Human Medicines Regulations 2012 Advisory Bodies

Annual Report 2015

Commission on Human Medicines

British Pharmacopoeia Commission

Medicines & Healthcare products Regulatory Agency

HUMAN MEDICINES REGULATIONS 2012
ADVISORY BODIES ANNUAL REPORT 2015

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

Commission on Human Medicines

British Pharmacopoeia Commission

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FOREWORD BY THE PARLIAMENTARY UNDER SECRETARY OF STATE FOR LIFE SCIENCES

It gives me great pleasure to present the Annual Reports for 2015 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.

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 2015

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 Secretary of State for Health and the Northern Ireland Minister for Health, Social Services and Public Safety (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 EU legislation applies.

MEMBERSHIP

3. 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**.

4. The Commission warmly congratulates **Professor Sir Munir Pirmohamed**, member of the CHM and Chair of the Pharmacovigilance EAG, on receiving a knighthood in the 2015 Birthday Honours List.

5. The Commission also warmly congratulates **Professor Sir Ian Weller**, Chair of the Alteplase Working Group and former vice-chair of the CHM, on receiving a knighthood in the 2015 Birthday Honours List.

6. The Commission warmly congratulates **Professor Helen Cross**, member of the Paediatric Medicines EAG and the Anti-Epileptic Drugs Working Group, on receiving an OBE in the Queen's Birthday Honours.

7. The Commission warmly congratulates **Professor Kevin Park** on the award of the British Pharmacological Society's Lilly Prize for distinction in clinical pharmacology.

8. 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 2015

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 **Professor Angela E Thomas**

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

Infection (IEAG) – formerly Anti-Infectives, HIV/AIDS and Hepatology (AIHHEAG)
Chaired by **Professor Jonathan Friedland** (from 17th July 2015)

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 **Professor Martin Gore**

Paediatric Medicines (PMEAG)
Chaired by **Dr Rebecca Mann**

Patient and Public Engagement (PPEEAG)
Chaired by **Mr Harry Cayton** (from 1st January until 29th January 2015)
Chaired *Pro Tem* by **Mr Phil Willan** (from 30th January 2015)

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

Working Groups 2015

Alteplase Working Group
Chaired by **Professor Sir Ian Weller**

Anti-Epileptic Drugs Working Group
Chaired by **Professor Malcolm Macleod**

Hormonal Pregnancy Tests Working Group
Chaired by **Dr Ailsa Gebbie**

9. The Committee for Medicinal Products for Human Use (CHMP) is the European Medicines Agency's (EMA) committee responsible for preparing the Agency's opinions on all questions concerning medicines for human use. The Commission notes with great pleasure the extent of its influence within the CHMP's Scientific Advisory Groups (SAGs).

   Commissioners, EAG members and Working Group members serving as SAG members are as follows:

   - Professor Deborah Ashby (Cardiovascular Issues SAG)
   - 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)
   - Dr Siraj Misbah participated in the Neurology SAG during November

10. **Professor B Kevin Park** retired from his role as a member of CHM in December. Professor Park has served as a member of CHM since 2005 and was a member of its predecessor, the Committee on Safety of Medicines, from 1993 to 2005. The Commission wishes to place on record its sincere gratitude to Professor Park for his outstanding contribution over 25 years, including his membership of nine Subcommittees, Expert Advisory Groups and Working Groups of the CSM and CHM.

11. **Lady Carolyn Roberts** retired from her role as a member of CHM in October. The Commission wishes to extend its thanks to Lady Roberts for her valued contribution to the work of CHM, its Expert Advisory Groups and Working

Groups, which has spanned over 11 years in total. Lady Roberts will continue to contribute to the work of the Commission via the MWHEAG and PPEEAG.

12. **Professor Simon Thomas** retired from his role as a member of CHM in December. The Commission wishes to extend its thanks to Professor Thomas for his valued contribution to the work of the CHM, its Expert Advisory Groups and Working Groups, as well as the CSM and its Subcommittees, which has spanned over 15 years in total.

13. 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

14. The Commission held 11 meetings during 2015. Two day meetings were held in February, April, July, September, October 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

15. 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

16. 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

17. The Commission considered and advised on a total of 103 applications for marketing authorisations. The table below shows the outcome for National, Mutual Recognition, Decentralised and 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	**7**	**20**
Abridged Applications	**4**	**38**

18. The Commission was extensively involved in applications made through the European Centralised Procedure. The Commission considered 25 new active substances, or new combinations of active substances, via the Centralised Procedure.

19. The Commission considered seven papers under the Early Access to Medicines Scheme.

20. The Commission considered an average of nine applications at each of its 11 meetings in 2015, in addition to clinical trial applications, appeals, reclassifications, pharmacovigilance issues and other matters.

APPEALS

21. The Commission held one oral hearing, which concerned a variation application. The Commission advised against the approval of this variation application.

22. The Commission considered a total of eight written representations covering 12 applications. Of these, for three written representations covering five applications, the Commission advised that marketing authorisations could be granted, subject to the resolution of the outstanding concerns. For the remaining five written representations covering seven applications, the Commission advised against the grant of marketing authorisations.

TRIENNIAL REVIEW

23. The Commission's Triennial Review Report was published in March[1].

[1] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/417625/chm-review-report.pdf

EXTERNAL STAKEHOLDERS

24. The Commission received the following as observers:

Dr Nick Crabb
Programme Director for Scientific Affairs, Centre for Health Technology Evaluation, National Institute for Health and Care Excellence

Dr James Fullerton MRCP MB ChB MA
Academic Clinical Fellow, Clinical Pharmacology and Therapeutics, Wellcome Trust Clinical Research Fellow, University College London

Dr Hafid Narayan
Consultant Physician in Clinical Pharmacology & General Medicine, Royal Infirmary, Edinburgh

Dr Peter Nightingale FRCA FRCP FFICM FRCPE
Chair of the Devices Expert Advisory Committee and Consultant in Anaesthesia and Intensive Care Medicine, University Hospital of South Manchester

Dr David Owen
NIHR Clinical Lecturer and Clinical Pharmacology SpR, Imperial College Healthcare NHS Trust, London

Mr Campbell Stewart
Medical Student, St Hilda's College, University of Oxford

Professor Annie Young
Professor of Nursing, Division of Health Sciences, University of Warwick

CONSIDERATION OF OTHER MATTERS

25. 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:

WIDENING ACCESS TO MEDICINES FOR PARAMEDICIS, RADIOGRAPHERS, DIETITIANS AND ORTHOPTISTS

26. 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. There are various exemptions from these restrictions. In particular, the Regulations allow supplementary.

27. Over recent years, changes to the law have permitted a number of professions other than doctors and dentists to play an increasing role in prescribing and managing medicines for their patients.

28. In September and October the Commission was asked to advise on proposals by NHS England to amend the Regulations to allow independent prescribing by appropriately trained registered paramedics and radiographers (diagnostic and therapeutic) as well as access to a specific list of medicines for orthoptists. The proposal for orthoptists would enable them to supply and administer medicines directly to patients. NHS England also put forward proposals for supplementary prescribing by registered dietitians. Supplementary prescribing is an arrangement whereby after a diagnosis by an independent prescriber, a supplementary prescriber can prescribe medicines as part of an agreed Clinical Management Plan.

29. Commissioners agreed in principle to the proposals for dietitians and orthoptists given the potential benefits for patients and the fact that the scope of prescribing for dietitians and use of exemptions by orthoptists would fall within clearly defined areas of expertise for both professions. They also concluded that the case for independent prescribing by therapeutic radiographers was reasonable.

30. The Commission was unable to recommend independent prescribing for diagnostic radiographers on the grounds that there was insufficient information as to the range of conditions they might be expected to prescribe for; and how they would be trained in the assessment and diagnosis of these conditions so that an appropriate treatment could be prescribed. Similarly, Commissioners were unable to recommend independent prescribing by paramedics since it was clear that paramedics could potentially encounter a very wide range of conditions and it was not clear if they would have adequate training to assess and diagnose these conditions and prescribe the appropriate treatment. It was therefore felt that at present independent prescribing may represent a risk to patient safety.

Anti-Epileptic Drugs Working Group

31. In April 2015, the Commission considered a paper “Update on the Commission’s advice on formulation switching of antiepileptic drugs”. The purpose of the paper was to update the Commission on issues relating to brand/generic prescribing and switching between formulations for antiepileptic drugs (AEDs), following on from the publication of the Commission’s advice in November 2013. The advice was intended to address particular concerns for AEDs because a number of them have a narrow therapeutic index and the consequences of therapeutic failure can be catastrophic.

32. Since the Commission’s advice was published the MHRA has received substantial feedback from various sources representing patients and healthcare professionals (HCPs). Certain aspects of the Commission’s advice for the three

risk based categories of AEDs and the measures taken to implement this advice have been generally welcomed but others have raised some concerns amongst stakeholders.

33. An updated review of the published literature and a full review of UK Spontaneous suspected adverse drug reaction (ADR) reports of product substitution associated with anti-epileptic drugs were undertaken for this 2015 paper. The Commission advised that further advice should be sought in the first instance from an ad hoc expert Anti-Epileptics Working Group and that patient organisations and other stakeholders should be involved in a review.

SAFETY OF MARKETED MEDICINES

Risk of pneumonia with inhaled corticosteroids (beclomethasone, budesonide, fluticasone propionate and fluticasone furoate)

34. The Commission considered an assessment of the risk of pneumonia with inhaled corticosteroids (ICS) when used in chronic obstructive pulmonary disease (COPD) in the context of a Europe wide review[1]. The Commission advised that the data confirmed an increased risk of pneumonia in COPD patients treated with ICS and that there was no conclusive evidence of a difference in the risk of pneumonia between the different corticosteroids. The Commission advised that the data on an association between increasing dose of ICS and increased risk of pneumonia was unclear and also that the evidence did not support a differential risk of pneumonia between ICS containing products. The Commission advised that the risk of pneumonia should be considered a class effect of ICS and that harmonised and specific warnings should be included in the product information for all ICS. The outcome of the Europe wide review, which completed in April 2016, was fully in line with the advice of the Commission.

Paracetamol prophylaxis with Meningitis B vaccine in infants

35. The Commission considered plans from Public Health England for the upcoming national immunisation programme to offer three doses of paracetamol with Bexsero meningitis B vaccine to prevent post-vaccination fever. Bexsero is associated with high rates of fever when given with other vaccines at 2 and 4 months of age, and the Joint Committee on Vaccination and Immunisation had recommended that paracetamol be given at the time or shortly after the vaccinations, with a further two doses every 4 to 6 hours thereafter to reduce the rate of fever. The Commission noted that the Summary of Product Characteristics (SmPCs) and the PIL for paracetamol infant suspensions stated that no more than two doses should be given to children aged 2 months without the advice of a doctor or pharmacist. The Commission advised that the SmPCs should be amended to state that paracetamol may be given to children from 2 months for the treatment or prevention of post-vaccination fever for up to 48 hours following vaccination. The Commission advised that it was important that

parents or carers continued to adhere to the two dose paracetamol treatment limit for non-vaccine fever in children aged 2 to 3 months and that PILs should be amended to ensure that patients and carers fully understand the rationale for this, which is to avoid delay in diagnosis and treatment of serious infections.

