yes	
Dr Richard Hobson	None	None	None	None	No	None
Dr Susan M Hopkins	None	None	None	None	No	None
Dr Hermione Lyall	None	None	None	None	No	None
Dr Philip N Monk	None	None	None	None	No	None
Professor Kevin Moore						
Professor Robert Read	None	None	Genentech	Consultancy	No	None
Ms Hilary A Shenton	None	None	None	None	No	None
Professor Ian V D Weller	None	None	None	None	No	None

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Colin Forfar (Chair) Dr Houman Ashrafian	None	None	None	None	No	None
Dr Susan Benbow	Novo Nordisk	General insulins & GLP-1 drugs: Conference in June 2014	None	None	No	Attendance at American Diabetes Association - conference fee, hospitality and travel. N.B. I attended this after I had resigned from the committee.
Professor Peter M A Calverley						
Professor Richard Donnelly	Janssen	Canagliflozin - Consultancy	None	None	No	None
	Servier Laboratories	Gliclazide MR - Speaker Fees				
	Astra Zeneca	Dapagliflozin - Speaker Fees				
	Merck Sharp and Dohme	Sitagliptin - Consultancy				
Dr Iolo Doull	Gilead	Nebulised Aztreonam - Advisory	None	None	No	None
	Novartis	Omalizumab - Educational lecture				
	AstraZeneca	Symbicort - Educational lecture				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr John Firth	None	None	Amgen	Aranesp, Mimpara - Support of renal anaemia service / research and renal mineral and bone disease studies and of renal educational meetings	Yes	None
			Astellas	Advagraf, Prograf - Support of renal transplantation service / research and of renal educational meetings	Yes	
			Genzyme	MabCampath, Renagel, Renvela, Thymoglobuline - Support of renal mineral and bone disease studies and of renal educational meetings	Yes	
			Novartis	Sandimmun, Simulect - Support of renal transplantation service / research and of renal educational meetings	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Roche	Cellcept, NeoRecormin, Rocaltrol, Valcyte - Support of renal transplantation and renal anaemia service / research and renal mineral and bone disease studies and of renal educational meetings	Yes	
			Shire	Calcichew, Fosrenol - Support of renal mineral and bone disease studies and of renal educational meetings	Yes	
			Wyeth	Rapamune - Support of renal transplantation service / research and of renal educational meetings	Yes	
Dr Andrew Grace	Xention Ltd	Consultancy, Options	None	None	No	None
Professor Wasim Hanif	Novo Nordisk	Degludec/Liraglutide - Consultancy/PI for research/grants	Novonordisk	Liraglutide - PI for research/ Grants/Fellowship	No	None
	Sanofi	Insuman/Glargine/Lixisenatide - Consultancy/PI for research/grants	Sanofi	Non-Specific agreement with Trust - PI for research/Grants	Yes	
	Merck	Sitagliptin - Consultancy/Grants	BI	Linagliptin - PI for research/Grants	Yes	
	BI/Lilly	Linalgiptin/Empagliflozin - Consultancy/PI for research/grants	Janssen	Canagliflozin - PI for research/Grants	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Janssen	Canagliflozin - Consultancy/PI for research/grants				
	Astra Zeneca	Dapagliflozin/Bydueron - Consultancy/PI for research/grants				
Professor Richard I G Holt	Novo Nordisk	Novorapid, Novomix, Levemir, Tresiba, Xultophy, Liraglutide - 14 lectures to health care professionals, 4 advisory boards	Novo Nordisk	Various insulin plus Liraglutide - funding to develop a web-based CBT programme for people with diabetes and depression	Yes	None
	Otsuka	Aripiprazole - 2 lectures to health care professionals				
	Eli Lilly	Various insulins, duloxetine - 3 lectures to health care professionals				
	Janssen	Canagliflozin - 4 lectures to healthcare professionals, programme committee for two educational courses				
	Takeda	Pioglitazone - 1 advisory board, chaired a lecture, received funding to attend EASD meeting				
	Merck, Sharpe & Dohme	Sitagliptin - 2 advisory boards				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Sanofi Aventis	Various insulins and Lixisenatide - 1 lecture to health care professionals				
	Lundbeck	Aripiprazole - 1 lecture to health care professionals				
	Boehringer Ingelheim	Linagliptin - Funding to attend the American Diabetes Association				
Dr Philip Ind	Trinity-Chiesi	Fostair - Chairing meeting / Chairing sessions at sponsored educational meeting	None	None	No	I have signed letters to parliament and for the press lobbying against tobacco interests
	Napp Pharmaceuticals	Flutiform - Hospitality at BLF meeting (1 glass of wine)				
	GlaxoSmithKline	Relvar / Anoro - Hospitality (breakfast meeting)				
Professor Alan Jardine	OPSONA	TLR-2 blockers - DMC	None	None	No	None
	Astellas	Tacrolimus - lecture fees				
	Roche	Antiviral drugs - lecture and consultancy fees				
Professor Ann Millar	Boehringer Ingelheim	Travel grant enabling attendance at European Respiratory Society	Boehringer Ingelheim	BIBF - Clinical trial	Yes	None
			Intermune	Pirfenidone - Clinical trial	Yes	
			Gilead	GS- 6624 - Clinical trial	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Hilary Pinnock	Circle Partnerships	Private healthcare - 1,500 'restricted' shares in Circle in recognition of the contribution the practice has made to developing care pathways	None	None	No	Primary Care Respiratory Society-UK. (A registered charity which receives financial support from a number of pharmaceutical and respiratory device companies). I am a member of the education sub-committee - some of the projects are supported by unrestricted educational grants from respiratory interested Pharmaceutical Companies.
	Mundipharma	Fee for non-promotional lecture at respiratory update for Norwegian GPs				International Primary Care Respiratory Group. (A registered charity which receives financial support from a number of pharmaceutical and respiratory device companies). I am education lead - some of the projects are supported by unrestricted educational grants from respiratory interested Pharmaceutical Companies.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Boeringher Ingelheim	Fee for non-promotional lecture at national respiratory forum				Scottish Allergy and Respiratory Academy. (A national training programme and resource in allergic and respiratory disorders for healthcare professionals in primary, secondary and tertiary care and other interested individuals). I am course co-ordinator for this initiative which is supported by unrestricted educational grants from respiratory interested Pharmaceutical Companies.
	Boeringher Ingelheim	Fee for non-promotional lecture at national respiratory forum for Danish respiratory specialists (Copenhagen)				
Dr Pallav Shah	Olympus	Consultancy	PneumRX	RePneu Coil - RCT with RenPneu coils Royal Brompton Hospital and Chelsea & Westminster Hospital reimbursed for clinical trial expenses	Yes	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	PneumRX	Renew lung volume reduction coils - Lecture/workshop	ERBE, Cook medical, Immotech, Superdimension, Olympus, PneumRX, Pulmoanx	Sponsor Imperial college for bronchoscopy course	Yes	
	Pulmonax	Endobronchial valves for emphysema - Consultancy/lecture				
	Covidien	iLogic Superdimension/navigation bronchsocopy - Consultancy				
Dr Caroline Vaughan	None	None	None	None	No	None
Mr Phil Willan	None	None	None	None	No	None

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Kevin M G Taylor (Chair)	None	None	AstraZeneca	Research project and contribution to EPSRC Doctoral Training Centre in my department	Yes	None
			Boots	Contribution to EPSRC Doctoral Training Centre in my department	Yes	
			Pfizer	Contribution to EPSRC Doctoral Training Centre in my department	Yes	
			GlaxoSmithKline	Contribution to EPSRC Doctoral Training Centre in my department	Yes	
			Quadrant	Contribution to EPSRC Doctoral Training Centre in my department	Yes	
Professor Michael E Aulton	Novartis	Fees – patent advice	None	None	No	None
Professor Graham Buckton	Actavis	Consultancy	AstraZeneca	Grant	Yes	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Roxane	Rufinamide - Consultancy	Pfizer	Grant	Yes	
	Allergan	Consultancy	GlaxoSmithKline	Grant	Yes	
	Mylan	Consultancy	Alliance Boots	Grant	Yes	
	Watson	Levalbuterol - Consultancy	Quotient	Grant	Yes	
	Par	Rivastigmine - Consultancy				
Professor Derek H Calam	None	None	None	None	No	None
Professor Brian J Clark	Lundbeck Pharmaceuticals Denmark/Canada	Citalopram/s-Citalopram - Consultancy related to a suggested patent violation	None	None	No	None
Professor Ruth Duncan	None	None	None	None	No	None
Professor Gillian M Eccleston	None	None	None	None	No	An immediate family member works for Aptuit Glasgow Ltd
Mr V'lain G Fenton-May	General Pharmaceutical Council	Fitness to practice comm. (Investigating) - Fees	None	None	No	None
Professor Geoffrey W Hanlon	None	None	None	None	No	None
Dr Gillian M Hawksworth	None	None	None	None	No	None
Miss Carol Knott	Baxter	Common shares	None	None	No	None
Mr Robert A Lowe	B Braun	Sponsored a factory visit to B Braun factory in Melsingen, Germany - October 2014	None	None	No	None
Professor Christopher Marriott	Vectura Ltd	Shares	None	None	No	An immediate family member has shares in Vectura Ltd, Halation Ltd and MedPharm Ltd

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	MedPharm Limited	Shares				
	Remedica Limited	Directorship, Fees				
	Halation Limited	Directorship, Fees, Shares				
Professor Yvonne Perrie	None	None	Diagenode	Grant	Yes	None
			Izon	Grant	Yes	
			Novartis	Grant	Yes	
			Colorcon	Grant	Yes	
			Mologics	Grant	Yes	
Ms Hilary A Shenton	None	None	None	None	No	None
Professor Michael D Threadgill	None	None	None	None	No	None
Professor Peter York	Nektar Therapeutics Inc	Shares	Novobiotics	Funded project at CrystecPharma	Yes	None
	CrystecPharma	Director, Shares	Xiang Xue (China)	Funded project at CrystecPharma	Yes	
	LenaNanoceutics	Director	Takeda (USA)	Funded project at CrystecPharma	Yes	
	Intelligensys	Director	Chiesi	Funded project at CrystecPharma	Yes	

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Angela E Thomas (Chair)	None	None	Baxter	Sponsor for a conference on haemophilia run by the Journal of Internal Medicine	No	None of the support listed has been direct but through unconditional educational grants given to the organising body. I have not received any honoraria. I attended the Haemostasis Academy dinner which was arranged for all participants and teachers on the course
			Bayer	Sponsor for a conference on haemophilia run by the Journal of Internal Medicine	No	
			CSL Behring	Sponsor for a conference on haemophilia run by the Journal of Internal Medicine	No	
			Octapharma	Sponsor for a conference on haemophilia run by the Journal of Internal Medicine	No	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			SOBI	Sponsor for a conference on haemophilia run by the Journal of Internal Medicine	No	
			Novo Nordisk	Sponsor for a conference on haemophilia run by the Journal of Internal Medicine. Also a supporter of the Haemophilia Academy Edinburgh October 2014 at which I was a speaker	No	
Professor Derek H Calam	None	None	None	None	No	None
Professor Janet H Darbyshire	None	None	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Andrew J T George	Smart Targeting	I hold shares	Action Medical Research (a charity that carries out research on diseases of pregnancy and children)	Trustee (Chair of the Scientific Advisory Panel until Jan 2012)	Yes	An immediate family member acts as a consultant and advisor to a number of pharmaceutical companies. They are a hospital consultant, employed by Imperial Healthcare NHS Trust and by London NHS. I am employed by Brunel University London. This gives me a conflict of interest in studies sponsored by them. In addition the University has close links with industry and a large amount of its research is funded by industry.
	Illness	It is possible that I will be asked to review a study that is directed at the treatment of a disease or condition that I or a member of my family might have.	National Research Ethics Advisors' Panel, Health Research Agency	Chair	Yes	Previously I was employed by Imperial College London, and I retain links with researchers in that university. I am Chair of the National Research Ethics Advisors' Panel. I give talks on research ethics process to conferences, and have given talks to ethics committees that review Phase I studies.
	Lencnzer Slaght Royce Smith Griffin LLP	Antibody therapy - I provided expert advice with respect to a patent case	Imperial Health Care Partners	Director of Imperial Health Care Partners	No	As lead for gene therapy and cell therapy studies for NRES I will also review (or have reviewed) a proportion of the studies from an ethical perspective that come before the expert advisory group.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	General Medical Council	Research governance - I acted as an expert witness for a fitness to practice panel that was looking at an alleged case of research malpractice	West London REC and GTAC	Member and alternate vice chair with special responsibilities for GTAC business	No	I will also interact with a number of companies or other stakeholders as a result of their applications (or provide pre application advice). I also hold discussions with organisations that encourage and foster research in particular areas (such as the Stem Cell Catapult). I belong to a number of learned societies that are sponsored by pharmaceutical companies. I attend conferences, lectures and seminars that are sponsored by pharmaceutical companies. If I am an invited speaker at a conference or seminar then it is possible that my travel and costs will be paid for by such sponsorship.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Elwyn Griffiths	None	None	None	None	No	In March 2014 I participated, as speaker and session chariman, in an international symposium entitled “Beyond Quality” held in Istanbul organized by Sanofi, les entreprises du medicaments and the Turkish Medicines and Medical Devices Agency. My presentation was on who’s perspective and activities for convergence of regulatory approaches to biotechnology products and to biosimilars. Participants included national regulatory authorities, academics and public health service staff from several middle east and African countries, as well as from Europe. My expenses were covered by the organizers and I received an honorarium of £2000 for preparation and chairing.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						I am a member of a special advisory board of the Korean Ministry of Food and Drug Safety. I am also a member of the Board of the International Alliance for Biologicals (IABS) which has membership drawn from regulatory agencies, academia and industry (unpaid). An immediate family member is the manager of the Respiratory Clinical Research Facility, Imperial College and Royal Brompton Hospital, London. They have no personal interest in the pharmaceutcal industry.
Professor John D Isaacs	Roche Pharma and Chugai Pharma	Tocilizumab - Advisory board, speaker at company sponsored meeting	Napp Pharmaceuticals	Biosimilar infliximab - Advisory board meeting	No	I am academic lead on the MRC/ABPI consortium, an academic/industrial partnership, developing biomarkers for rheumatoid arthritis.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Pfizer	Tofacitinib - Advisory board, speaker at company sponsored meeting, chairman of investigator initiated research funding committee	Lilly	Baricitinib - Advisory board meeting	No	The industrial partners are not required to contribute financially to the partnership but contribute 'in kind' (attendance at meetings etc). I chaired the NOCRI Translational Research Partnership for Joint and Related Inflammatory Diseases from 2011-November 2014, and am now a member.
	Abbvie	Adalimumab - Attendance at international meeting (travel and accommodation), speaker at company sponsored meeting	GlaxoSmithKline	Funding of posts within the Institute of Cellular Medicine	Yes	This is a group of academic researchers who interact with industrial partners to advise on and assist with the development of their pipeline, including designing and performing early phase clinical trials:
	Bristol-Myers Squibb	Abatacept - Advisory board, speaker at company sponsored meeting	Roche	Tocilizumab - clinical trial participation	Yes	http://www.nocri.nihr.ac.uk/media/12500/nocri_trp_joint_and_related_inflammatory_disease_brochure_lr_-_october_2012.pdf . Any income derived from activities is paid to our employers

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Merck	Biosimilar infliximab - Advisory board meeting	Pfizer	Research grant	Yes	I chair the Arthritis Research UK Clinical Studies Group for inflammatory arthritis, and also sit on the MRC/DPFS and stratified medicine funding panels. In both of these roles I may receive applications that incorporate an Industry partner.
	Boehringer	Biosimilar infliximab - Advisory board meeting	Genzyme	Research grant	Yes	I am currently in receipt of an MRC/Biomedical Catalyst research grant in partnership with the SME Cyclacel.
	Celltrion	Biosimilar infliximab - Advisory board meeting				
Dr Helen J Lachmann	Novartis	Ilaris - Fees, consultancy	Novartis	Principal Investigator on trial	Yes	None
	SOBI	Anakinra - Part funding of travel for EULAR consensus group meetings	None	None	No	None
Professor Christopher Mason						
Professor Elizabeth Miller	None	None	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Siraj Misbah	None	None	CSL Behring	UK National Co-ordinator for multicenter,open-label extension study of IgPro20 in maintenance treatment of chronic inflammatory demyleinating polyneuropathy (CIDP) in patients completing study IgPro20_3003	Yes	20% SCIg – IgPro20 Hizentra. Honorarium will be paid into departmental funds
Professor Clive W Mulholland						
Professor B Kevin Park	None	None	Janssen Pharmaceutica N.V.	Project grant on the role of the Nrf2 system in DILI	Yes	None
			AstraZeneca	Joint supervision on AZ sponsored BBSRC CASE studentship	Yes	
			GlaxoSmithKline	Supervisor on GSK funded PhD studentship	Yes	
			Pfizer	Pfizer award for innovative science	No	
			Merck	Donation for the Centre for Drug Safety Science	Yes	
			Merck	Project grant on translational biomarkers for DILI	Yes	
			Amgen	Project grant on Keap1-Nrf2 system	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Andrew Pollard	None	None	Johnson and Johnson	Ebola vaccine - Grant to Oxford University (PI MD Snape)	Yes	Chair of JCVI
			Novartis	Bexsero - Grant to Oxford University (PI MD Snape)	Yes	
			GlaxoSmithKline	Synflorix (PCV10) - Grant to Oxford University (Phase IV vaccine trial)	Yes	
			Okairos	RSV vaccine - Grant To Oxford University (Phase I vaccine trial)	Yes	
			Pfizer	Prevenar 13 - Grant to Oxford University (pneumococcal carriage study)	Yes	
			Pfizer	Grant to Oxford University (epidemiological study of meningitis in children)	Yes	
			Pfizer	Meningococcal vaccine - Grant to Oxford University (vaccine trial)	Yes	
Dr Stephen Poole	Debiopharm International S.A.	Monoclonal antibodies - Consultancy	None	None	No	None
Professor Robert Read	None	None	Genentech	Consultancy	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Peter F Searle	Amgen	Oncolytic viruses - I contributed presentations at a training day on melanoma and oncolytic viruses, organised for amgen employees by University Hospitals Birmingham NHSFT; for which I was paid a fee	None	None	No	I have worked, and continue to work, in the field of cancer gene therapy. My group has conducted gene therapy clinical trials in collaboration with biotech/pharmaceutical companies. We have an ongoing trial, and are working towards clinical trials of further gene therapy agents. I have on occasion undertaken paid consultancy work for biotech/pharmaceutical companies and may do so again in the future. I also advise the University Hospitals Birmingham NHSFT on matters relating to biological safety of genetically modified organisms.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						Since February 2010, my research group has held a Licence Agreement with Crucell Holland BV, relating to the use of PER.C6 technology for manufacture of our genetically modified adenovirus, AdNRGM, and its subsequent use in clinical trials. This arrangement has involved both the payment of fees to Crucell, and granting Crucell certain rights over the AdNRGM virus. I am also involved with others in discussions with Oncos Therapeutics (Finland), about a possible collaboration leading to clinical trials, and we have MTA with them providing access to some of their viruses for laboratory research.
Professor Kevin Shakesheff						
Mrs Margaret V Shotter	None	None	None	None	No	None
Professor Owen Thomas						
Mrs Madeleine Wang	None	None	None	None	No	Abbvie - an immediate family member received member fees and hospitality expenses

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Christopher Weir	Reneuron Ltd	DSMB membership fees (until 14/12/14)	GE Healthcare	Responsiveness monitor - Co-funding of a research project on which I am a co-investigator	No	None
	Celgene	DSMB membership fees (Nov 2014 until 14/12/14)				

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Anthony G Wilson (Chair)	Hospira	Lecture on Biosimilars x 2	Pfizer	Tofacitinib - Fees for chairing Ad Board	No	None
	Celltrion	Inflectra - Ad Board	UCB	Certulizumab - Research Grant	No	
	Abbvie	Discussion on research potential research collaboration				
	Bristol-Myers Squibb	Abatacept - Ad Board				
	Cellgene	Apremilast - Ad Board				
	Bristol-Myers Squibb	Attendance at EULAR AGM in Paris				
Dr Ian Barrison	GlaxoSmithKline	Shares	None	None	No	None
Professor Deborah Bax	None	None	None	None	No	AstraZeneca and GlaxoSmithKline shares are held within an immediate family member's ISAs