Human papillomavirus (HPV) vaccine – update on safety

36. The Commission considered a detailed overview of the safety of human papillomavirus (HPV) vaccines, including UK Yellow Card Data, published safety studies and information from other countries. The Commission also noted that a safety review, focusing on reports of postural orthostatic tachycardia syndrome (POTS) and complex regional pain syndrome (CRPS) had been initiated by the European Medicines Agency[2]. The Commission thoroughly reviewed the latest safety data, including careful consideration of POTS and CRPS, as well as chronic fatigue syndrome (CFS) and concluded that the evidence did not support a link between HPV vaccination and these conditions, or other chronic illnesses. The Commission advised that HPV vaccines could be associated with some side effects, such as redness at the injection site and transient fever, but noted that these appeared to be similar in frequency and type to those that had been reported with other vaccines routinely given to adolescents and adults.

37. The Commission was encouraged that nearly 3 million young women had been vaccinated in the UK and noted that this already had resulted in a decline in HPV infection rates. The Commission further noted that this would be expected to prevent many deaths from cervical cancer, other cancers of the ano-genital system and head and neck cancer that might have otherwise occurred in the future. The Commission noted and understood the concerns that had been raised by recipients of the HPV vaccine and their parents with regard to reports of POTS, CFS and CRPS but concluded that these were unlikely to be caused by the vaccine. The Commission noted that active measures had been and were still being taken to ensure that all reports of suspected side effects were reviewed to ensure that the important health benefits of the vaccine continue to outweigh potential risks.

[2] http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Human_papillomavirus_vaccines/human_referral_prac_000053.jsp&mid=WC0b01ac05805c516f

Hydrogen peroxide in surgery and risk of gas embolism

38. The Commission further considered the risk of gas embolism associated with the use of hydrogen peroxide during surgery following an article in Drug Safety Update in December 2014 which reminded healthcare professionals of an existing contraindication to the use of hydrogen peroxide in closed body cavities or deep wounds.[3] Feedback from surgeons following this article highlighted that hydrogen peroxide was sometimes used in orthopaedic surgery for preparing the bone for cementing. The Commission considered the available evidence and advised that the case reports of gas embolism received through the Yellow Card Scheme, together with the plausible biological mechanism, supported a causal association between the use of hydrogen peroxide in surgery and gas embolism. The Commission advised that the available evidence supported the need for the current contraindication to use of hydrogen peroxide in surgical wounds.

Antibiotics during pregnancy and long term safety outcomes in children

39. The Commission considered a published study[4] which aimed to examine whether there was an increased risk of childhood cerebral palsy and/or epilepsy in children born to mothers who had taken antibiotics during pregnancy. The Commission took into account the advice of their Medicines for Women's Health Expert Advisory Group (MWHEAG) on this issue. The Commission noted that the main finding of this study was that there is no evidence of an association between overall antibiotic prescribing for the treatment of infection during pregnancy and the risk of a child developing cerebral palsy and/or epilepsy. The Commission advised that the secondary analysis which suggested a risk with use of macrolide antibiotics (which include erythromycin) during pregnancy should be treated with great caution. This analysis did not make allowances for important factors, such as the type or severity of the infection being treated, which could themselves pose a risk for cerebral palsy and/or epilepsy in the child. The Commission advised that the study was insufficient to suggest that use of macrolides in pregnancy is a cause of these conditions.

Increased reports of eye irritation following change to formulation of Xalatan

40. The Commission considered data on an increased rate of reporting of cases of eye irritation following a change in formulation of Xalatan (latanoprost), a treatment for glaucoma (increased pressure within the eye). The formulation had been changed to enable the product to be kept at room temperature, whereas the previous formulation had required refrigeration. The Commission noted that the overall number of reports of eye irritation with Xalatan was low in the context of the number of doses dispensed. The Commission concluded that the benefit

[3] https://www.gov.uk/drug-safety-update/hydrogen-peroxide-reminder-of-risk-of-gas-embolism-when-used-in-surgery

[4] Association between Antibiotic Prescribing in Pregnancy and Cerebral Palsy or Epilepsy in Children Born at Term: A Cohort Study Using The Health Improvement Network. Published: March 25, 2015, DOI: 10.1371/journal.pone.0122034

risk balance of the product remained positive and that no further study of this issue was warranted. However, it advised that the Patient Information Leaflet (PIL) should be updated to emphasise to patients the importance of discussing any excessive eye irritation promptly with their healthcare provider. An article was published in the July edition of Drug Safety Update[5] to make healthcare professionals aware of the potential for eye irritation with the new formulation of Xalatan.

MEDICINES AVAILABLE WITHOUT PRESCRIPTION

41. The Commission considered three applications for change of legal status during the year. One application was for a topical medicine indicated for the relief of cold sores for General Sales List (GSL) availability. The Commission advised that the application could be approvable subject to proposed changes in the product information. 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 of a medicine for the relief of symptoms in mild to moderate osteoarthritis of the knee could be approvable subject to proposed changes in the product information. The Commission advised against the other application to reclassify a topical product from POM to P for the treatment of mild rosacea.

Increasing Stakeholder Engagement in Reclassification

42. 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 (EAGs)

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

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

44. The CDRRAEAG met once in 2015, convened four times via teleconference, and provided advice by written correspondence on eight items.

[5] https://www.gov.uk/drug-safety-update/latanoprost-xalatan-increased-reporting-of-eye-irritation-since-reformulation

45. In January, the EAG convened via teleconference and made recommendations on:

- a medicine indicated for the treatment of hypercholesterolaemia and mixed dyslipidaemia, and for the treatment of homozygous familial hypercholesterolaemia (excesses of cholesterol in the blood)
- a medicine indicated for the treatment of severe orthostatic hypotension (a rapid decrease in blood pressure experienced when standing) in adults
- an application to extend the indications of a product for the treatment of asthma in adults and children, and the treatment of chronic obstructive pulmonary disease (COPD) in adults. The application was to extend the indications to include the treatment, in combination with an inhaled glucocorticosteroid (a type of steroid hormone which exerts anti-inflammatory actions) of patients with asthma

46. In February, the Chair and respiratory experts provided written comments on a medicine indicated as an add-on treatment for severe eosinophilic asthma (distinct phenotype of asthma that is associated with tissue and sputum eosinophilia, thickening of the basement membrane zone) in adult patients.

47. In February, the chair and respiratory experts also provided written comments on a medicine for the treatment of cystic fibrosis (a genetic condition in which the lungs and digestive system become clogged with thick, sticky mucus) in patients aged 12 years and older.

48. In April, the EAG convened via teleconference and made recommendations on:

- a medicine indicated for the treatment of pulmonary arterial hypertension (PAH) (a type of high blood pressure that affects the arteries in the lungs and the right side of the heart)

49. In May, the EAG convened and made recommendations on:

- a medicine indicated for the treatment of sinus tachycardia (increased heart rhythm, above 100bpm) or supraventricular tachyarrhythmias (abnormal heart rhythm arising from improper electrical activity of the heart)
- a medicine indicated for the treatment of heart failure
- a proposed amendment to the wording, in the SmPC, of a medicine indicated for the treatment of patients with bronchial asthma (a chronic, inflammatory disease of the respiratory tract)
- a product submitted under the Early Access to Medicines Scheme (EAMS) indicated for the treatment of heart failure.

50. In June, the EAG convened via teleconference and made recommendations on:

- a medicine indicated for the prophylactic (preventative) treatment of asthma in adults and children over four years of age
- safety concerns relating to a medicine indicated for the treatment of patients with cystic fibrosis

51. In June, the cardiologists provided written comments on the safety, in patients with a cardiac impairment, of a medicine indicated for the treatment of motion sickness.

52. In July, the EAG convened via teleconference and made further recommendations on:

- a medicine indicated for the prophylactic treatment of asthma in adults and children over four years of age

53. In July, the cardiologists provided written comments on a medicine to reduce the chances of having a heart attack or stroke in patients with a previous history of heart attacks. The medicine works by reducing the clumping of platelets (small blood cells which can help to stop bleeding by clumping together to plug tiny holes in blood vessels that are cut or damaged.

54. In August, the cardiologists provided written comments on safety issues relating to a medicine indicated for the regular treatment of patients with arrhythmia, and for the management of heart failure.

55. In October, the respiratory experts provided written comments on the risk of pneumonia with the use of inhaled corticosteroids.

56. In October, the cardiologists provided written comments on an application to extend the indications of an antithrombotic medicine, currently indicated for the reduction of atherothrombotic events in adult patient with a history of myocardial infarction, to include patients with peripheral arterial disease (a common circulatory problem in which narrowed arteries reduce blood flow to the limbs).

57. In December, the renal experts provided written comments on a medicine indicated for the treatment of secondary hyperparathyroidism (the excessive secretion of parathyroid hormone by the parathyroid glands and associated hyperplasia of the glands) in adult patients with chronic kidney disease (CKD) on haemodialysis therapy.

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

58. The CTBVEAG met six times in 2015, convened twice via teleconference and provided advice by written correspondence on eight occasions.

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

- a medicine indicated for the treatment of adults with skin cancer that is metastatic, i.e. has spread to other parts of the body
- a medicine indicated to treat non-small cell lung cancer (NSCLC) that is advanced or metastatic in adults.
- a medicine for the treatment of advanced solid tumours.

60. In February, the EAG convened and made recommendations on:

- a long-term hormone supplement for adult patients with underactive parathyroid glands. Underactive parathyroid glands lead to low blood calcium concentration that is associated with a variety of symptoms.
- a medicine for the treatment of severe eosinophilic asthma, a condition in which there are too many eosinophils (a type of white blood cell) in the blood and lungs, causing damage to the airways and worsening asthma
- a medicine for the use in the treatment and prevention of bleeding in all age groups of patients with haemophilia A, an inherited bleeding disorder caused by a congenital deficiency of factor VIII (a protein that helps clot the blood)
- a treatment for Alzheimer's disease, a progressive neurological disease which affects multiple brain functions, including memory.
- a treatment for Clostridium Difficile infection (a type of bacterial infection that can affect the digestive system).

61. In March, the EAG convened via teleconference and made recommendations on

- a vaccine indicated for the treatment of Ebola.

62. Also in March, the EAG convened and made recommendations on:

- two medicines for the treatment of bleeding in adults, adolescents and children of all ages with haemophilia A
- a medicine for the treatment of Paroxysmal Nocturnal Hemoglobinuria (a rare disease in which red blood cells break down more rapidly than normal).
- a product submitted under the Early Access to Medicines Scheme (EAMS).

63. In April, the EAG convened via teleconference and made recommendations on

- a vaccine indicated for the treatment of Ebola.

64. In April, the EAG also provided written comments on a vaccine indicated for the treatment of Ebola.

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

- a medicine for use in paediatric patients with relapsed or refractory neuroblastoma, a rare cancer that mostly affects young children. a medicine for the treatment of Primary Familial Haemophagocytic Lymphohistiocytosis (pHLH), a rare genetic disorder where the immune system is overactive.

66. In May, the EAG also provided written comments on two occasions for a vaccine indicated for the treatment of Ebola.

67. In June, the EAG convened and made recommendations on

- a medicine used to help prevent venous thromboembolism, (blood clots in the vein)

The EAG also considered a company response to MHRA scientific advice relating to a clinical trial application for a medicine for the treatment of Alzheimer's Disease.