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Mr David Chandler	None	None	None	None	No	I'm employed by a patient charity, but the charity has a policy not to receive any funding or financial support whether monetary, in kind or via a third parties from pharmaceutical companies or other commercial organisations. Any events or meetings I attend in relation to my work for the charity are funded by the charity, this includes: registration fees, travel, subsistence and accommodation. An immediate family member also works for the same charity, and the above also applies to them. No other members of my immediate household have any connections or financial interests in the pharmaceutical industry or associated organisation.
Professor David Gawkrodger (Vice-Chair)	GlaxoSmithKline	Shares	None	None	No	None
	AstraZeneca	Shares				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Clive Grattan	Novartis	Omalizumab - honoraria for Symposium talks Advisory Board for RTI concerning research studies	Novartis	Chief Investigator of two data collection studies	Yes	None
	GlaxoSmithKline	GSK 200196 under development - consultancy	AB Science	Masitinib - Chief Investigator phase III study	Yes	
	CSL Behring	CSL830 trial - Chair, DSMB				
Dr Richard Groves	KArus Therapeutics	Experimental HDAC and PI3 kinase inhibitors - Scientific advisory board	None	None	No	None
Professor John D Isaacs	Roche Pharma and Chugai Pharma	Tocilizumab - Advisory board, speaker at company sponsored meeting	Napp Pharmaceuticals	Biosimilar infliximab - Advisory board meeting	No	I am academic lead on the MRC/ABPI consortium, an academic/industrial partnership, developing biomarkers for rheumatoid arthritis.
	Pfizer	Tofacitinib - Advisory board, speaker at company sponsored meeting, chairman of investigator initiated research funding committee	Lilly	Baricitinib - Advisory board meeting	No	The industrial partners are not required to contribute financially to the partnership but contribute ‘in kind’ (attendance at meetings etc). I chaired the NOCRI Translational Research Partnership for Joint and Related Inflammatory Diseases from 2011-November 2014, and am now a member.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr John C Mansfield	Abbvie	Adalimumab - Attendance at international meeting (travel and accommodation), speaker at company sponsored meeting	GlaxoSmithKline	Funding of posts within the Institute of Cellular Medicine	Yes	This is a group of academic researchers who interact with industrial partners to advise on and assist with the development of their pipeline, including designing and performing early phase clinical trials:
	Bristol-Myers Squibb	Abatacept - Advisory board, speaker at company sponsored meeting	Roche	Tocilizumab - clinical trial participation	Yes	http://www.nocri.nihr.ac.uk/media/12500/nocri_trp_joint_and_related_inflammatory_disease_brochure_lr_-_october_2012.pdf . Any income derived from activities is paid to our employers
	Merck	Biosimilar infliximab - Advisory board meeting	Pfizer	Research grant	Yes	I chair the Arthritis Research UK Clinical Studies Group for inflammatory arthritis, and also sit on the MRC/DPFS and stratified medicine funding panels. In both of these roles I may receive applications that incorporate an Industry partner.
	Boehringer	Biosimilar infliximab - Advisory board meeting	Genzyme	Research grant	Yes	I am currently in receipt of an MRC/Biomedical Catalyst research grant in partnership with the SME Cyclacel.
	Celltrion	Biosimilar infliximab - Advisory board meeting				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Kevin Moore	Servier	Agomelatine - Consultancy	None	None	No	None
Dr Frances Williams	None	None	Pfizer	Grants held by Dept of Twin Research, KCL, to study chronic pain and metabolomics	No	None
			Globus	Grant held by Dept of Twin Research, KCL, for spine research	Yes	
Professor Patricia Mang Ming Woo	Roche	Tocilizumab - PI and CI of clinical trial in sJIA. No personal renumeration				
			None	None	No	None
	Novartis	Canakinumab - PI and CI of clinical trial in sJIA. No personal renumeration				
	GlaxoSmithKline	Belimumab - Chair of independent data monitoring committee of a phase III trial in juvenile SLE. Fees received for WebEx conference x 2				

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Ailsa Gebbie (Chair)	None	None	None	None	No	None
Professor Juliet Compston	None	None	None	None	No	None
Dr Katherine Darton	None	None	None	None	No	None
Dr E Jane Dickson	None	None	None	None	No	None
Professor Philip Hannaford	None	None	None	None	No	None
Dr Sally Hope	Amgen	Denosumab - Lecture fee/Educational grant to Bone Metabolic Dept, Nuffiled Orthopaedic Centre, to pay my time to talk to Oxfordshire GPs about the whole of osteoporosis including NICE guidelines/QoF and all treatments	Abbott Labs	Lecture Fee - HRT GP Round table discussion and article in GP magazine	No	Medical Primary Care advisor [unpaid] to the National Osteoporosis Society ; RCGP representative on the Menopause NICE guidelines group [2013-2015] unpaid; Deputy Editor of Maturitas Journal [Elservier]: paid
	Consilient Health	Vitamin D - Paid to lecture GPs the clinical importance of Vitamin D in Bone health				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Haymarket Medical Publishing	Lecture fee for GP education day in London. Talks and workshop on antibiotic stewardship and overactive bladder but I believe Haymarket were sponsored by drug companies for this GP education day				
Professor Mary Lumsden (Vice-Chair)	None	None	None	None	No	None
Professor Julietta Patnick	AstraZeneca	19 shares	None	None	No	None
Professor Siobhan Quenby	None	None	Abbvie	EGOLIX - Local principle investigator in trial, I receive no money but my hospital receives money to cover costs per patient recruited	Yes	None
			Nora Therapeutics	GCSF - Local principle investigator in trial, I receive no money but my hospital receives money to cover costs per patient recruited	Yes	
Carolyn, Lady Roberts	None	None	None	None	No	Member of Council, University of Hull
Mrs Margaret V Shotter	None	None	None	None	No	None
Professor Jonathan Tobias	Eli Lilly	Forsteo - Speaker fees	Amgen	Denosumab - Research grant to my department	Yes	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Amgen	Denosumab - Speaker fees				

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor David G C Owens (Chair) Dr Jonathan Cavanagh Dr Beverley Jane Collett	None	None	None	None	No	None
Professor John Duncan	Ervitech	Apnoea detector - Founder shareholder	Medtronic	Neuronavigation systems - Research collaboration	Yes	None
Dr Nicholas Fletcher Mr Michael Harnor	Smith and Nephew	Shares	None	None	No	I am a trustee and company director for the British Epilepsy Association (working name Epilepsy Action) and am a former Chairman. (Whole year) This body is a registered charity and a company limited by guarantee. The Association receives from time to time financial grants for particular purposes from healthcare industry companies.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	AstraZeneca	Shares				These vary in amount from year to year but in conformity to the charity's own policies do not do not exceed 15% of total income. Under the ABPI Code of Practice for sponsorship any awards provide no influence whatsoever upon decisions regarding the operations of the charity. As a trustee/director of the charity there is no mechanism whereby I can receive and quantifiable or notional personal benefit other than repayment of travel expenses already incurred.
	GlaxoSmithKline	Shares				
	Worldwide Healthcare Trust	Shares (listed investment trust)				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
		All those listed are held as nominee investments in a self- select ISA account with Barclays. Consequently my personal name does not appear in the share registers and I am unable to have any direct influence upon company policies.				I am vice chair of the Association's research committee. I have in the past year been in receipt of one training day meeting for the Epilepsy Action Commissioning Advocates scheme which received an educational grant from UCB Pharma. I am an elected public governor for the North-West Ambulance NHS Trust (Whole year). I am an accredited lay member of research ethics committees (north west) NRES/ HRA. (Whole year). I am also an ordinary member of Headway - the Brain Injury charity which supports research.
Dr Anthony L Johnson	None	None	None	None	No	None
Professor Malcolm R Macleod	None	None	None	None	No	None
Professor John T O'Brien	GE Healthcare	Flurbetaben - Lecture Fees	Lilly	Flurbetapir - Investigator initiated grant	Yes	None
	TauRx	Methylthioninium - Consultancy				
	Lilly	Flurbetapir - Advisory board meeting and lecture fees				
	Cytox	Diagnostic blood test for dementia - Consultancy				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Martin Rossor						
Professor Peter A G Sandercock	None	None	Boehringer Ingelheim	Actilyse - I am chief investigator of an MRC-funded trial of the drug	No	None
			Boehringer Ingelheim	Actilyse - Lecture fees (paid to the Division of Clinical Neurosciences, University of Edinburgh) and travel expenses for occasional lectures given at international conferences in the past	No	
			Boehringer Ingelheim	Dabigatran - Member of the Independent Data and Safety Monitoring Board (DSMB) of the Randomized Evaluation of Long-Term Anticoagulation Therapy (RE-LY)	No	
			GlaxoSmithKline	Darapladib - Member of the Independent DSMB for the Phase 3 studies of Lp-PLA2 inhibitor (darapladib) (STABILITY and SOLID)	No	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Merck	Anacetrapib - Chair of the Independent DSMB for Randomized EValuation of the Effects of Anacetrapib through Lipid-modification (REVEAL)	Yes	
			Merck	Ezetimibe - Chair of the Independent DSMB for SHARP trial	No	
			Pfizer	Tranexamic acid - Independent Chair of the Steering Committee for the NIHR funded CRASH-3 trial	Yes	
Dr Catherine F Stannard	None	None	None	None	No	None
Professor Eric A Taylor	None	None	None	None	No	None
Dr Christopher Weir	Reneuron Ltd	DSMB membership fees (until 14/12/14)	GE Healthcare	Responsiveness monitor - Co-funding of a research project on which I am a co-investigator	No	None
	Celgene	DSMB membership fees (Nov 2014 until 14/12/14)				
Dr John B Winer	None	None	Novartis	Fingolomid - About to start trial of drug in patients with chronic Inflammatory demyelinating neuropathy	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			CSL Behring	Privigen Ig - Attended sponsored neuro advisory board for one day in London	No	
			CSL Behring	Privigen - Sponsored attendance Peripheral Nerve Society Meeting in St Malo France	No	
			LFB Biotechnology	I10E Immunoglobulin - About to start trial in CIDP	No	

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Martin Gore (Chair from 01/09/14, previously a Member)	None	None	None	None	No	None
Dr Angela E Thomas (Acting Chair until 31/08/14, then continued as a Member)	None	None	Baxter	Sponsor for a conference on haemophilia run by the Journal of Internal Medicine	No	None of the support listed has been direct but through unconditional educational grants given to the organising body. I have not received any honoraria. I attended the Haemostasis Academy dinner which was arranged for all participants and teachers on the course
			Bayer	Sponsor for a conference on haemophilia run by the Journal of Internal Medicine	No	
			CSL Behring	Sponsor for a conference on haemophilia run by the Journal of Internal Medicine	No	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Octapharma	Sponsor for a conference on haemophilia run by the Journal of Internal Medicine	No	
			SOBI	Sponsor for a conference on haemophilia run by the Journal of Internal Medicine	No	
			Novo Nordisk	Sponsor for a conference on haemophilia run by the Journal of Internal Medicine. Also a supporter of the Haemophilia Academy Edinburgh October 2014 at which I was a speaker	No	
Mrs Eileen J Barrett	None	None	None	None	None	None
Professor Mark D Bower	ViiV	Speaker fees	None	None	No	None
	BMS	Speaker fees				
	Boehringer Ingleheim	Speaker fees				
	Gilead	Speaker fees				
	Janssen	Speaker fees				
Professor Stephen Devereux	Roche	Rituximab and Obinutuzumab - Conference travel, Advisory boards	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Janssen	Ibrutinib - Speaker fees & travel				
	Gilead	Idelalisib - Advisory board & conference travel				
	Janssen	Ibrutinib - Advisory board				
Dr Chris Gallagher	Amgen	Denosumab - Fees for lectures	None	None	No	None
Dr Charlie Gourley	None	None	Roche	Bevacizumab - Consultancy Conference travel and accommodation Lecture Fees	Yes	None
			AstraZeneca	Olaparib, Cediranib - Consultancy Conference travel and accommodation Lecture Fees Commercially sponsored clinical research	Yes	
Professor John Gribben Professor Barry W Hancock Professor Peter Hillmen	None	None	None	None	No	None

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Rebecca Mann (Chair)	None	None	None	None	No	None
Dr Eileen M Baildam	Abbvie	Adalimumab - Small consultancy fee for single Expert Advisory Group meeting	Merck	Odanacatib - I am PI for ongoing drug trial in the department	Yes	None
	Abbvie	Adalimumab - Small educational grant to attend PRES scientific meeting	GlaxoSmithKline	Belimumab - I am PI for ongoing drug trial in the department	Yes	
			Roche	Rituximab - I am PI for ongoing drug trials in the department	Yes	
			Roche	Tocilizumab - I am PI for ongoing drug trials in the department	Yes	
			Abbvie	Adalimumab - I am investigator for ongoing drug trial in the department	Yes	
Dr Helen Burdett	None	None	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Steven Cunningham	Gilead	Cayston (Aztreonam) - Consultancy	Ablynx	ALX-0171 - Consultancy via NHS Lothian. International Coordinating Investigator for this investigational medical product	Yes	None
			Alios	ALS-8176 - Principle Investigator for this investigational medical product	Yes	
			Vertex	Ivacaftor - Principle Investigator for this medical product	Yes	
Professor Peter C Hindmarsh	Medtronic Diabetes	Medtronic Insulin Pump - Consultancy for Product Development	None	None	No	None
	Pfizer	Growth Hormone - Participation in Pfizer sponsored satellite symposium at the 53rd Annual ESPE Meeting				
	Eli Lily	Growth Hormone - Lecture to Portuguese Paediatric Endocrinologists in Lisbon on Congenital Adrenal Hyperplasia				
Dr Meriel Jenney	None	None	None	None	No	None
Professor Nigel Klein	None	None	None	None	No	None
Ms Fiona Lynch	None	None	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Rubin Minhas	None	None	None	None	No	I am an unpaid member of the following committees at this time: BMJ Ethics Committee Dr Foster Ethics Committee NICE Quality Standards Committee
Professor Marie-Louise Newell	Merck Sharp & Dohme	One general HIV epidemiology lecture at the 4th HIV symposium, Hamburg, 24 Jan 2014, for which accommodation and travel was paid, and a small fee	None	None	No	None
Professor Anthony Nunn	None	None	None	None	No	I was a member of the EMA Paediatric Committee until 31 July 2014. I am a registered scientific expert with EMA and a member of the EMA PDCO Formulation Working Group. I am a member of the European Paediatric Formulations Initiative (EuPFI, www.eupfi.org)
Ms Sara Payne	None	None	None	None	No	An immediate family member represents pharmaceutical and medical device companies in patent law disputes, both UK and non UK
Professor Shirley Price	None	None	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Jane Tizard	GlaxoSmithKline	Shares	Otsuka Pharmaceutical	Longitudinal observational study of patients with ADPKD Protocol 156-10-291 (not a clinical trial but sponsored by pharmaceutical sponsor)	No	None
			Mitsubishi Pharma (Europe)	MCI-196-E15 Long term open label extension study of colestilan for participants previously in E14 or E16 protocols. MCI-196-E14-RCT of colestilan in children CKD stage 5 ON dialysis. MCI-196-E16: RCT of colestilan in children with CKD stage 3b - not on dialysis. Department will be paid for patients entered. I am not an investigator but my patients could be enrolled.	Yes	
Dr Beverly Tsai-Goodman	None	None	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Catherine L C Tuleu	None	None	Novartis; Piramal Healthcare; Roche; Sanofi; Abbvie; Boehringer; Ingelheim Pharma GmbH; GlaxoSmithKline; Merck Sharp & Dohme; Janssen; Pfizer	These companies contribute in membership to the European Paediatric Formulation Initiative (EuPFI) which is a consortium working in a pre-competitive way on paediatric drug formulations. Members are from academia, hospital pharmacies, pharmaceutical industry (Innovators, Generics,Contract Research Organizations (CRO), Specials and Excipient Manufacturers) with European Medicine Agency (EMA) as an observer.	Yes	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
				Its main aim and objective is to identify/scope issues and challenges in paediatric formulation development in order to raise awareness and facilitate preparation of better/safe medicines for children.		
			GlaxoSmithKline; Novartis; Pfizer	Grants to support a PhD studentship	Yes	
Professor Heather M Wallace	Novabiotics (University spin out company)	Shares	GlaxoSmithKline	Letter request for support for EUROTOX 2014	No	None
	Antoxis (University spin out company)	Shares	AstraZeneca	Letter request for support for EUROTOX 2014	No	
	Precious Cells	Shares	Syngenta	Letter request for support for EUROTOX 2014	No	
	Cell ProTx	Shares	Covance	Letter request for support for EUROTOX 2014	No	
			Shire	Letter request for support for EUROTOX 2014	No	
			Roche	Letter request for support for EUROTOX 2014	No	
			Unilever	Letter request for support for EUROTOX 2014	No	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Mrs Madeleine Wang	None	None	None	None	No	Abbvie - an immediate family member received member fees and hospitality expenses
Dr Mark Whiting	None	None	None	None	No	None
Dr Morris Zwi	None	None	None	None	No	None

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Mr Harry Cayton (Chair)	None	None	None	None	No	None
Ms Hellen Adom	None	None	None	None	No	None
Mrs Alison Bowser	None	None	None	None	No	None
Mr David Chandler	None	None	None	None	No	I'm employed by a patient charity, but the charity has a policy not to receive any funding or financial support whether monetary, in kind or via a third parties from pharmaceutical companies or other commercial organisations. Any events or meetings I attend in relation to my work for the charity are funded by the charity, this includes: registration fees, travel, subsistence and accommodation.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						An immediate family member also works for the same charity, and the above also applies to them. No other members of my immediate household have any connections or financial interests in the pharmaceutical industry or associated organisation.
Mr John Chapman	None	None	None	None	No	None
Mrs Joyce Epstein	None	None	None	None	No	None
Dr Nicola Jane Gray	AstraZeneca	Inhalers - Support of Evaluation Project	Pfizer Inc USA	Corporate sponsor of annual meeting of an organisation where I am on the board (US Society for Adolescent Health and Medicine)	Yes	An immediate family member is contracted to provide a system to GlaxoSmithKline for collection of data in community pharmacy project
	Boehringer Ingleheim	Inhalers - Support of Evaluation Project				
	Chiesi	Inhalers - Support of Evaluation Project				
	Clement Clarke	Inhalers - Support of Evaluation Project				
	GlaxoSmithKline	Inhalers - Support of Evaluation Project				
	Napp Pharmaceuticals	Inhalers - Support of Evaluation Project				
	Teva	Inhalers - Support of Evaluation Project				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Ms Amanda Hoey	None	None	None	None	No	I am an independent consultant. I have a contract with the BMJ to provide health care policy analysis and strategy advice. The BMJ has advertising and sponsorship contracts with the pharmaceutical industry which follow a strict code of practice, including separation between the editorial and pharma ad sales teams. I do not work directly on projects or journals that receive pharma advertising or sponsorship. An immediate family member is an Executive Director of BMJ.They lead the Clinical Improvement Division which develops clinical decision support and education products to help doctors improve care and outcomes for patients. These include BMJ Learning, BMJ Quality, BMJ Masterclasses, BMJ Best Practice and BMJ Informatica.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						Some of these products are licensed by pharmaceutical companies who make the content freely accessible to clinicians internationally. Others receive pharmaceutical company sponsorship (e.g. the International Forum on Quality and Safety in Healthcare and BMJ Masterclasses). The BMJ retains full editorial control over all its content and how it is used.
Mrs Anne Joshua	None	None	None	None	No	Advisory Board member for DataPharm Medicines Guides. The group had nil meetings in 2014 and closed down within the year. An immediate family member is Director of a market research company that provides services to the biopharmaceutical global industry.
Professor Angus Mackay	None	None	None	None	No	None
Mrs Farrah Pradhan	None	None	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor DK Theo Raynor	None	None	AbbVie	ABT-450/ritonavir/ABT-267 plus ABT-333, Kaletra, Norvir - Advice on wording of RMP Lay Summaries	No	I founded a University spin-out company, Luto Research Ltd in 2004. The company provides patient information development and testing services to pharmaceuticals companies and other healthcare information providers.
			AbbVie	Duodopa, Norvir - Advice on wording and layout of patient leaflets and IFUs	No	The company was sold in 2009 and I remain academic advisor. I provide research-based input into the work of the company. This includes providing advice on specific leaflets before and after testing.
			Basilea	Cresemba - Advice on wording and layout of patient leaflet	No	Sometimes this is minor input - for example advising on the wording a particular point of information or section. Other times it is more major - if it is a particularly complex leaflet.
			Boehringer Ingelheim	Buscopan Cramps Relief & Buscopan IBS Relief - Advice on wording and layout of patient leaflets & packaging	No	I have no shareholding in the company. My principal employment remains as an academic at the University of Leeds, where I spend the majority of my time.
			Celgene	Revlimid - Advice on wording and layout of patient leaflet	No	At meetings I will declare a 'personal interest' if a particular leaflet on which I have given advice is on the agenda.