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

- a medicine indicated for the treatment of age-related macular degeneration (AMD), an eye condition causing loss of central vision.
- a company response to MHRA scientific advice, relating to a clinical trial application for a medicine for the treatment of Alzheimer's Disease.
- a medicine indicated to treat relapsing forms of Multiple Sclerosis (MS).

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

- a medicine for the treatment of neuroblastoma, a rare childhood form of cancer that arises in the adrenal glands.
- a medicine for the treatment of moderate to severe plaque psoriasis (the most common form of psoriasis, an autoimmune disease)
- a medicine for the treatment of severe combined immunodeficiency (group of autosomal recessive metabolic disorders causing abnormalities of the immune system).

The EAG also noted the draft guidance on good pharmacovigilance practices for biological medicinal products which is due for public consultation and suggested a number of changes.

70. In October, the EAG provided written comments on a medicine used to treat blood clots (venous thromboembolism) and to prevent their recurrence.

In December, the EAG provided written comments on a medicine for the treatment of children and adults with Acute Lymphoblastic Leukaemia (a cancer

Chemistry, Pharmacy and Standards Expert Advisory Group (CPSEAG)

71. In 2015, 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 15 papers.

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

- a medicine intended for the chronic treatment of cystic fibrosis (CF) in patients aged 12 and older
- a medicine indicated for the treatment of multiple myeloma, a type of bone marrow cancer, in adults
- a medicine used for the relief of signs and symptoms of rheumatoid arthritis, osteoarthritis and ankylosing spondylitis
- a medicine used to treat low blood pressure when other treatments have not worked
- a medicine used in the treatment of epilepsy, glaucoma and the abnormal retention of fluids.
- a medicine used for the treatment of asthma from the age 6 and over and chronic obstructive pulmonary disease (COPD) in adults

The EAG considered and advised the Commission about a medicine to correct the loss of sodium chloride in the body.

In January, the EAG also provided written comments on the following:

- a medicine indicated to treat moderate to severe atopic dermatitis (eczema) in adults and children 2 years of age and older
- a medicine indicated to speed up healing of skin wounds in adults

73. In February, the EAG considered and made recommendations on the following:

- a nonsteroidal anti-inflammatory drug (NSAID) indicated to reduce pain and inflammation
- a medicine indicated for the treatment of fungal infections

- a medicine indicated for the treatment of glaucoma, raised pressure in the eye
- a medicine indicated to treat underactive thyroid gland.

The EAG considered and made recommendations on a Notified Body consultation for a medical device product for use with certain medicines. The drug/device combination alters blood flow to tumours and destroys the cancer cells.

The EAG considered a company's response to questions and advised the Commission on a medicine indicated to aid smokers wishing to quit smoking.

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

- a medicine for the treatment of Parkinson's disease (a progressive disease of the nervous system that affects movement) and associated movement problems
- a medicine intended to be used as a preventive and curative treatment of corneal (eye) cystinosis, a rare disease characterised by abnormal accumulation of the amino acid, cystine
- a medicine intended for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents 12 years of age
- a medicine indicated for the emergency treatment of anaphylactic shock (a severe allergic reaction to insect stings or bites, foods or drugs).a medicine indicated to be used in children with medical conditions that cause too much drooling
- a medicine to be used as a replacement therapy for children with congenital adrenal hyperplasia, (affects the body's natural production of steroids), and to treat severe asthma and allergic reactions

The EAG considered a company's response to questions and advised the Commission on a medicine for the treatment of vitamin D deficiency.

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

- a medicine for the treatment of serious lung infections in adult patients and for the management of chronic lung infections caused by Pseudomonas aeruginosa, in patients aged 6 years or older with cystic fibrosis.
- a medicine indicated to treat gout, a type of arthritis, in adult patients by lowering the levels of uric acid in the blood
- a medicine indicated to treat seizures in patients with epilepsy, from 16 years of age
- a medicine indicated for the long-term treatment of pulmonary arterial hypertension (PAH), high blood pressure in the blood vessels that supply the lungs

- a medicine intended for the detection of ureteral injuries during abdominal and pelvic surgery
- a medicine indicated for vitamin D deficiency
- a medicine indicated for use in patients who suffer cardiac arrhythmia arising from improper electrical activity of the heart
- two medicines for the treatment of eye infections.

The EAG received an update on progress by marketing authorisation holders in submission of variations following reformulation of the excipient composition of approved products.

The EAG heard a presentation and noted a paper on a medicine indicated to be used as local anaesthesia of the nasal passage and upper respiratory airway prior to minor surgical or investigative procedures.

The EAG considered a company's response to questions and advised the Commission on a medicine for the topical treatment of mild to moderate acne.

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

- a medicine for the treatment of mild and moderate heart failure in adults
- a medicine for use during or after surgery for sinus tachycardia, or tachyarrhythmia, (fast and/ or irregular heart beat)
- a medicine for the treatment of mild or moderate anxiety and as a sedative before surgery or operative dental treatment
- three medicines indicated for the treatment of glaucoma
- a medicine indicated for long-term maintenance of alcohol abstinence in and treatment of alcohol withdrawal syndrome in adult patients
- a medicine indicated to treat pneumonia and some infections in the skin
- two medicines indicated to treat thyroid hormone deficiency

The EAG considered and made recommendations on the proposed revision of the European Pharmacopoeia Monograph for Water for Injections in bulk.

In May, the EAG also provided written comments on a medicine used to treat two indications, chronic immune (idiopathic) thrombocytopenic purpura (ITP) in adults and children over 1 year old to increase platelet counts and reduce or prevent bleeding.

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

- a medicine for the treatment of adult patients with multiple myeloma
- a medicine indicated for the treatment of adult patients with metastatic melanoma, a type of skin cancer that has spread to other parts of the body
- a medicine indicated for the treatment of HIV-1 infected children

- two medicines to reduce the symptoms of asthma and to help prevent asthma attacks
- a medicine for the treatment of acute gout (a type of arthritis) in adults, and familial Mediterranean fever, a hereditary inflammatory disorder in children
- a medicine for the prevention and treatment of lower urinary tract; kidneys, ureters, bladder, or urethra, infections
- a topical medicine for the treatment of joint and muscular pain

The EAG considered and made recommendations on the draft good practice guidance on risk minimisation and prevention of medication errors.

The EAG noted the European Medicines Agency (EMA) concept paper on the development of a guideline on quality and equivalence of topical products: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2015/04/WC500186088.pdf

The EAG considered a company's response to questions and advised the Commission on a medicine indicated to treat various illnesses involving inflammation in the body and a number of different diseases of the immune system.

In June, the EAG also provided written comments on a medicine used in the treatment HIV infection.

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

- a topical treatment indicated for a type of skin cancer, [mycosis fungoides-type cutaneous T-cell lymphoma (MF-type CTCL)], in adult patients
- a medicine indicated for the treatment for several types of infections in adult patients
- a medicine indicated for the treatment of chronic non-infectious uveitis, inflammation of the middle layer of the eye
- a medicine indicated for the treatment of adult patients with metastatic colorectal cancer.
- a medicine for the treatment of colon, rectal, gastric, or breast cancers
- a medicine indicated for the sedation of children between the ages of 2 months and 5 years

The EAG also heard a presentation and considered a paper on the review of the hydrated crystal form of a well-known active substance.

79. In July, the EAG also provided written comments on the following:

- a medicine indicated to treat thyroid hormone deficiency

- a medicine solution used as a carrier for other medicines in a process called radiolabelling specially developed to target malignant tissue.
- a medicine indicated for the treatment of adults with irritable bowel syndrome with diarrhoea (IBS-D)
- a medicine indicated to treat iron deficiency

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

- a medicine intended for the treatment of HIV-1 infection in adults and adolescents more than 12 years of age
- a medicine intended for the treatment of asthma and Chronic Obstructive Pulmonary Disease (COPD)
- a medicine intended for the treatment of metastatic adenocarcinoma of the pancreas,
- a medicine intended to help prevent breathing problems such as asthma in adults and children.
- a medicine intended for the treatment of diabetes insipidus, extreme thirst and the continuous production of large volumes of dilute urine, Primary Nocturnal Enuresis, bedwetting from the age of 6, and nocturia (frequent need to get-up and urinate at night) in adults up to 65 years
- a medicine intended to treat eye infections
- a medicine indicated for the treatment for several types of infections in adults and children over 8 years
- a topical treatment indicated to relieve pain caused by anal fissures
- a topical treatment indicated for psoriasis vulgaris in adults, (a chronic skin condition)
- a medicine indicated to treat various illnesses involving inflammation in the body and a number of different diseases of the immune system

In September, the EAG also provided written comments on a diagnostic agent indicated for radiological examinations in adults.

81. In October, the EAG provided written comments on the following:

- a medicine indicated for the treatment of glaucoma
- a medicine used to treat adult patients with multiple myeloma
- a medicine used in the treatment of type 2 diabetes mellitus
- a medicine for treating non-small cell lung cancer patients who have progressed on previous treatment(s) [in the context of the UK Early Access to Medicine Scheme (EAMS)]
- a medicine indicated for the treatment of Duchenne muscular dystrophy, (a genetic defect that affects normal muscle function)
- a medicine for the treatment of nocturia (frequent need to get up to urinate at night) due to nocturnal polyuria (overproduction of urine during the night) in adults

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

- a medicine indicated for the treatment of HIV-1 infection in adults and adolescents 12 years of age and over
- a medicine indicated for the treatment of hepatitis C infection in adults
- a medicine indicated for the treatment of multiple myeloma
- a medicine indicated for the treatment of asthma and Chronic Obstructive Pulmonary Disease (COPD)
- a topical treatment indicated for mild to moderate scalp psoriasis in adults.

The EAG heard a presentation on the follow-up and handling of defect reports on a range of sterile, single use eye drop products.

The EAG also considered two company's response to questions and advised the Commission on:

- two medicines for the short term treatment of mild to moderate bacterial skin infections
- a medicine used for the relief of signs and symptoms of rheumatoidarthritis, osteoarthritis and ankylosing spondylitis

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

- a medicine indicated for the treatment of adult patients with GNE Myopathy, also known as Hereditary Inclusion Body Myopathy (HIBM), a severe muscle disease which causes progressive muscle weakness and wasting
- a medicine indicated for the treatment of breast cancer that has spread to other parts of the body
- a medicine indicated to treat thyroid hormone deficiency
- a medicine indicated for the prevention of damage to the urinary tract by anticancer drugs
- an immunosuppressant medicine indicated for protection against organ transplant rejection.

The EAG considered and made recommendations to the responses of a notified body consultation for a medical device product for use with drug substances. The drug/device combination is used to block blood flow to cancer tumours and to deliver drugs to destroy the cancer cells.

The EAG also considered a company's response to questions and advised the Commission on a nonsteroidal anti-inflammatory drug (NSAID) indicated to reduce pain and inflammation.

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

84. The GRIDEAG met once during 2015, convened twice via teleconference and provided written comments and advice on three occasions.

85. In March the EAG provided written comments on a draft European Medicines Agency (EMA) guidance document for evaluating the baseline frailty status of older patients enrolled in a clinical trial or other clinical investigation.

86. In April the EAG convened and made recommendations on

- a medicine for the treatment gout (a type of arthritis in adult patients).