MEMBER	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS	WHETHER CURRENT	ADDITIONAL INFORMATION
			Duchesnay	Diclectin - Advice on wording and layout of patient leaflet	No	In terms of 'non-personal interests', I have listed those leaflets where I have provided significant levels of advice on layout and wording in 2014.
			Eisai	Lenvatinib, PIL template - Advice on wording and layout of patient leaflets	No	
			GSK Biologicals	Rotarix IFU - Advice on wording and layout of IFU	No	
			Helsinn Birex	Akynzeo - Advice on wording and layout of patient leaflet	No	
			Hyperion Therapeutics	Ravicti - Advice on wording and layout of patient leaflet	No	
			Moltini	Levomethadone - Advice on wording and layout of patient leaflet	No	
			MSD	Long Acting Reversible Contraception (LARC) - Advice on assessment of educational materials (no specific product)	No	
			MSD	Zontivity - Advice on wording and layout of patient leaflet	No	
			Novartis	Signifor, Farydak - advice on wording and layout of patient leaflet	No	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Novo Nordisk	Ideglira, Xultophy, Novo Thirteen - Advice on wording and layout of patient leaflet & educational materials for professionals	No	
			Phebra	Methylene Blue - Advice on wording and layout of patient leaflet	No	
			Rosemont	Sertraline - Advice on wording and layout of patient leaflet	No	
			Sanofi Aventis	Mercury manually operated injector, Praluent - Advice on wording and layout of patient leaflet	No	
			UCB	Brivaracetam - Advice on wording and layout of patient leaflet	No	
Carolyn, Lady Roberts	None	None	None	None	No	Member of Council, University of Hull
Mrs June Rogers	None	None	Norgine Pharmaceuticals Limited	Donation of £500 to sponsor bowel care award – paid to winner	No	None
			Norgine Pharmaceuticals Limited	Sponsorship of training event re nice quality standards childhood constipation – paid to charity disabled living	No	
			Ferring Pharmaceuticals	Unrestricted core funding grant to disabled living	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Bella Starling	None	None	Innovative Medicines Joint Undertaking (European Commission and European Federation of Pharmaceutical Industries and Associations)	European Patient Academy on Therapeutic Innovations EUPATI - Grant Beneficiary is University of Manchester. Dr Starling is Workpackage leader/principal investigator for University of Manchester	Yes	None
Mr Paddy Storrie	None	None	None	None	No	An immediate family member does occasional paid work for Coloplast and Shire Pharmaceuticals, chairing training and presenting at conferences. They are an NHS clinical nurse specialist in gastroenterology.
Mr Phil Willan	None	None	None	None	No	None

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Munir Pirmohamed (Chair)	None	None	GlaxoSmithKline	NP, NS Support of the MRC Clinical Pharmacology Training Scheme	Yes	None
			Astra Zeneca	NP, NS Support of the MRC Clinical Pharmacology Training Scheme	Yes	
			Pfizer	Bosutinib - Research grant to investigate mechanisms of diarrhoea associated with bosutinib	Yes	
Dr Robert C G Bracchi	None	None	None	None	No	None
Dr Jamie Coleman	None	None	None	None	No	None
Dr William Dixon	None	None	None	None	No	None
Dr Ian J Douglas	GlaxoSmithKline	Share holding	None	None	No	None
	GlaxoSmithKline	HIV portfolio				
		Paroxetine (1012 only) - Consultancy				
	Gilead	HIV portfolio - Consultancy				
Professor Alison B Ewing	None	None	None	None	No	None
Ms Amanda Lee	None	None	None	None	No	None
Professor Glyn Lewis	None	None	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Simon R J Maxwell	None	None	None	None	No	None
Dr Karen Miller	None	None	None	None	No	None
Dr Nicholas J Plant	Boehringer Ingelheim	GLP-1 and DPP4 inhibitors - Consultancy	AstraZeneca	BBSRC-CASE funded PhD student	Yes	None
	Zealand Pharma	GLP-1 and DPP4 inhibitors - Consultancy	Pfizer	BBSRC-CASE funded PhD student	Yes	
			Breast Cancer Campaign	PhD Student	Yes	
Professor Alan Silman	None	None	None	None	No	None
Dr Ruben Thanacoody	None	None	None	None	No	None
Dr Caroline Vaughan	None	None	None	None	No	None
Professor Patrick Waller	None	None	None	None	No	None
Mr Phil Willan	None	None	None	None	No	None

EXTERNAL EXPERTS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Leon Aarons	Eli Lilly	Consultancy	AstraZeneca	Research Funding	Yes	None
			AstraZeneca	Case Studentship	Yes	
			GlaxoSmithKline	Research Funding	Yes	
			Eli Lilly	Research Funding	Yes	
			Pfizer	Research Funding	Yes	
			Johnson & Johnson	Research Funding	Yes	
Professor D John Betteridge	Takeda	During 2014 I presented lectures at a meeting sponsored by Taxeda	None	None	No	None
Dr Andrew Bowhay	None	None	None	None	No	None
Mr Chris Chapple	Allergan	Speaker and Consultant	Allergan	Research Grant and Trial Participation	Yes	None
	Astellas	Speaker and Consultant	Astellas	Research Grant and Trial Participation	Yes	
	Pfizer	Speaker and Consultant	Pfizer	Research Grant and Trial Participation	Yes	
	Recordati	Speaker and Consultant	Recordati	Research Grant and Trial Participation	Yes	
Professor Peter Clayton	None	None	Merck Serono	Saizen (recombinant human growth hormone) - Chief Investigator for the PREDICT studies; Consultant to Merck Serono on matters related to PREDICT	Yes	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Thomas Clutton-Brock	None	None	None	None	No	Senior Medical Officer (Part-time) Devices Clinical, MHRA; Medical Advisory Board (Paid), Sphere Medical, Cambridge (Medical Devices); Clinical Director NIHR Trauma Management Health Technology Cooperative (Medical Devices)
Professor Gordon Cook	Janssen	Bortezomib, Daratumumab - Consultancy, Speaker Bureau	Celgene	Thalidomide, Lenalidomide, Pomalidomide - Research grant	Yes	None
	Celgene	Thalidomide, Lenalidomide, Pomalidomide - Consultancy, Speaker Bureau	Takeda Millennium	Ixazomib - Research Grant	Yes	
	Onyx/Amgen	Carfilzomib - Consultancy				
	Sanofi	Plerixafor - Consultancy				
	Jazz Pharmaceuticals	Defibreotide - Consultancy, Speaker Bureau				
	Takeda Millennium	Ixazomib - Consultancy				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Peter Crome	None	None	None	None	No	Paid appointment as Dementia Lead for the Comprehensive Research Network, West Midlands. In this role I support the delivery of both commercial and non-commercial dementia research projects. Member of NICE Technology Appraisal Committee C; Honorary Professor, University College London; Emeritus Professor, Keele University; Honorary Consultant, Royal Free Hospital
Professor Karen Forbes	None	None	None	None	No	None
Professor Jayne Franklyn						
Dr Robin Grant	UCB Pharma	Fees: Lecture on Masterclass to Neurologists in London. Fees donated to brain tumour charity	UCB	Lacosamide - UK Lead on a Planned RCT of Lacosamide vs Placebo as Prophylaxis in Patients with Glioblastoma who do not have epilepsy	Yes	None
	UCB Pharma	Lacosamide - Consultancy: Advice on European Trial of Lacosamide. Fees donated to brain tumour charity	UCB	Lacosamide - European Lead on a Non-Intervention Study of Efficacy and Side Effects in Low Grade Glioma patients with Epilepsy	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Clive Grattan	Novartis	Omalizumab - honoraria for Symposium talks Advisory Board for RTI concerning research studies	Novartis	Chief Investigator of two data collection studies	Yes	None
	GlaxoSmithKline	GSK 200196 under development - consultancy	AB Science	Masitinib - Chief Investigator phase III study	Yes	
	CSL Behring	CSL830 trial - Chair, DSMB				
Professor Paul Griffiths	None	None	GE Healthcare	Institutional research partnership	Yes	None
			Philips Medical Systems	Institutional research partnership	Yes	
Professor Nedim Hadzic	Alnylam Pharmaceutics, Boston, Mass	Drug development for alpha-1-antitrypsin deficiency - Ad hoc consultant	None	None	No	None
Professor Freddie Hamdy	None	None	None	None	No	None
Professor Jonathan Hill	Lilly	Amyvid UK training one day course for scan interpretation held in London. Required for all UK nuclear medicine/ radiologist clinicians to comply with ARSAC certificate regulations - Hotel 6/3/14 and rail travel paid by Lilly	None	None	No	None
Dr Nigel Hoggard	None	None	General Electric	Department has research agreement in place	Yes	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Philips Medical Systems	Department has research agreement in place	Yes	
			Ansys	Ansys have supplied several licences as part of an MRC infrastructure grant I am a co-investigator on	Yes	
Professor David Isenberg	Merck-Serono	Atacicept - I advise re. likely benefits/side-effects. I ask for my fees to be paid to a local arthritis charity	None	None	No	None
	Eli-Lilly	Tabalimumab, Eprutuxumab and Blisibimab - I advise re. likely benefits/side-effects. I ask for my fees to be paid to a local arthritis charity				
Professor Colin Kennedy	None	None	None	None	None	None
Professor Karen Luker	None	None	None	None	No	None
Professor Hugh MacDougall	None	None	None	None	No	None
Mr Paul Maltby	None	None	None	None	No	None
Dr Harriet Mitchison	Norgine	Rifaximin - Subsidy to attend conference	None	None	No	None
Professor Michael O'Doherty						
Professor Robert Pickard	None	None	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Stephen Powis	Novartis	Transplant related products - I was paid through a one-off contractual arrangement for speaking in an after-dinner debate at an educational meeting for transplant professionals. The debate was entitled 'current regulation is murdering innovation'.	None	None	No	None
Professor Shakeel Qureshi	NuMED Inc, Hopkinton, New York, USA Medtronic Inc Abbott Inc	Paediatric cardiology related balloons and stents - Consultancy Melody valve - Proctor on an ad hoc basis Cardiovascular products - Shares	None	None	No	None
Dr Patricia Richardson	None	None	None	None	No	None
Dr Jonathan Ross	None	None	None	None	No	None
Professor Amin Rostami	Certara	Shares via Certara's Holding Company, contribution to university salary	None	None	No	The following Pharmaceutical companies are part of the Simcyp Consortium and they are relied on to fund research in Simcyp:

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Diurnal	Shares				Abbvie, Actelion, Amgen, Astellas Pharma Inc., AstraZeneca, Biogen Idec, Bristol Myers Squibb, Celgene Corporation, Daiichi-Sankyo, Dainippon-Sumitomo, Eisai, Eli Lilly, F. Hoffmann-La Roche Ltd, Forest Laboratories, GlaxoSmithKline, Grunenthal, H Lundbeck A/S, Johnson & Johnson Pharmaceutical Research & Development,
	Zilico	Shares & a Non-Exec Director				Merck & Co., Merck KGaA, Nektar Therapeutics, Novartis Pharma, Ono Pharmaceutical Co, Otsuka Pharmaceutical Group, Pfizer, Sanofi-aventis, Servier, Shionogi & Co., Taisho Pharmaceutical, Takeda, UCB Pharma, Vertex Pharmaceuticals