87. In July the EAG convened via teleconference and made recommendations on

- a medicine for the reduction of inflammation associated with diseases such as arthritis and psoriasis.

88. Also in July the EAG convened via teleconference and made recommendations on:

- a medicine for use in the treatment of irritable bowel syndrome with diarrhoea
- a medicine for the short term relief of constipation.

89. In September the EAG provided written comments on a medicine for the topical treatment of psoriasis vulgaris in adults.

90. In October the EAG provided written comments on draft CHMP guidelines on the development of new medicinal products for the treatment of ulcerative colitis and Crohn's Disease (two different forms of inflammatory bowel disease).

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

91. In September 2015, the Commission on Human Medicines endorsed a proposal to change the name of the EAG from the Anti-Infectives, HIV and Hepatology Expert Advisory Group (AIHHEAG) to the Infection Expert Advisory Group (IEAG). In October 2015 the Commission also endorsed the change in remit for the IEAG to include 'viral hepatitis' rather than 'hepatic diseases'. The remit of the IEAG is now 'to advise the Commission on the safety and efficacy of medicines for use in infections including HIV, AIDS and viral hepatitis'.

92. In 2015 the IEAG met twice and provided written comments and advice on five papers.

93. In June, the EAG provided written comments on a medicine indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infected children.

94. In September, the EAG provided written comments on a medicine indicated for the treatment of HIV-1 infection in adults and adolescents 12 years of age.

95. In October, the EAG considered and made recommendations on the following:

- a medicine indicated for the treatment of chronic hepatitis C infection in adults aged 18 years and older

The EAG discussed the future direction and membership of the EAG, including areas of expertise that could be added. EAGs members also discussed the format of the paperwork to be reviewed and the importance of lay member input.

96. In October, the EAG also provided written comments on a medicine indicated for the treatment of HIV-1 infection in adults and adolescents 12 years of age.

97. In November, the EAG considered and made recommendations on an application for pharmacy supply of a topical product for the treatment of rosacea, a mild inflammatory skin condition that mainly affects the face.

The EAG considered the need for risk minimisation activities to reduce the risk of off-label use of a product licensed for the treatment of cytomegalovirus retinitis (a viral infection of the light sensitive surface at the back of the eye), in patients who have human immunodeficiency virus (HIV) infection.

98. In December, the EAG also provided written advice on the results of the Mitochondrial Toxicity in Children (MITOC) study, which aimed to assess the prevalence of neurological manifestations of mitochondrial toxicity in HIV negative children exposed in utero or during the post-natal period to antiretroviral agents.

Medicines for Women's Health EAG (MHWEAG)

99. The MWHEAG met on six occasions during the year, with four face to face meetings and two teleconferences and provided comments by written communication for one new product.

100. The MWHEAG considered the evidence and made recommendations on the following issues with marketed medicines:

- use of hormone replacement therapy and the risk of ovarian cancer

- use of combined hormonal contraception and the risk of inflammatory bowel disease (IBD)
- use of antibiotics during pregnancy and long term safety outcomes in children
- levonorgestrel-containing emergency contraception and interactions with enzyme-inducing medicines and the implications for pharmacy supply

101. The MWHEAG considered and made recommendations on the extension of use of a product for luteal phase support during assisted reproduction and on a product for use as thyroid hormone therapy and/or replacement.

102. The MWHEAG considered and made recommendations on applications for new medicinal products for hormonal contraception and for the intra-operative detection of ureteral injuries during abdominal and pelvic surgery.

Neurology, Pain & Psychiatry Expert Advisory Group (NPPEAG)

103. The NPPEAG met on four occasions in 2015, and provided advice by written correspondence on 14 items.

104. In February, the EAG convened and provided recommendations on

- a paper in relation to a safety signal associated with a medicine used to treat relapsing-remitting multiple sclerosis (RRMS).

105. Also In February, the EAG provided written comments on safety concerns relating to the use of an antihistamine with sedative properties.

106. In March, the EAG convened and provided recommendations on

- a medicine indicated for the treatment of Parkinson's disease (a progressive disease of the nervous system marked by tremor, muscular rigidity, and slow, imprecise movement) and associated movement problems.

107. Also In March, the EAG provided written comments on safety concerns relating to a product used to treat multiple sclerosis.

108. In April, the EAG provided written comments on:

- a medicine indicated for the treatment of epilepsy in adults
- a medicine indicated for the control of tonic-clonic or focal status epilepticus (formerly known as grand mal seizures, a type of generalized seizure that affects the entire brain) in adults and in children from the age of 4

- draft CHMP guideline on the clinical development of medicinal products intended for the treatment of pain
- the risk of cognitive impairment with a medicine indicated for the treatment of heart failure
- a medicine indicated for the treatment of chronic severe drooling
- an update on CHM advice on formulation switching of antiepileptic drugs

109. In May, the EAG provided written comments on a medicine indicated for the long-term maintenance of alcohol abstinence in alcohol-dependent adult patients.

110. In June, the EAG convened and provided recommendations on:

- a medicine for the treatment of relapsing forms of multiple sclerosis in adult patients
- new indications for a product currently indicated for use as a diagnostic radiopharmaceutical in Positron Emission Tomography (PET). The proposed indications were:
    i) biomarker for early diagnosis of Alzheimer's disease
    ii) differential diagnosis between Alzheimer's disease, frontotemporal lobar degeneration and other types of dementias
- the Risk Management Plan (RMP) for a product indicated for: i) control of tonic-clonic epilepsy; ii) prevention and treatment of seizures relating to neurosurgery and/or head traumas; iii) a substitute for oral treatment where oral administration is not possible and/or contra-indicated

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

- a product for the sedation of children aged between 2 months and 5 years, weighing up to a maximum of 15kg, undergoing diagnostic imaging procedures within a hospital setting
- a medicine for use in the treatment of RRMS
- the risk of cognitive impairment with a medicine indicated for the treatment of heart failure.

112. In August, the EAG provided written comments on a medicine for the treatment of relapsing multiple sclerosis in adult patients.

113. In November, the EAG convened and provided recommendations on

- Safety issues relating to a class of medicines for the treatment of disabling motor fluctuations ('on-off' phenomena) in patients with Parkinson's disease, which are not adequately controlled by levodopa or other treatments.

114. In December, the EAG provided written comments on a medicine indicated for the treatment of GNE Myopathy (an inherited condition leading to weakness in

the legs and feet), also known as Hereditary Inclusion Body Myopathy (HIBM) in adult patients.

Oncology and Haematology Expert Advisory Group (OHEAG)

115. In 2015, the OHEAG met on one occasion and convened by teleconference on three occasions. The EAG also provided written comments on 16 papers.

116. In January the EAG provided written comments on the following:

- a medicine used to treat adult patients with multiple myeloma, a type of bone marrow cancer
- a medicine indicated to treat non-small cell lung cancer (NSCLC) that is advanced or metastatic in adults
- a medicine indicated for the treatment of adults with skin cancer that is metastatic

117. In February the EAG provided written comments on the following:

- a medicine indicated to treat and prevent bleeding in patients with haemophilia A (an inherited condition that affects the blood's ability to clot)
- a medicine to treat mantle cell lymphoma (MCL) and chronic lymphocytic leukaemia (CLL), including small lymphocytic lymphoma (SLL) which are particular forms of blood cancer

118. In March the EAG provided written comments on the following:

- a medicine used to treat an advanced stage of lung cancer in adults
- a medicine proposed for use in the treatment of relapsed and refractory mantle cell lymphoma (cancer of the immune system)
- a medicine indicated for use in combination with other medicines for the treatment of adult patients with multiple myeloma who have received at least one prior therapy
- a draft European Medicines Agency (EMA) guidance document for evaluating the baseline frailty status of older patients enrolled in a clinical trial or other clinical investigation.

119. In April, the EAG convened by teleconference and made recommendations on the following:

- a product submitted under the Early Access to Medicines Scheme (EAMS), indicated for advanced melanoma

- a communication with patients and healthcare professionals regarding a blood product undergoing investigation with reference to Good Manufacturing Practice (GMP)standards

120. In June, the EAG provided written comments on the following:

    - a medicine indicated for the treatment of adult patients with multiple myeloma, who have received at least one prior therapy
    - a medicine indicated for the treatment of adult patients with metastatic colorectal cancer (colon or rectal cancer)

121. In July, the EAG provided written comments on a medicine to be used for the treatment of adult patients with unresectable or metastatic melanoma.

122. In August, the EAG provided written comments on a topical medicine indicated for mycosis fungoides-type cutaneous T-cell lymphoma (MF-type CTCL), a type of skin cancer, in adult patients.

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

    - a medicine to treat adult patients with lung cancer
    - a product submitted under the Early Access to Medicines Scheme (EAMS), indicated for the treatment of non-small cell lung cancer

    The EAG also discussed a new medicine for treating non-small cell lung cancer patients who have progressed on previous treatment(s). The product was discussed in the context of the UK Early Access to Medicine Scheme (EAMS).

    In October, the EAG also provided written comments on a medicine used to treat oral mucositis (soreness, dryness and inflammation of the mouth), which is a side effect of cancer treatments.

124. In November the EAG convened by teleconference and made recommendations on a medicine indicated for the treatment of multiple myeloma.

125. In November, the EAG also provided written comments on a medicine indicated for the treatment of metastatic breast cancer.

126. In December, the EAG convened by teleconference and made recommendations on an extension of indication of a medicine for the treatment of locally advanced or metastatic non-small cell lung cancer in adults. The product was discussed in the context of the UK Early Access to Medicine Scheme (EAMS).

    In December, the EAG also provided written comments on a medicine intended for the treatment of metastatic adenocarcinoma of the pancreas.

Paediatric Medicines Expert Advisory Group (PMEAG)

127. The Paediatric Medicines Expert Advisory Group (PMEAG) advises 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. The PMEAG met 6 times in 2015 and provided advice through written correspondence for 19 papers. 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 Paediatric Committee (PDCO), its working-groups and *ad hoc* groups.

Paediatric Investigation Plans

128. PMEAG and its individual members advise on Paediatric Investigation Plans (PIPs) where UK is Rapporteur or Peer Reviewer. The PMEAG discussed 7 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 4 PIPs for which UK was Rapporteur or Peer Reviewer for which the EU deadlines fell between EAG meetings. The advice given covered a range of therapeutic areas. The PMEAG also provided comments for a PIP for which the UK was volunteer reviewer and which concerned the development of a drug for treatment of high-grade glioma in paediatric cancer patients.

Advice on work-sharing procedures

129. The PMEAG considered 2 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 PMEAG 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). The therapeutic areas for these procedures included drugs used for contraception, drugs used for the treatment of bedwetting, drugs used in cancer patients and for cardiovascular diseases. The PMEAG also provided comments for 2 procedures (one under Article 46 and one combined procedure under Articles 45 and 46) for which the UK was not Rapporteur and which concerned the development of two drugs in paediatric cancer patients.

Advice related to marketing authorisation applications supported by paediatric data

130. The PMEAG reviewed 4 applications for new products and 5 applications to add or extend paediatric use to an existing product. The products covered a range of indications including treatment of asthma, treatment of cystic fibrosis, treatment of overactive bladder, paediatric sedation, treatment of Duchenne muscular dystrophy and 2 drugs for the treatment of paediatric cancers.