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Diurnal	Shares				Prof Rostami-Hodjegan is also a member of the Centre for Applied Pharmacokinetic Research (CAPKR) group at the University of Manchester. CAPKR is a consortium operating in collaboration with, and supported by the pharmaceutical industry. CAPKR's industrial consortium members represent the following pharmaceutical companies: GlaxoSmithKline, Janssen Pharmaceutica NV, Eli Lilly, Pfizer.
Dr Lindsey Rylah						
Dr Andrew Scarsbrook	None	None	None	None	No	None
Professor Alan Smyth	MPEX	Levofloxacin - Trial steering committee	Forest	Colobreathe (colistin) - Funding to hold clinical meeting	Yes	None
	Vertex	Ivacaftor - Advisory Board	Insmed	Arikace (liposomal amphotericin) - Payment for trial participation	No	
	Gilead	Cayston (aztreonam lysine) - Advisory Board & Lecture fee	Pharmaxis	Bronchitol (inhaled mannitol) - Payment for trial participation	Yes	
			Vertex	Kalydeco (Ivacaftor) & Lumacaftor - Payment for trial participation	Yes	
Dr Neil Soni	Smiths Industries	Consultancy	None	None	No	None
Professor Paul Stewart	None	None	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Roger Sturrock	None	None	None	None	No	None
Professor Gilbert Thompson	Novartis	Alisporivir - Member, Data & Safety Monitoring Committee	None	None	No	Shares held by GRT in AstraZeneca and GlaxoSmithKline
	Medpace	Pitavastatin - Consultancy				
	Aegerion	Lomitapide - Consultancy				
Dr Alison Thomson	GlaxoSmithKline	Education of GSK staff who are undertaking a part-time MPhil or Phd degree at the University of Strathclyde. This involved one day of teaching on a GSK site in December 2013 (with associated travel expenses) and ongoing supervision of a student undertaking a part-time Phd. A fee for teaching is pending.	GlaxoSmithKline	Agreement between the University of Strathclyde Institute of Pharmacy and Biomedical Sciences to provide training for GSK staff leading to a master of philosophy or doctor of philosophy degree.	Yes	An immediate family member provides occasional consultancy services to the pharmaceutical industry. In the past year and currently they have been undertaking research, providing educational sessions and consultancy advice for Bayer.
Dr David Tuthill	Time for Medicine	Shares - I own shares in the Telemedicine company and advise them as a director. The directorship has been unremunerated	None	None	No	None
	Mead Johnson	Advisory Board member and occasional speaker				
	SMA/Nestle	Occasional speaker fees				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Nutriticia	Occasional speaker fees				
	Cardiff Paediatrics	Director				
Dr David Wheeler Dr Alistair R W Williams	PregLem SA / Gedeon Richter	Ulipristal acetate ("Esmya") - Consultancy, honoraria for speaking. Travel expenses and accommodation for conferences	None	None	No	None
	HRA Pharma	Ulipristal acetate - Consultancy				
	Bayer	Unspecified progesterone receptor modulator(s) - Consultancy				
Dr Christopher Wren Professor Sir Nicholas Wright						

OPHTHALMIC EXTERNAL EXPERT PANEL: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Sajjad Ahmad	Alcon Allergan	Centurion - Instructional Workshop Atlantic Dry Eye Meeting	None	None	No	None
Mr Bruce Allan	None	None	None	None	No	In addition to an NHS consultant contract, I derive an income from private practice specializing in refractive surgery. The main procedures I perform in private practice are LASIK and other forms of excimer laser refractive surgery, ICL implantation, cataract surgery and refractive lens exchange. I have no paid or unpaid consultancy agreements with any company. I receive technical support for a current clinical trial (NCT02208089) of combined excimer laser photherapeutic keratectomy and corneal collagen crosslinking from Schwind GMBH (excimer laser manufacturers).

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Mr Ejaz Ansari	None	None	Aquesys	Xen - funding received for research	Yes	None
			Allergan	Fellowship - funding	Yes	
Professor Paul N Bishop						
Mr Charles Claoué	Rayner Intravascular Lenses Ltd	Medical adviser	None	None	No	None
	Kowa Pharmaceuticals	Medical adviser				
Professor Baljean Dhillon						
Ms Cecilia H Fenerty	None	None	None	None	No	None
Mr Philip G Hykin	Novartis	Lucentis - Advisory Board Panels, Consultant Advisor, Travel expenses	Novartis	Lucentis - Unrestricted research grant	Yes	None
	Bayer	Eylea (VEGF-Trap-Eye) - Advisory Board Panels, Travel expenses	Allergan	Ozurdex - Unrestricted research grant	Yes	
	Allergan	Ozurdex - Advisory Board Panel	Bayer	Eylea - Unrestricted research grant	Yes	
Mr Teifion Emlyn James	Allergan	Optive, Restasis, Ozurdex - Consultancy Fees, Speakers Fees / Hospitality	None	None	No	I invented and patented a re-usable eyelid-warming device in 2005. It is called the MGDRx EyeBag. It is registered as a Class 1 Medical Device with the MHRA. Over 300,000 EyeBags have since been sold. I distribute the EyeBag in 19 countries.

MEMBER	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS	WHETHER CURRENT	ADDITIONAL INFORMATION
	CIBA Vision, Alcon and Novartis	Contact lenses, Systane Eye Drops - Speakers fees / Hospitality				I set up the company which markets and sells The EyeBag. I have a controlling interest in the company. Because of my invention, I am frequently asked to speak at 'Dry Eye' meetings.
	Bausch & Lomb	Multiple ocular lubricant products - Speakers fees / Hospitality				The corollary is that sales of the EyeBag increase as a consequence of my lectures. This increase in sales occurs because the product / device is an effective treatment for dry eye as confirmed by peer reviewed publications in learned Journals.
	Spectrum Thea	Blepha range - Speakers Fees / Hospitality				Subsequently, because I am well known for speaking about dry eye and MGD (Meibomian Gland Dysfunction) my expertise is sought by diverse companies. All these issues serve synergistically to increase sales of the EyeBag.
	Johnson and Johnson	Contact Lenses - Speakers fees, Hospitality				An immediate family member (who is a consultant radiologist) is a major shareholder in the EyeBag Company. Other immediate family members are also Directors of and hold shares in the EyeBag Company.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Specsavers	Optical items - Speakers Fees / Hospitality				
	The EyeBag Co	MGDRx EyeBag - Managing Director, Medical Director, Majority Shareholding				
	Allergan	Speakers Fees / Hospitality				
	Malosa Medical	Surgical Instruments - Non-Exec Director				
Professor Sir Peng T Khaw						
Mr Anthony King						
Mr Martin McKibbin	Bayer	Eylea (Aflibercept) - Paid attendance at advisory board and speaker at Educational meeting. Accommodation and registration at international conference	Bayer	Eylea (aflibercept) - Leeds Teaching Hospitals Trust received an educational travel grant for staff to attend an international conference / Principal Investigator for Aura observational study (Leeds Trust is paid for patient visits)	Yes	None
	Novartis	Lucentis (ranibizumab) - Paid speaker at sponsored educational meeting. Travel, accommodation and registration for international conference	Novartis	Ranibizumab (Lucentis) - Principal Investigator for Luminous and Ash observational studies (Leeds Trust is paid for patient visits)	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Alimera Sciences	Iluvien (fluocinolone implant) - Paid speaker at Webinar	Alcon	Ocriplasmin (Jetrea) - Principal Investigator for Inject observational study (Leeds Trust is paid for patient visits). Also Leeds Trust has received research support	Yes	
	Alcon	Jetrea (ocriplasmin) - Paid speaker at sponsored educational meeting				
Professor Sunil Shah	None	None	None	None	No	None

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Ian V D Weller (Chair)	None	None	None	None	No	None
Professor Deborah Ashby	None	None	GlaxoSmithKline	Methodological Collaboration	Yes	None
			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	
			AstraZeneca A/S	Methodological Collaboration	Yes	
			Novo Nordisk A/S	Methodological Collaboration	Yes	
			Takeda	Methodological Collaboration	Yes	
			Lundbeck A/S	Methodological Collaboration	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Eli Lilly	Methodological Collaboration	Yes	
			Genetech	Methodological Collaboration	Yes	
			LA-SER	Methodological Collaboration	Yes	
Professor Colin Baigent						
Dr Dennis Briley	None	None	None	None	No	None
Dr David Collas						
Dr Jeremy Dwight	None	None	None	None	No	None
Professor Stephen Evans	None	None	None	None	No	LSHTM and the Medical Statistics department receive grant funding from various companies, notably GSK, but I am neither funded by, nor responsible for, any of this funding. It does not fund my research
Dr Jeff Keep						
Mr Joe Korner	None	None	None	None	No	The Stroke Association, for whom I work, has been in receipt of funding, grants and sponsorship from Boehringer Ingelheim Ltd
Professor Peter Langhorne						
Professor Mike Laffan	Roche	ACE910 - Consultancy	Bayer	Haemophilia - Research funding	No	None
	Bayer	Haemophilia - Advisory Board fees				
	Pfizer	Haemophilia - Advisory Board fees, Lecture fees				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	LFB	Coagulation - Travel and Advisory Board fees				
	Baxter	Haemophilia - Advisory Board fees				
	Octapharma	Haemophilia. VWD - Advisory Board fees, lecture fees, travel accommodation				
	CSL Behring	VWD - Lecture fees, Advisory Board fees				
Dr Clifford Mann						
Professor Keith Muir	None	None	Bayer	Rivaroxaban - Chief Investigator / National Leader fee for NAVIGATE-ESUS clinical trial paid to University of Glasgow	No	None
Dr Martin Punter	None	None	None	None	No	None
Professor Liam Smeeth	GlaxoSmithKline	Ad hoc consultancy	None	None	No	None
Dr David Werring	Shire	Replagal - Honorarium and travel expenses to attend Fabry workshop, Prague	Allergan	Educational grant towards International Cerebral Amyloid Angiopathy Congress held at UCL, September 2014	No	None
Mr Phil Willan	None	None	None	None	No	None
Dr Peter Wilmshurst	None	None	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr H Bart van der Worp	None	None	Boehringer Ingelheim	Alteplase, Dabigatran - Speaker's fee (note that my presentation was on TIA in general and not related to alteplase or any other product of the company). This was a single payment to our research foundation, excluding reimbursement of travel expenses	No	As of May 2014, I am vice president of the European Stroke Organisation (ESO). ESO is supported financially by Boehringer Ingelheim, as one of several other companies. This company will also support the ESO Conference in 2015, as one of many companies. I do not represent ESO in the alteplase working group