Safety of medicines in children

131. From the beginning of 2015 the PMEAG received monthly statistics on adverse drug reactions in paediatric patients reported to MHRA, and an overview of all identified paediatric signals. The EAG advised on the safety of paediatric use of products for infant teething and for mouth ulcers in children. Furthermore the PMEAG provided advice regarding the risks associated with the use of chloral hydrate in paediatric sedation and evaluated the risk of infantile hypertrophic pyloric stenosis in association with perinatal use of azithromycin. The PMEAG provided comments regarding the safety concerns identified in an ongoing observational post-marketing safety study in patients with Cystic Fibrosis and also advised on potential gastrointestinal risks associated with the use of NSAIDs in paediatric patients with Sickle Cell Disease. The PMEAG considered the Pharmacovigilance Risk Assessment Committee (PRAC) recommendations regarding the use of hydroxyzine in the paediatric population as the result of a European referral procedure.

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

132. ***Regulatory guidance:*** The PMEAG was informed of the EMA publication of the outcome of PDCO's Revision of the current Class Waiver list, for which the committee has previously provided comments. Furthermore the PMEAG was informed on EMA's Questionnaire seeking views of children and adolescents on taking medicines and participating in medical research. The PMEAG commented on EMA's draft Inventories of Drugs in Paediatric Gastroenterology and in Paediatric Immunology and provided comments on the draft guidelines on the development of medicinal products for Crohn's disease / Ulcerative Colitis.

133. ***Discontinuations:*** In 2015, the PMEAG members gave advice on the discontinuation of one medicine for children, the only available paediatric strength of suppositories intended for use in perioperative analgesia. Following the advice from the PMEAG on the significant impact that this would have for patients, the MAH decided to maintain the availability of this product in the UK.

134. ***Clinical trial protocols:*** The PMEAG reviewed the protocol of a proposed clinical study which aims to assess the long term safety of a drug licensed for the treatment of attention deficit hyperactivity disorder (ADHD).

Patient and Public Engagement Expert Advisory Group (PPEEAG)

135. Members of the PPEEAG are primarily lay people although a small number have a health professional background. The PPEEAG is supported by two former lay members from the Commission. Two meetings were held during the reporting period.

    The PPEEAG work continued to progress within three work-streams which had been endorsed by the Commission

    - Information improvement
    - Internal influence (ensuring uptake of best practice principles across all assessment areas within MHRA)
    - External influence

136. As part of the information improvement work-stream the PPEEAG reviewed and advised on a number of pieces of case-work following the Commission review of safety data. Patient information was optimised for medicines used in the treatment of acne, sodium valproate and an over-the-counter analgesic preparation.

137. The internal influence work-stream focussed on patient involvement in the regulatory decision-making process. The group considered a report from the Vigilance and Risk Management of Medicines Division concerning the involvement of patients in national regulatory work through a national stakeholder platform for the reclassification of medicines.

138. As part of the external influence work-stream the PPEEAG advised the Commission and the MHRA on the report produced by the European Commission on the shortcomings of medicines information produced under the auspices of article 59(4) of Council Directive 2001/83/EC.

139. The PPEEAG also advised on the strand of work under the Yellow Card Road Map entitled *"My Yellow Card – meeting the patient's needs"*, and provided comment on the Web-RADR mobile app for reporting adverse drug reactions.

Pharmacovigilance Expert Advisory Group (PEAG)

140. The Commission's Pharmacovigilance EAG membership includes expertise in pharmacovigilance, clinical pharmacology, toxicology, epidemiology, general practice, nursing, pharmacy and also includes lay representation. The PEAG met on 9 occasions during 2015, and provided advice by written procedure on a

further occasion. The PEAG considered papers on the following drug safety signals:

- Gadolinium-containing contrast agents – deposition of gadolinium in brain tissue in patients exposed for diagnostic procedures
- SGLT2 inhibitors (canagliflozin, dapagliflozin, empagliflozin) – diabetic ketoacidosis
- Fosphenytoin – medication errors and off-label use in children aged less than 5 years
- Fluoroquinolone antibiotics – possible link with retinal detachment
- Proton pump inhibitors – spontaneous bacterial peritonitis
- Dimethyl fumarate - progressive multifocal leukoencephalopathy
- Natalizumab – progressive multifocal leukoencephalopathy
- Dofosbuvir & daclastavir – cardiac arrhythmia
- Mycophenolate mofetil – congenital malformations
- Methadone & buprenorphine - fatal poisoning
- Citalopram and cocaine abuse – subarachnoid haemorrhage
- Bisacodyl – constipation with long-term use
- Benzodiazepines –review of associated (all-cause) mortality
- Hydroxyzine – QT interval prolongation

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

142. The PEAG gave advice on 5 Risk Management Plans including one for a new product being considered under the Early Access to Medicines Scheme (EAMS), on draft protocols for three post-authorisation safety studies (PASS) and on MHRA's vaccine surveillance strategies for new national vaccination programmes (Meningitis B & Meningitis ACWY). In addition to the monthly Yellow Card reporting statistics, the PEAG considered proposed updates to the Yellow Card Scheme including revisions to the format for presenting aggregated Yellow Card data on the Agency website. The PEAG also noted plans for a Joint Patient Safety and Vigilance Strategy, the aim of which is to integrate, where appropriate, MHRA safety surveillance activities and systems for medicines and medical devices.

143. Summary reports based on the minutes of each meeting are published on the GOV.UK website. The safety advice given by the PEAG on 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 Expert Working Group

144. In 2014, the Commission advised that an ad hoc Expert Working Group (EWG) be set up to consider the balance of benefits and risks of alteplase in the treatment of acute ischaemic stroke. This was because new evidence had become available since 2012 when the treatment time-window for alteplase in acute ischaemic stroke had been increased to 4.5 hours post-symptom onset and because concerns on the data underpinning the Marketing Authorisation (MA) for alteplase had been raised by some physicians [Ref:Do risks outweigh benefits in thrombolysis for stroke? BMJ 2013;347:f5215]

145. The EWG comprised experts in neurology, cardiology, emergency medicine, statistics, epidemiology and patient representation and included a broad range of experience. Interests were managed in accordance with a pre-specified policy which stipulated that no member could have a financial interest. Potential members were asked to declare any involvement in clinical trials. The Group reviewed the findings from a large number of studies and carefully considered all specific concerns that had been raised. The group also took evidence from experts from various scientific and health professional backgrounds.

146. After careful consideration of every issue, the EWG concluded that the data that have become available since 2012 added substantially to the understanding of the balance of benefits and risks of alteplase over time and in different patient populations. The EWG concluded that the balance of benefits and risks of alteplase in the treatment of acute ischaemic stroke was positive when used within the conditions of the MA, up to 4.5 hours post-symptom onset. The Group concluded that benefit of alteplase is highly time-dependent and therefore minimising the time to onset of treatment was critical to ensuring the best possible outcome.

    At its meeting in July 2015 the Commission fully endorsed the conclusions and recommendations of the EWG and advised that the benefit-risk balance of alteplase treatment was positive in the treatment of acute ischaemic stroke when used in accordance with the MA. All assessment reports and data considered by the Group and minutes of meetings were placed on the MHRA website on 28th July 2015 (https://www.gov.uk/government/publications/alteplase-for-treatment-of-acute-ischaemic-stroke-independent-review).

Anti-Epileptic Drugs Working Group

147. The Anti-Epileptics Working Group met on Wednesday 28th October 2015. The group considered the literature on switching of AEDs, spontaneous reports received by MHRA and heard a presentation from Epilepsy Action of the results

of a web based survey of patient experiences conducted by them in conjunction with the Epilepsy Society.

148. The group agreed that the current categorisation of AEDs into three groups based on their pharmacokinetic and pharmacodynamics properties remained appropriate and that there was no basis to re-classify any specific drug. However the group were concerned that this categorisation had been interpreted as being the sole or major determinant of clinical decision making with regard to switching between formulations; the group were keen that emphasis was also given to other factors, including any anxiety, misunderstanding or loss of faith in a familiar medication on the part of the patient or their carers which might result. The group were therefore keen to emphasise the cardinal importance of involving patients in such prescribing decisions.

149. The group noted prescribing data showing very high levels of generic prescribing (>95%), which supports the prevailing impression that there has been a low uptake of the Commission's advice to ensure consistent supply of a specific product for Category 1 AEDs and as appropriate also for Category 2 and 3 AEDs. The group advised on measures to be taken to improve this situation, including measures to increase awareness of the advice, possible enhancements of GP prescribing software and measures at the dispensing level. The group advised on communication strategies and noted that further research using record linkage databases might be helpful.

Hormonal Pregnancy Tests Working Group

150. In 2015 the Commission convened an Expert Working Group (EWG) to review the available data on a possible association between Hormone Pregnancy tests (HPTs) and congenital anomalies. HPTs were used in the 1950's-1970's but licenses were withdrawn in the late 1970's.

151. The EWG met first in October 2015 to consider the remit and work plan for the Group, and whether any additional expertise was required and noted a review of the social, medical and legal perspective from the time that HPTs were available, together with a chronology of events from 1958 to the present day. The Group agreed that its terms of reference should focus on the scientific evidence on the possible association between exposure in pregnancy to HPTs and adverse effects in pregnancy (including birth defects in the child, abortion and stillbirth), what lessons may be learned for improving existing regulatory systems in relation to medicines used in pregnancy, and whether the findings have any implications for currently licensed medicines.

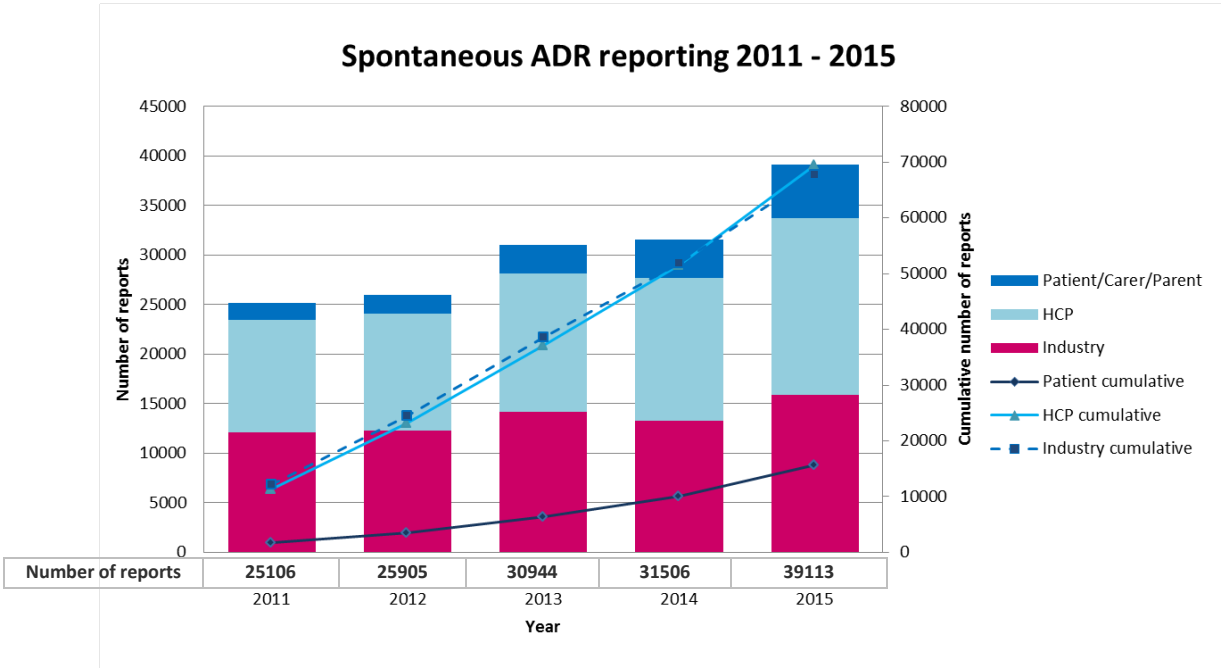
152. A second meeting of the Group was held in December 2015 to consider the information from spontaneous case reports including Yellow Card data and testimonials from a number of individuals who consider they have been affected by HPTs. Further meetings to consider the basic science and epidemiological evidence are planned for 2016.