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Munir Pirmohamed (Chair)	None	None	GlaxoSmithKline	NP, NS Support of the MRC Clinical Pharmacology Training Scheme	Yes	None
			Astra Zeneca	NP, NS Support of the MRC Clinical Pharmacology Training Scheme	Yes	
			Pfizer	Bosutinib - Research grant to investigate mechanisms of diarrhoea associated with bosutinib	Yes	
Dr Anthony Bewley	Abbvie	Ad hoc consultancy	Abbvie	Sponsored annual psychodermatology meeting	No	Advisor to the following charities: Changing Faces, Vitiligo Society, Psoriasis Association, National Eczema Society, Psychodermatology. Chair of Psychodermatology UK
	Leo Pharma	Ad hoc consultancy	Galderma	Sponsored annual psychodermatology meeting	No	
	Janssen	Ad hoc consultancy	Dermol	Sponsored annual psychodermatology meeting	No	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Galderma	Ad hoc consultancy	Leopharma	Sponsored annual psychodermatology training for SPRs	No	
	Thornton & Ross	Ad hoc consultancy	Novartis	Sponsored annual psychodermatology training for SPRs	No	
	Novartis	Ad hoc consultancy	Janssen	Sponsored annual psychodermatology training for SPRs	No	
Mrs Alison Bowser	None	None	None	None	No	None
Dr David Coghill	Shire	Lisdexamfetamine and Equasym XL - Includes both specific and nonspecific: In both cases this includes consutancy work, fee paid work at advisory boards and honoraria for speaking at and chairing meetings	Shire	Lisdexamfetamine (Elvanse) - Specific and non specific grants: Research grants and grants to sponsor a post or staff member	Yes	None
	Eli Lilly	Straterra - Includes both specific and nonspecific: In 2014 this only involved honoraria for speaking or chairing meetings				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Janssen Cilag	Concerta XL - Includes both specific and nonspecific: In 2014 this only involved honoraria for speaking or chairing meetings				
	Lundbeck	Non-specific: Consultancy regarding development of ADHD programme				
Dr Katherine Darton	None	None	None	None	No	None
Professor I Nicol Ferrier	None	None	None	None	No	None
Professor David Gawkrodger	GlaxoSmithKline	Shares	None	None	No	None
	AstraZeneca	Shares				
Professor Ian Goodyer	None	None	None	None	No	None
Dr Clive Grattan	Novartis	Omalizumab - honoraria for Symposium talks Advisory Board for RTI concerning research studies	Novartis	Chief Investigator of two data collection studies	Yes	None
	GlaxoSmithKline	GSK 200196 under development - consultancy	AB Science	Masitinib - Chief Investigator phase III study	Yes	
	CSL Behring	CSL830 trial - Chair, DSMB				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor David Gunnell	None	None	None	None	No	Over the last 15 years I have carried out and published findings from research studies (funded by NIHR and MHRA) investigating the following pharmaco-epidemiological issues: 1. The ease of availability of paracetamol and its use in fatal and non-fatal overdoses / self-harm 2. The association of SSRIs and other antidepressants with self-harm and suicide 3. The relative toxicity in overdose of different antidepressants 4. The burden of mortality caused by co-proxamol overdose 5. The impact of regulatory actions concerning a) Paracetamol; b) SSRIs; c) Co-proxamol on suicide / self-poisoning 6. The possible increased risk of suicide associated with the smoking cessation products: varenicline and bupropion (I have received royalties from the BMJ in relation to our paper on this issue published in 2009)

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						7. The impact of restricting prescribing of Cox-2 Inhibitors. These studies have not been funded by the pharmaceutical industry. 8. The medicines most frequently associated with the reporting of suicide, self-harm and depression-related ADRs on the yellow card reporting system.
Dr Stephen Kownacki	Galderma UK Ltd	Daylight PDT - Advisory board member	Almirall Galderma	Corporate sponsors of the Primary Care Dermatology Society (PCDS)	Yes	I am the Executive Chair of the Primary Care Dermatology Society, a charity dedicated to the education of GPs which receives sponsorship support from all the listed companies but they exert no influence regarding educational content or specific products.
	Celgene	Apremilast Relating to Psoriasis and Arthritis - Advisory board member Psoriasis education for journalists	Leo Meda	Corporate sponsors of the Primary Care Dermatology Society (PCDS)	Yes	
			Stiefel Alliance	Corporate sponsors of the Primary Care Dermatology Society (PCDS)	Yes	
			Archimedes Dermal	Corporate sponsors of the Primary Care Dermatology Society (PCDS)	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Aveeno Intrapharm	Corporate sponsors of the Primary Care Dermatology Society (PCDS)	Yes	
			MoInlycke ReckittBenckiser	Corporate sponsors of the Primary Care Dermatology Society (PCDS)	Yes	
			Brymill; Clinique; MSD; T&R; Typharm; Dermquest	Corporate sponsors of the Primary Care Dermatology Society (PCDS)	Yes	
Dr Alison Layton	None	None	GlaxoSmithKline	Unrestricted grant to perform research into psychological impact of acne	Yes	Member of Global and European Acne Panel. Unpaid Director of PCOS UK and Acne Academy, charitable company
			Galderma	Unrestricted grant to perfom study looking at mircoRNA's in acne vs acne scarring	Yes	
Professor David G C Owens	None	None	None	None	No	None
Dr Anshoo Sahota	None	None	None	None	No	None

NATIONAL EMERGENCY STOCKPILE QUALITY PANEL: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Stuart Ralston (Chair)	None	None	Amgen	Blososumab - Investigator on trial	Yes	None
			Merck	Odanacatib - DSMB member	Yes	
			Novartis	Zoledronic acid - DSMB chair	Yes	
			Lilly	Teriparatide - research grant	Yes	
Dr Barbara A Bannister	None	None	None	None	No	None
Professor Derek H Calam	None	None	None	None	No	None
Professor Janet H Darbyshire	None	None	None	None	No	None
Professor B Kevin Park	None	None	Janssen Pharmaceutica N.V.	Project grant on the role of the Nrf2 system in DILI	Yes	None
			AstraZeneca	Joint supervision on AZ sponsored BBSRC CASE studentship	Yes	
			GlaxoSmithKline	Supervisor on GSK funded PhD studentship	Yes	
			Pfizer	Pfizer award for innovative science	No	
			Merck	Donation for the Centre for Drug Safety Science	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Merck	Project grant on translational biomarkers for DILI	Yes	
Professor Munir Pirmohamed	None	None	GlaxoSmithKline	NP, NS Support of the MRC Clinical Pharmacology Training Scheme	Yes	None
			Astra Zeneca	NP, NS Support of the MRC Clinical Pharmacology Training Scheme	Yes	
			Pfizer	Bosutinib - Research grant to investigate mechanisms of diarrhoea associated with bosutinib	Yes	
Dr Angela E Thomas	None	None	Baxter	Sponsor for a conference on haemophilia run by the Journal of Internal Medicine	No	None of the support listed has been direct but through unconditional educational grants given to the organising body. I have not received any honoraria. I attended the Haemostasis Academy dinner which was arranged for all participants and teachers on the course
			Bayer	Sponsor for a conference on haemophilia run by the Journal of Internal Medicine	No	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			CSL Behring	Sponsor for a conference on haemophilia run by the Journal of Internal Medicine	No	
			Octapharma	Sponsor for a conference on haemophilia run by the Journal of Internal Medicine	No	
			SOBI	Sponsor for a conference on haemophilia run by the Journal of Internal Medicine	No	
			Novo Nordisk	Sponsor for a conference on haemophilia run by the Journal of Internal Medicine. Also a supporter of the Haemophilia Academy Edinburgh October 2014 at which I was a speaker	No	

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Ian V D Weller (Chair)	None	None	None	None	No	None
Ms Deborah Arnott						
Professor Deborah Ashby	None	None	GlaxoSmithKline	Methodological Collaboration	Yes	None
			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	
			AstraZeneca A/S	Methodological Collaboration	Yes	
			Novo Nordisk A/S	Methodological Collaboration	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Takeda	Methodological Collaboration	Yes	
			Lundbeck A/S	Methodological Collaboration	Yes	
			Eli Lilly	Methodological Collaboration	Yes	
			Genetech	Methodological Collaboration	Yes	
			LA-SER	Methodological Collaboration	Yes	
Professor Paul Aveyard	None	None	None	None	No	None
Professor John R Britton	None	None	None	None	No	I am director of the UK Centre for Tobacco Control Studies, chair of the Royal College of Physicians Tobacco Advisory Group, and a member of the board of trustees of Action on Smoking and Health
Professor Brian J Clark	Lundbeck Pharmaceuticals Denmark/Canada	Citalopram/s-Citalopram - Consultancy related to a suggested patent violation	None	None	No	None
Professor Henry Dargie	Servier	Ivabradine - Data and Safety Monitoring Committee	None	None	No	None
	Boston Scientific	Vagus Nerve Stimulator - Data and Safety Monitoring Committee				
	Novartis	LCZ 696 - Data and Safety Monitoring Committee				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Amgen	Omecamtiv Mecarbil - Data and Safety Monitoring Committee				
	Vifor	Ferric Carboxy Maltose - Data and Safety Monitoring Committee				
	TEVA	Allogenic Mesenchymal Precursor Cells (CEP-41750) - Data and Safety Monitoring Committee				
	Janssen	Rivaroxaban - Data and Safety Monitoring Committee				
Professor Peter Helms	None	None	None	None	No	None
Ms Amanda Hoey	None	None	None	None	No	I am an independent consultant. I have a contract with the BMJ to provide health care policy analysis and strategy advice. The BMJ has advertising and sponsorship contracts with the pharmaceutical industry which follow a strict code of practice, including separation between the editorial and pharma ad sales teams.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						I do not work directly on projects or journals that receive pharma advertising or sponsorship. An immediate family member is an Executive Director of BMJ. They lead the Clinical Improvement Division which develops clinical decision support and education products to help doctors improve care and outcomes for patients. These include BMJ Learning, BMJ Quality, BMJ Masterclasses, BMJ Best Practice and BMJ Informatica. Some of these products are licensed by pharmaceutical companies who make the content freely accessible to clinicians internationally. Others receive pharmaceutical company sponsorship (e.g. the International Forum on Quality and Safety in Healthcare and BMJ Masterclasses). The BMJ retains full editorial control over all its content and how it is used.
Professor Martin Jarvis	None	None	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Mike Knapton	None	None	None	None	No	I am a trustee of the Genetic Alliance UK. I am a non-executive director of Cambridge University Hospitals NHS Foundation Trust. Both organizations have links with the pharmaceutical industry, but I have no direct contact myself
Dr Rebecca Mann	None	None	None	None	No	None
Professor Christopher Marriott	Vectura Ltd	Shares	None	None	No	An immediate family member has shares in Vectura Ltd, Halation Ltd and MedPharm Ltd
	MedPharm Limited	Shares				
	Remedica Limited	Directorship, Fees				
	Halation Limited	Directorship, Fees, Shares				
Professor Marcus Munafò	Servier	Consultancy	Pfizer	Varenicline - Research grant	Yes	None
Dr Nicholas J Plant	Boehringer Ingelheim	GLP-1 and DPP4 inhibitors - Consultancy	AstraZeneca	BBSRC-CASE funded PhD student	Yes	None
	Zealand Pharma	GLP-1 and DPP4 inhibitors - Consultancy	Pfizer	BBSRC-CASE funded PhD student	Yes	
			Breast Cancer Campaign	PhD Student	Yes	
Dr Rosalind Ranson	None	None	None	None	No	None
Carolyn, Lady Roberts	None	None	None	None	No	Member of Council, University of Hull
Professor Liam Smeeth	GlaxoSmithKline	Ad hoc consultancy	None	None	No	None