REPORTING OF SUSPECTED ADVERSE DRUG REACTIONS 2015

153. Suspected Adverse Drug Reactions (ADRs) to medicinal products and vaccines are reported to the Commission 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.

154. Figure 1 shows the total number of UK spontaneous Yellow Card reports received from pharmaceutical companies, healthcare professionals and patients over a five year period between 1 January 2011 and 31 December 2015. The number of suspected ADR reports has increased by 14055 reports (56%) over the five year period. Overall the annual number of UK spontaneous ADR reports received since 2011 shows an increasing trend as depicted by the cumulative lines on the graph.

Figure 1 – Graph showing the number of UK spontaneous suspected Adverse Drug Reaction reports received between 2011 and 2015 for industry, healthcare professionals and patients.



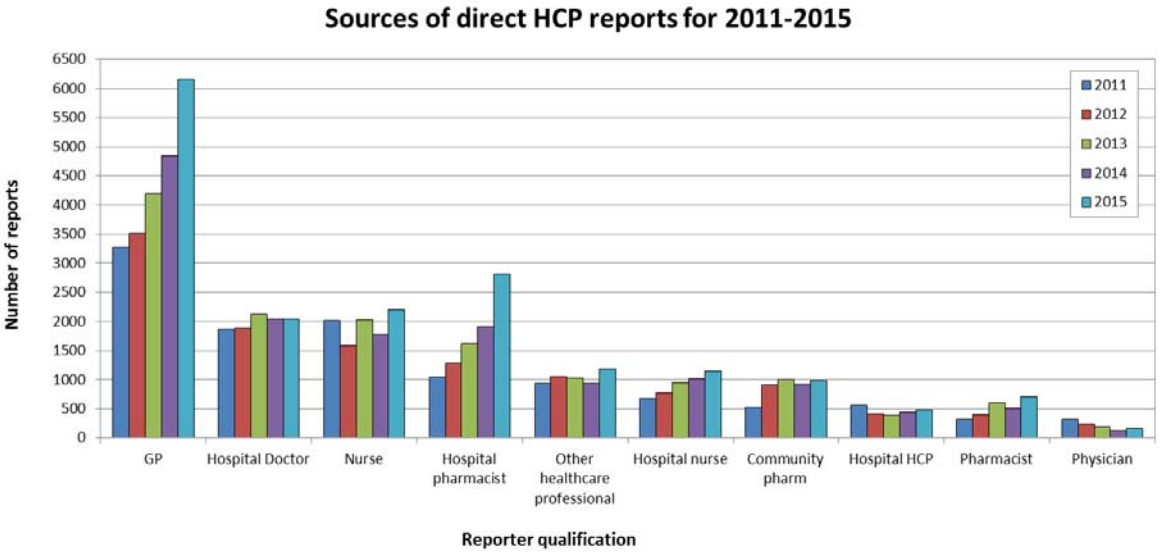
155. The total number of UK spontaneous suspected ADR reports increased by 24% (7655 reports) in 2015 when compared to the previous year. The proportion of serious ADR reports has remained relatively constant at 85% (compared to 86%

in 2014). Of the total number of UK spontaneous suspected ADR reports received in 2015, 41% (15853) of reports were received from pharmaceutical industry, 45% (17827) directly from healthcare professionals and 14% (5459) from members of the public (patients, parents and carers). A breakdown of direct healthcare professional reports by reporter qualification between 2011 and 2015 is shown in Figure 3.

156. Reports from GPs continue to form the highest proportion of direct reports received through the Yellow Card Scheme, showing the continued impact of direct electronic reporting from the GP IT system SystmOne which was introduced in 2010. A key focus of the Yellow Card strategy is to improve access to and ease of reporting by GPs. In total, GP reports accounted for 34% (6152 reports) of all direct healthcare professional Yellow Cards received by the MHRA in 2015.

Figure 2 – Graph showing the number of direct ADR reports received between 2011 and 2015 by reporter qualification.

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



157. In 2015, Yellow Cards completed by hospital pharmacists accounted for the second largest proportion of all direct healthcare professional reports accounting for 2,819 reports (16%). The majority of hospital pharmacist reporting is electronic, with 31% (889 reports) being reported directly from the MiDataBank system used within 118 different Medicines Information Centres, whilst 56% (1588) were reported through the MHRA's electronic Yellow Card website. Reports through both mechanisms have increased by approximately 40% compared to 2014. It is encouraging to note that the numbers of Yellow Cards received from hospital pharmacists have almost tripled between 2011 and 2015.

158. Interactive e-learning modules for healthcare professionals on pharmacovigilance and the Yellow Card Scheme continued to be available in 2015. These included modules on SSRIs, opioids and corticosteroids. These

modules will have contributed to the number of reports received from healthcare professionals. This is reflected by responses collected through the Yellow Card website question “Where did you hear about us” in which those selecting CPD/training category increased by 28% in 2015 compare to 2014.

Patient Reporting

159. Overall there has been a 43% increase in patient, parent and carer reports compared to 2014. Patient reporting is an established part of the Yellow Card Scheme and 2015 saw our highest ever proportion of Yellow Card reports from patients, with 5459 reports received making up 14% of all direct reports. Significant efforts to increase awareness of the Scheme through a specific communication campaign targeting parents and carers took place in 2014 and through most of 2015. This included displaying information on patient websites such as patient.co.uk and WebMD, and blog articles for organisations such as the Association of Medical Research Charities and Royal Colleges in the last quarter of 2015. We have also been working with patient organisations and the Yellow Card Centre (YCC) network to promote and raise awareness of the scheme by attending events such as the Patient Safety Congress and Patient First in 2015.

160. From 2014 onwards patient information leaflets have been updated to include a reference to reporting side effects via the Yellow Card Scheme with most updated print versions becoming available in 2015. This has contributed greatly to patient awareness of the Scheme. Data taken from our Yellow Card website, “where did you hear about us”, suggests an increase of 152% (466 reports in 2014 increasing to 1174 reports in 2015) in those selecting the “Patient Information Leaflet” category as the source of information.

Electronic Reporting

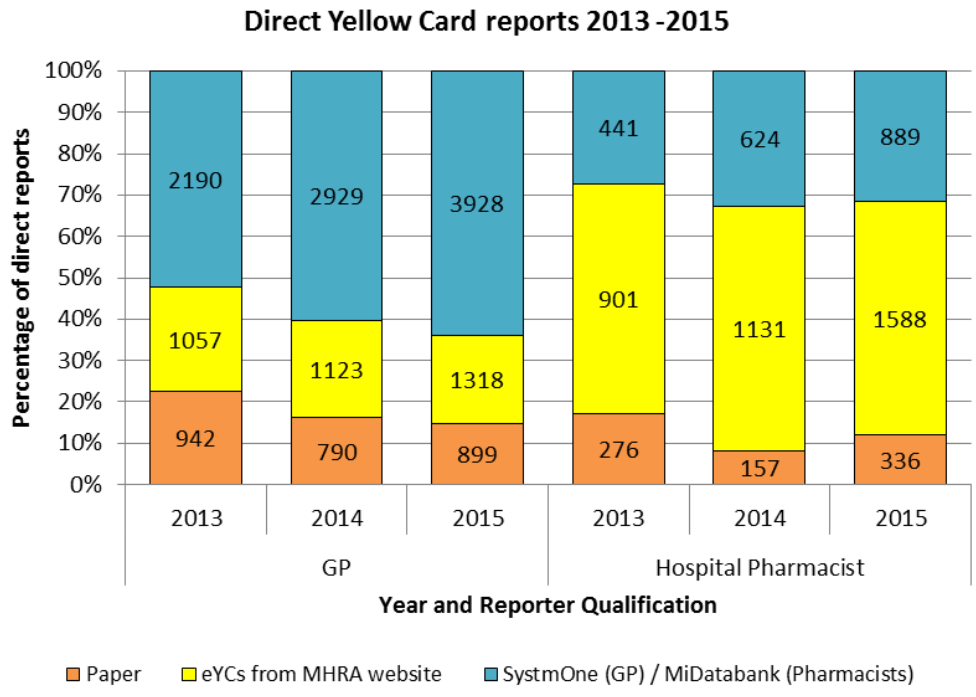


Figure 3 - Graph showing the breakdown of Yellow Card reporting methods (paper vs electronic) received directly from healthcare professionals between 2013 and 2015.

161. 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 under way to facilitate electronic Yellow Card reporting through integration into clinical IT systems used by healthcare professionals. Electronic reporting via both the Yellow Card website and clinical systems continues to increase in popularity amongst healthcare professionals.

162. In 2015, 81.8% of all direct healthcare professional reports were received electronically (47.5% by the Yellow Card website and 34.3% via clinical systems including SystmOne and MiDatabank) and 18.2% by paper forms. Work is continuing to increase the number of reports received via MiDatabank and SystmOne and to integrate Yellow Card reporting into other clinical systems 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 2013 to 2015 following efforts to increase reporting through SystmOne and MiDatabank systems.

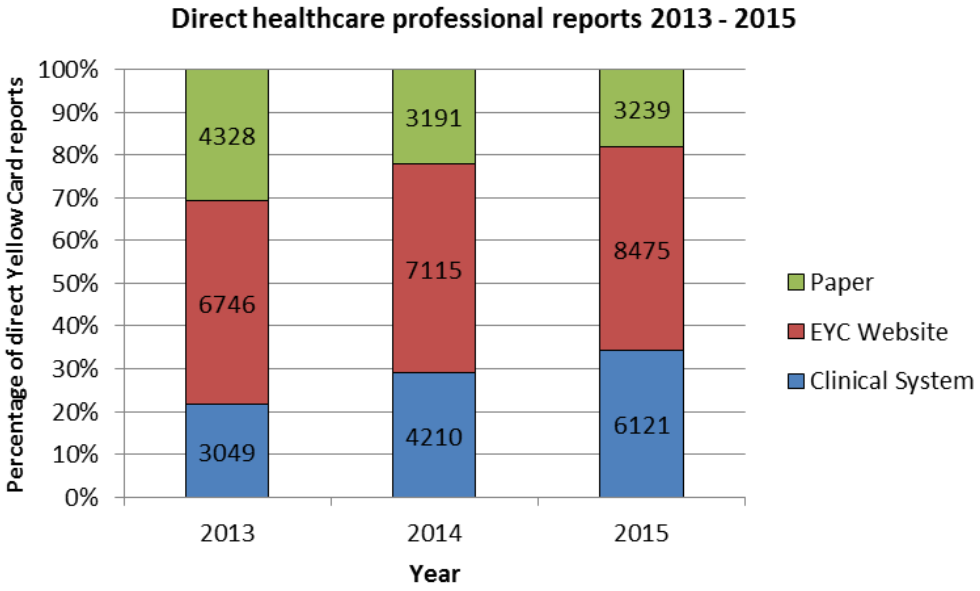


Figure 4 - Graph showing the breakdown of Yellow Card reports reported by GPs and hospital pharmacists by reporting method between 2013 and 2015.