REVIEW OF NON-PRESCRIPTION ANALGESICS WORKING GROUP: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Stuart Ralston (Chair)	None	None	Amgen	Blososumab - Investigator on trial	Yes	None
			Merck	Odanacatib - DSMB member	Yes	
			Novartis	Zoledronic acid - DSMB chair	Yes	
			Lilly	Teriparatide - research grant	Yes	
Professor Colin Baigent	None	None	Novartis	LC2696 - grant to University of Oxford (Co-PI)	Yes	None
Mrs Alison Bowser	None	None	None	None	No	None
Dr William Dixon	None	None	None	None	No	None
Dr Ian J Douglas	GlaxoSmithKline	Share holding	None	None	No	None
	GlaxoSmithKline	HIV portfolio Paroxetine (1012 only) - Consultancy				
	Gilead	HIV portfolio - Consultancy				
Dr J Colin Forfar	None	None	None	None	No	None
Professor Gillian M Hawksworth	None	None	None	None	No	None
Dr Rebecca Mann	None	None	None	None	No	None
Dr Karen Miller	None	None	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Munir Pirmohamed	None	None	GlaxoSmithKline	NP, NS Support of the MRC Clinical Pharmacology Training Scheme	Yes	None
			Astra Zeneca	NP, NS Support of the MRC Clinical Pharmacology Training Scheme	Yes	
			Pfizer	Bosutinib - Research grant to investigate mechanisms of diarrhoea associated with bosutinib	Yes	
Carolyn, Lady Roberts	None	None	None	None	No	Member of Council, University of Hull
Professor Kevin M G Taylor	None	None	AstraZeneca	Research project and contribution to EPSRC Doctoral Training Centre in my department	Yes	None
			Boots	Contribution to EPSRC Doctoral Training Centre in my department	Yes	
			Pfizer	Contribution to EPSRC Doctoral Training Centre in my department	Yes	
			GlaxoSmithKline	Contribution to EPSRC Doctoral Training Centre in my department	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Quadrant	Contribution to EPSRC Doctoral Training Centre in my department	Yes	

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Munir Pirmohamed (Chair)	None	None	GlaxoSmithKline	NP, NS Support of the MRC Clinical Pharmacology Training Scheme	Yes	None
			Astra Zeneca	NP, NS Support of the MRC Clinical Pharmacology Training Scheme	Yes	
			Pfizer	Bosutinib - Research grant to investigate mechanisms of diarrhoea associated with bosutinib	Yes	
Mrs Alison Bowser	None	None	None	None	No	None
Dr David Coghill	Shire	Lisdexamfetamine and Equasym XL - Includes both specific and nonspecific: In both cases this includes consutancy work, fee paid work at advisory boards and honoraria for speaking at and chairing meetings	Shire	Lisdexamfetamine (Elvanse) - Specific and non specific grants: Research grants and grants to sponsor a post or staff member	Yes	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Eli Lilly	Straterra - Includes both specific and nonspecific: In 2014 this only involved honoraria for speaking or chairing meetings				
	Janssen Cilag	Concerta XL - Includes both specific and nonspecific: In 2014 this only involved honoraria for speaking or chairing meetings				
	Lundbeck	Non-specific: Consultancy regarding development of ADHD programme				
Ms Nicole Crosby-McKenna	None	None	Sanofi	Grant towards e-learning for practice nurses project. I personally did not work on this project.	Yes	None
			Desitin	Grant towards e-learning for practice nurses project. I personally did not work on this project.	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Cyberonics	Unrestricted educational grant towards a campaign regarding epilepsy treatment options and the importance of treatment reviews. I led this project.	Yes	
Mr Sultan (Sid) Dajani	None	None	None	None	No	None
Dr Katherine Darton	None	None	None	None	No	None
Dr Brendan Davies						
Dr Christopher Derry	UCB	Vimpat (Lacosamide) - Attendance at educational event sponsored by UCB	None	None	No	None
Professor Helen Dolk	GlaxoSmithKline	Lamotrigine - Research grant to investigate whether lamotrigine is associated with an increased risk of orofacial clefts	None	None	No	None
Professor Guy Goodwin	Servier	Valdoxan - Fees, consultancy	GlaxoSmithKline	Non specific: drugs for bipolar disorder or depression - Fees	No	None
	Lundbeck	Brintellix, Brexpiprazole - Fees, consultancy, grant				
	Takeda	Brintellix - Fees, consultancy				
	Otsuka	Brexpiprazole - Fees, consultancy				
	Medscape	Brintellix - Fees, consultancy				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Sunovion AstraZeneca Lilly	Latuda - Fees Seroquel - Fees Non specific: drugs for bipolar disorder or depression - Fees				
Mr Michael Harnor	Smith and Nephew	Shares	None	None	No	I am a trustee and company director for the British Epilepsy Association (working name Epilepsy Action) and am a former Chairman. (Whole year) This body is a registered charity and a company limited by guarantee. The Association receives from time to time financial grants for particular purposes from healthcare industry companies. These vary in amount from year to year but in conformity to the charity's own policies do not do not exceed 15% of total income. Under the ABPI Code of Practice for sponsorship any awards provide no influence whatsoever upon decisions regarding the operations of the charity.
	AstraZeneca	Shares				

MEMBER	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS	WHETHER CURRENT	ADDITIONAL INFORMATION
	GlaxoSmithKline	Shares				As a trustee/director of the charity there is no mechanism whereby I can receive and quantifiable or notional personal benefit other than repayment of travel expenses already incurred.
	Worldwide Healthcare Trust	Shares (listed investment trust)				I am vice chair of the Association's research committee. I have in the past year been in receipt of one training day meeting for the Epilepsy Action Commissioning Advocates scheme which received an educational grant from UCB Pharma.
		All those listed are held as nominee investments in a self- select ISA account with Barclays.				I am an elected public governor for the North-West Ambulance NHS Trust (Whole year). I am an accredited lay member of research ethics committees (north west) NRES/ HRA. (Whole year). I am also an ordinary member of Headway - the Brain Injury charity which supports research.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
		Consequently my personal name does not appear in the share registers and I am unable to have any direct influence upon company policies.				
Dr Richard Hamish McAllister-Williams	Lundbeck	Chairing industry funded CPD meeting - Metro Centre Marriott (Feb 14)	Eli Lilly	Talk at industry funded meeting - Dubai	No	None
			Pfizer	Talk at industry funded meeting - Leeds (July and Oct 14)	No	
			AstraZeneca	Talk at industry funded meeting - ECNP Berlin	No	
			Sunovion	Chair industry funded meeting - Stephen Stahl Masterclass, London	No	
			Lundbeck	Chair industry funded meeting - Angel View Hotel and Talk at industry funded meeting - Bistro 21, Durham	No	
Dr Karen Miller	None	None	None	None	No	None
Carolyn, Lady Roberts	None	None	None	None	No	Member of Council, University of Hull
Dr Paramala Santosh	None	None	None	None	No	None
Dr Judy Shakespeare	AstraZeneca GlaxoSmithKline	Shares Shares	None	None	No	None
Professor Eric A Taylor	None	None	None	None	No	None
Dr Trudy Thomas	None	None	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Patrick Waller	None	None	None	None	No	None
Dr John B Winer	None	None	Novartis	Fingolomid - About to start trial of drug in patients with chronic Inflammatory demyelinating neuropathy	No	None
			CSL Behring	Privigen Ig - Attended sponsored neuro advisory board for one day in London	No	
			CSL Behring	Privigen - Sponsored attendance Peripheral Nerve Society Meeting in St Malo France	No	
			LFB Biotechnology	I10E Immunoglobulin - About to start trial in CIDP	No	
Dr Laura Yates	None	None	None	None	No	None

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Prof Kevin M G Taylor (Chair)	None	None	AstraZeneca	Contribution to EPSRC Doctoral Training Centre in own department	Yes	None
			Boots	Contribution to EPSRC Doctoral Training Centre in own department	Yes	
			GlaxoSmithKline	Contribution to EPSRC Doctoral Training Centre in own department	Yes	
			Pfizer	Contribution to EPSRC Doctoral Training Centre in own department	Yes	
			Quadrant	Contribution to EPSRC Doctoral Training Centre in own department	Yes	
Professor Donald Cairns	None	None	GlaxoSmithKline	Lecture sponsor	Yes	None
			AAH Pharmaceuticals	Prize sponsor	Yes	
			D M Wood Medical	Prize sponsor	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Equazen	Hospitality for speakers	Yes	
Mr Barry Capon	Norfolk & Suffolk NHS Foundation Trust	Non-Executive Director (until 30 June 2014)	None	None	No	None
Dr Graham D Cook	Pfizer	Salary, Shares	None	None	No	None
Mr Andrew Coulson	None	None	None	None	No	None
Professor Alastair Davidson (Vice-Chair)	None	None	None	None	No	None
Mr Christopher Goddard	Recipharm Ltd	Salary	None	None	No	None
Dr Keith Helliwell	Ransom Naturals Ltd	Salary	None	None	No	None
Dr Rodney L Horder	Abbott Laboratories	Shares	None	None	No	None
	AbbVie	Shares				
	Hospira	Shares				
Dr Gerard Lee	None	None	None	None	No	None
Dr Brian R Matthews	Alcon	Consultancy (Standards), Meeting expenses	None	None	No	None
	Association of Contact Lens Manufacturers	Consultancy (Standards), Meeting expenses				
	Association of British Healthcare Industries	Consultancy (Standards), Meeting expenses				
	Kythera Biopharmaceuticals Inc	Consultancy				
	Pharmaceutical Development Services	Consultancy				
Professor John Miller	None	None	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Ronald Torano	GlaxoSmithKline	Salary, Shares	None	None	No	None
Dr Lincoln Tsang	Arnold & Porter LLP	Partner (legal advice to life sciences industry)	None	None	No	None
Mrs Josephine Turnbull	Tees, Esk & Wear Valleys NHS Foundation Trust	Chair (until 31 March 2014)	None	None	No	None
Dr Paul Varley	AstraZeneca-Medimmune Limited	Salary, Shares	None	None	No	None
Professor Elizabeth Williamson	None	None	None	None	No	None

Contact for information about these reports:
Fay Norris
MHRA, 151 Buckingham Palace Road, London SW1W 9SZ
020 3080 6060

Published by the Medicine & Healthcare products Regulatory Agency

ISBN 978-1-900731-14-0