163. The integration of the Yellow Card function into GP practice clinical systems was incorporated into the GP Systems of Choice (GPSOC) contractual framework in 2012, with the creation of an Information Standards Board (ISB 1582) standard for electronic Yellow Card reporting through GP clinical software. Yellow Card reporting direct from GP practices was demonstrated as a proof of concept by SystmOne and introduced in 2010 to increase GP reporting. An analysis of GP reports received in 2011 showed an increase in GP reports by 50% compared to 2010. The GPSOC project has provided the MHRA with an opportunity to update the existing functionality in SystmOne and to integrate the Yellow Card function across other system suppliers in England. The scope of the standard is the NHS in England; however, system suppliers also have contracts across the whole of the UK. It is now mandatory for all GP systems in England to include the capability of reporting a Yellow Card and testing of the remaining GP systems has been ongoing in 2015 with roll out anticipated in 2016. The standard is also open to other healthcare organisations and system suppliers who may wish to implement it.

164. Highlights of the GPSOC standard include: when entering information into the health record this can trigger a reminder for a healthcare professional to send a Yellow Card report; users can manually request to submit a Yellow Card; automated reminders for healthcare professionals to submit a card later; and an audit trail for follow- up which is stored on the patient record and practice system. SystmOne adopted the new standard in April 2015. In 2015 we received 3928 Yellow Card reports from GPs via SystmOne, an increase of 999 reports from 2014 as seen in figure 5.

165. Over the last 5 years we have seen an increase in overall numbers of reports and within that an increase in the percentage of these reports being received electronically. Electronic reporting is also the most popular way of reporting for members of the public; in 2015, the MHRA received 5459 suspected ADR reports from patients, parent and carers, for which 87% were reported via the online Yellow Card reporting tool.

166. The proportion of electronic reports across patient and healthcare professionals is anticipated to increase further over the next year as a result of the launch of the Yellow Card reporting app. On 14th July 2015, the MHRA launched the Yellow Card Scheme reporting app as part of the WEB-RADR project. The app (available on iOS and Android) is free to access and allows patients, carers and healthcare professionals to report directly without using the Yellow Card website or paper forms. Users can also select specific medicines or vaccines to track and receive news and alerts. Between its launch on 14th July 2015 and 31st December 2015, the app was downloaded a total of 1976 times (Android – 496, iOS – 1507), with a total of 65 reports being submitted.

167. As part of the 50th anniversary of the Yellow Card Scheme (see below), a new Yellow Card website was launched which provides a single point of access to

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

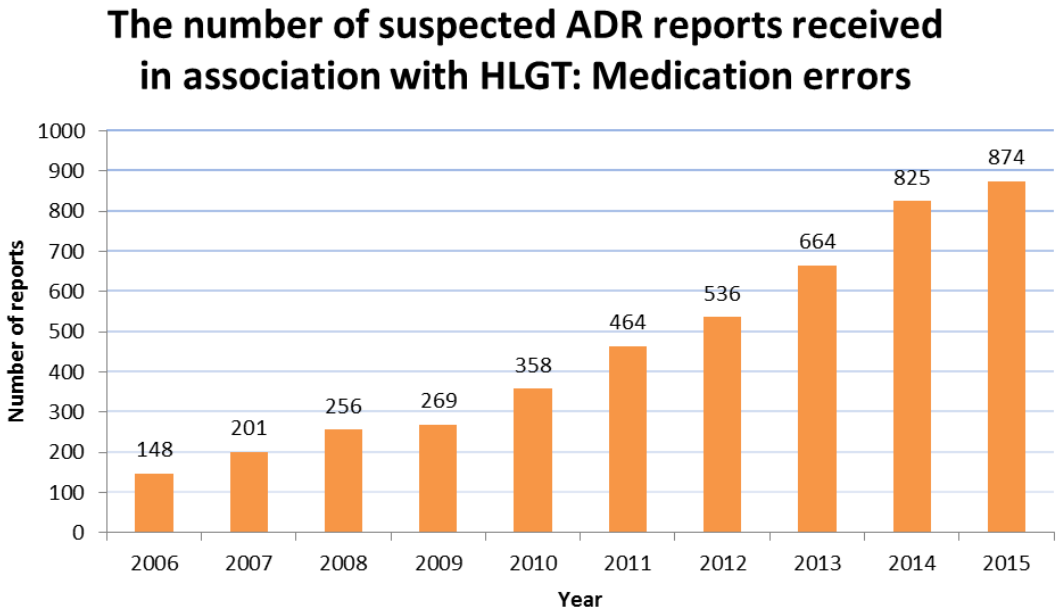
168. A year after implementation of the new online reporting site under the Yellow Card branding, the results have been positive. There is a 19% increase (2849 reports) of all MHRA healthcare product incidents received through the online Yellow Card website compared to the numbers received through the independent MHRA reporting systems a year before. This corresponds to an increase of 23% associated with medical device incidents (848 reports) and a 36% increase in defective medicines (148 reports) which for the first time have had a reporting form.

National Medication Safety Network of Medication Safety Officers in England

169. In collaboration with NHS England, in 2014 the MHRA established a 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. The MHRA has been working with the network 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 the 2012 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.
170. By the end of 2015, the National Medication Safety Network had a total of 380 registered Medication Safety Officers in England. The MSOs are nearly all hospital pharmacists who continue to report themselves as well as encourage reporting within their trusts. The increase in reports from hospital pharmacists can therefore be partly attributed to the work of the Safety Officers within this network.

171. This initiative has improved learning at local level, clarifying medication safety roles and identifying key safety contacts to allow better communication between local and national levels. As a result, the medication safety officer network is now well established with monthly web conferences taking place with approximately 100 attendees each month. The network has also seen the creation of smaller networks within the medication safety network. These consist of email discussion groups and online information forums for medication safety officers in a specified region, clinical speciality or healthcare setting. Currently there are 8 local medication safety officer networks and there are also dedicated web events for specialist areas. Figure 4 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 2015.

Figure 5 – Graph showing the number of UK spontaneous suspected Adverse Drug Reaction reports associated with medication errors received between 2006 and 2015.



172. Data from the National Reporting and Learning System (NRLS) shared with the MHRA have been analysed, and between December 2014 to November 2015, 9808 reports were received. From the reports assessed by MHRA scientists, 28% (2751) were valid cases reporting a conventional ADR or harm associated with a medication error. Efforts have been made through monthly WebEx conferences and communication with the network to focus on increasing reporting, and improving coding and quality.

173. MHRA is continuing to work with the UK Devolved Administrations (Scotland, Northern Ireland and Wales) to share learnings from this initiative and to promote similar initiatives UK-wide.

174. The MHRA is also working with local risk management system suppliers to harmonise data collection from healthcare organisations through integration of Yellow Card reporting into their systems; thus enabling direct reporting of ADR reports to the MHRA. This will ensure all relevant information is captured that is required for national safety assessment and pharmacovigilance purposes.

Signal detection

175. The signal detection and management system at the MHRA is designed to detect new and changing safety issues in a timely manner. Changes in the frequency of ADRs already known to be associated with drugs are also closely monitored through the signal detection process. The drug-event combinations from Yellow Card reports are assessed each week to identify potential safety

signals. In 2015 there were a total of 90 validated signals–potential signals that have been identified by a statistical algorithm or from external sources 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 [1] and assigned a timeframe during which a regulatory position on the action required is reached. A breakdown of the signals and assigned priorities is provided in table 1.

Table 6: Number of signals assessed in 2015

	Signal Priority			
	Top	**Increased**	**Standard**	**Not prioritised**
Number of signals	3	19	66	2

176. In 2015 ADR reports received from members of the public contributed towards 15 signals being detected. This includes 6 signals where a member of the public's report directly stimulated regulatory action. One example of a signal originated from a concerned hospital pharmacist who had noticed an increase in the number of drug interaction incidents between triamcinolone and ritonavir resulting in Cushing's syndrome. This led to a review and the addition of this drug interaction to product information. Another example of a signal that led to regulatory action was triggered from a patient report, and this led to the product information for levonorgestrel being updated to include drug- induced hepatitis as a possible adverse effect.

177. Towards the end of 2015 a review of the current signal detection processes was initiated in light of the results of the IMI PROTECT project[6]. The results of the PROTECT project have highlighted a number of areas within the current signal detection algorithm used at MHRA that could be optimised to maximise both sensitivity and precision[7,8]. By adjusting the approach to suit the MHRA's database, in combination with a review of frequency change signalling and rule-based criteria, this should lead to a more efficient system for detecting potential safety signals, enabling the MHRA to take prompt regulatory action when required to help protect public health. Work on this review will be completed by the end of 2016.

[6] http://www.imi-protect.eu/

[7] Candore G, Juhlin K, Manlik K, Thakrar B, Quarcoo N, Seabroke S, Wisniewski A, Slattery J. Comparison of Statistical Signal Detection Methods Within and Across Spontaneous Reporting Databases. Drug Safety 2015; 38:577-587

[8] Seabroke S, Candore G, Juhlin K, Quarcoo N, Wisniewski A, Arani R, Painter J, Tregunno P, Noren GN, Slattery J. Subgroup analyses outperform stratification for statistical signal detection in pharmacovigilance. Submitted to Drug Safety [Sep 2015]

The 50th anniversary of the Yellow Card Scheme

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

179. Along with the events held in 2014, in March 2015 a landmark scientific conference took place in Edinburgh. The purpose of the conference was to focus on exploring scientific and technological advances that are taking place, to ensure the Yellow Card Scheme remains a world leader.

180. The agency chairman Sir Michael Rawlins introduced the Yellow Card Roadmap **(attached)** which outlines the MHRA's current thinking on the future direction of the Yellow Card Scheme – recognising that it must continue to adapt to the changing technical and cultural environment and actively address the issue of under-reporting.

181. Some key projects which were raised at the conference included the launch of the Yellow Card app and improving interaction with ADR data through the development of the MHRA's new interactive Drug Analysis Profiles which will be launched in summer 2016. Delegates were able to see live demonstrations of this new facility and were asked to provide feedback. Presentations were also delivered on a wide range of topics from the impact of pharmacogenomics and increasing use of biological medicines, to new data sources which may complement Yellow Card reporting ranging from social media data mining to collaboration with the National Poisons Information Service.

182. Parallel breakout sessions were also hosted with discussions on integrating Yellow Card into healthcare and health education, best scientific use of Yellow Card data, and patient engagement. The final item on the agenda was to recognise and reward reporters for their contribution to medicine and patient safety, through the presentation of the Dunlop Award for the first report of a major new drug association. Following a video shortlist of nominations from VRMM staff, the winner was decided by a panel. It was jointly presented to Dr David Hunt and Dr Oliver Flossmann who recognised and reported thrombotic microangiopathy (TMA) associated with interferon beta treatment.

Yellow Card Centres

183. The Yellow Card Scheme covers the entire United Kingdom. However, to strengthen 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 of the Yellow Card Scheme, improving ADR reporting through the Yellow Card Scheme and communicating drug safety messages.

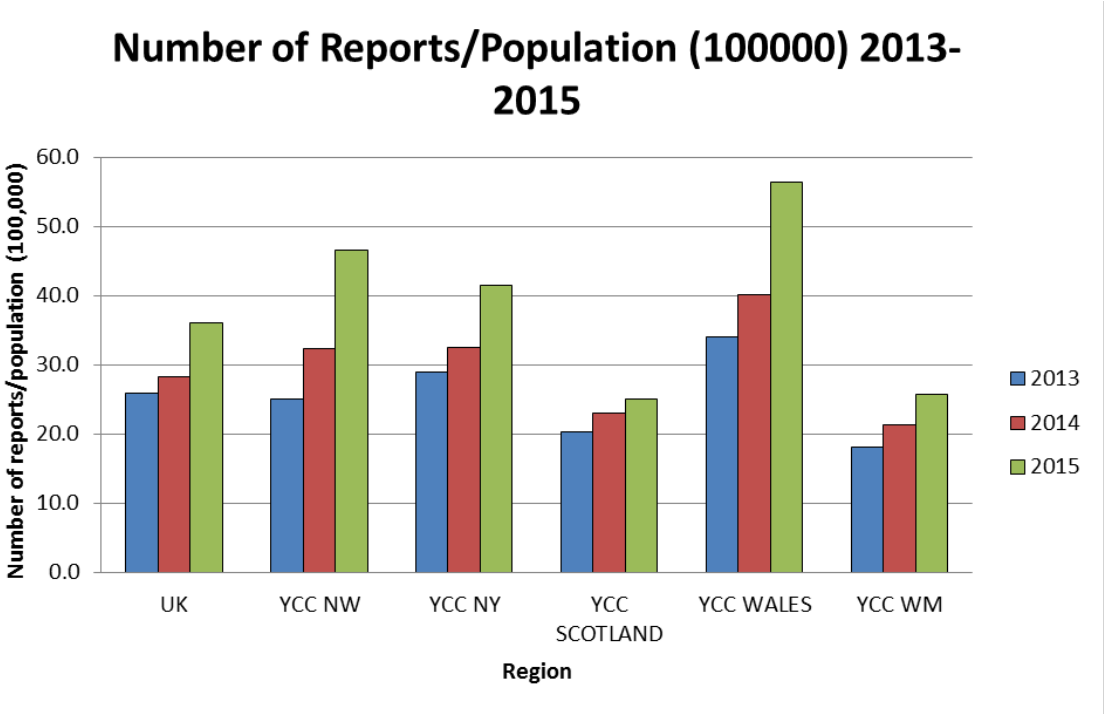
184. The YCCs are involved in various programmes that aim to increase ADR reporting in their specific region. A number of the YCCs have established 'ADR Champions' schemes that have proved to be successful in 2015. These involve establishing hospital pharmacists or pharmacy technicians as 'ADR Champions' who can then promote the Yellow Card Scheme from within the hospital.

185. The YCC Wales champions scheme, developed in 2013, has continued to be successful in 2015, and the YCC West Midlands scheme, which was set up this year, saw an 18% increase in Yellow Card reports in the first 3 months of the programme. A collaboration between YCC North West and the Liverpool Health Partners (a combination of hospitals and healthcare organisations, scientific, academic and innovation institutions) resulted in a 64% increase in reporting from the participants. Following this, YCC North West has set up their own champions scheme and is expecting good results in 2016.

186. The YCCs continue to provide valuable educational services for current healthcare professionals, as well as postgraduate and undergraduate students. The YCC Scotland developed a series of e-learning modules last year, and in 2015 these modules were officially added to the core learning for pre-registration pharmacists and FY1 doctors as well as being added to a learning platform for all healthcare professionals in Scotland.

187. The impact of the YCCs' actions can be seen from the reporting rates from these regions as shown in figure 7. In 2015, 3 YCCs had a higher number of reports per 100,000 people than the UK average (36.0): Northern & Yorkshire (41.5), North West (46.6) and Wales (56.4).

Figure 7 – Graph showing the number of reports per population for each Yellow Card Centre between 2013 and 2015



188. Of particular note is the increased reporting rate in Wales. Yellow Card reporting was launched as a National Prescribing Indicator for General Practitioners in Wales in 2014-15 via the All Wales Medicines Strategy Group. This has been associated with a 168% increase in submission of GP reports when compared to the previous year. All YCCs have seen a continued increase in reporting rates and we hope this continues in 2016.

189. The Commission is grateful for the co-operation of those healthcare professionals and patients who submit reports of suspected ADRs and contribute to public health protection, and encourages 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

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Lay Member. HR and Legal Director, Source BioScience, Nottingham

Dr J Colin Forfar[9] BSc (Hons) MBChB PhD MD MA FRCP FRCP (Edin)
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Medical Director and Consultant Medical Oncologist, The Royal Marsden NHS Foundation Trust and Professor of Cancer Medicine, Institute of Cancer Research

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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 Sarah Meredith
Deputy Director, MRC Clinical Trials Unit at UCL, Institute of Clinical Trials and Methodology, 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[10] MD (Hons) FRCP FRCPsych

[9] Reappointed 01 January 2016 – 31 December 2018

Professor of Clinical Psychiatry, Edinburgh University

Professor B Kevin Park[11] 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

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David Weatherall Chair of Medicine, University of Liverpool, NHS Chair of Pharmacogenetics, Director of the Wolfson Centre for Personalised Medicine, Director of the MRC Centre for Drug Safety Science

Professor Shirley Price MSc PhD FBTS FRSB ERT FHEA FRSC MBPharmacolSoc
Head of Academic Appeals and Academic Quality and Professor of Toxicology, University of Surrey

Carolyn, Lady Roberts[13] HV Cert. MSc D Univ
Member of The Ethox Foundation - Oxford Foundation for Ethics and Communication in Healthcare Practice. Health Visitor

Professor Kevin M G Taylor[14] BPharm PhD MRPharmS
Chair of the British Pharmacopoeia Commission and Professor of Clinical Pharmaceutics, UCL School of Pharmacy, London

Professor Angela E Thomas[15] MB BS PhD FRCPE FRCPath FRCPCH **(Vice-Chair)**
Consultant Paediatric Haematologist, Royal Hospital for Sick Children, Edinburgh

Professor Simon H L Thomas[16] 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 BSc (Hons) PhD MSc FRSS C.Stat C. Sci
Reader in Medical Statistics, Usher Institute for Population Health Sciences and Informatics, University of Edinburgh

Invited Experts to Commission meetings:

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

Dr. Paula Bolton-Maggs DM FRCP FRCPath
Medical Director, Serious Hazards of Transfusion Scheme (SHOT), Manchester Blood Centre, Manchester (Attended May by teleconference)

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[10] Reappointed 01 January 2016 – 31 December 2018
[11] End of appointment 31 December 2015
[12] Reappointed 01 January 2016 – 31 December 2018
[13] End of appointment 31 October 2015
[14] Reappointed 01 January 2016 – 31 december 2018
[15] Reappointed 01 January – 31 December 2018
[16] End of appointment 31 December 2015

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

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

Professor Ann Daly BA PhD FBPhS
Professor of Pharmacogenetics, Institute of Cellular Medicine, Newcastle University
Observers (Attended July)

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

Dr Ailsa E Gebbie MB ChB FRCOG FRCPE FFSRH
Consultant Gynaecologist and Co-Director of the FSRH Clinical Effectiveness Unit
Edinburgh (Attended September by teleconference)

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 (Attended July and October by teleconference)

Dr Richard Groves FRCP
Head, Clinical Immunodermatology, St. John's Institute of Dermatology, Guy's Hospital (Attended February)

Ms Amanda Hoey
Lay Representative. Director, Consumer Health Consulting Ltd (Attended January)

Dr Clifford Mann MB BS FRCP FCEM
President of the College of Emergency Medicine and Consultant in Emergency Medicine, Taunton and Somerset NHS Foundation Trust (Attended October)

Professor Christopher Marriott PhD DSc Hon DSc FRPharmS CChem FRSC FRSM Emeritus Professor of Pharmaceutics, King's College, London and Vice Chair of the Chemistry, Pharmacy and Standards Expert Advisory Group (Attended March)

Carolyn, Lady Roberts HV Cert. MSc D Univ
Member of The Ethox Foundation - Oxford Foundation for Ethics and Communication in Healthcare Practice. Health Visitor (Attended November and December)

Dr Catherine F Stannard MB ChB FRCA FFPMRCA, Pain Clinic Macmillan Centre, Frenchay Hospital, Bristol (Attended October)

Professor Paddy Stone MA MD FRCP
Marie Curie Chair in Palliative and End of Life Care, University College London (Attended November)

Dr Raman Uberoi BMSc Path MBBChir MRCP FRCR
Honorary Senior Lecturer and Consultant Interventional Radiologist, John Radcliffe Hospital, Oxford and President of the British Society of Interventional Radiology (Attended December)

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

Professor Mark Wilkinson PhD, FRCS (Tr&Orth)
Professor of Orthopaedics, Department of Human Metabolism, The Mellanby Centre for Bone Research, University of Sheffield (Attended April by teleconference)

Professor Anthony G Wilson MB BCH BAO DCH PhD FRCP
Professor of Rheumatology, Medical School, University of Sheffield (Attended April and September by teleconference)

Observers of Commission meetings:

Dr Nick Crabb
Programme Director for Scientific Affairs, Centre for Health Technology Evaluation, National Institute for Health and Care Excellence (Observed July)

Dr James Fullerton MRCP MB ChB MA
Academic Clinical Fellow, Clinical Pharmacology and Therapeutics, Wellcome Trust Clinical Research Fellow, University College London (Observed March)

Dr Hafid Narayan
Consultant Physician in Clinical Pharmacology & General Medicine, Royal Infirmary, Edinburgh (Observed November)

Dr Peter Nightingale FRCA FRCP FFICM FRCPE
Chair of the Devices Expert Advisory Committee and Consultant in Anaesthesia and Intensive Care Medicine, University Hospital of South Manchester (Observed February)

Dr David Owen
NIHR Clinical Lecturer and Clinical Pharmacology SpR, Imperial College Healthcare NHS Trust, London (Observed April)

Mr Campbell Stewart
Medical Student, St Hilda's College, University of Oxford (Observed November)

Professor Annie Young
Professor of Nursing, Division of Health Sciences, University of Warwick (Observed January)

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

Dr Mary Ramsay
Consultant Epidemiologist, Immunisation, Hepatitis & Blood Safety Department, Public Health England (Attended May)

Dr Vanessa Saliba
Consultant Epidemiologist, Immunisation, Hepatitis & Blood Safety Department, Centre for Infectious Disease Surveillance and Control Public Health England (Attended May)

The following NHS England officials attended for specific agenda items:

Mrs Jan Beattie
Allied Health Professions Officer, Primary Care in Scottish Government (Attended September and October)

Ms Rebecca Blessing
Section Head - Non-Medical Prescribing and General Prescribing Issues, Department of Health (Attended September and October)

Ms Nicole Casey
Policy Manager, Health and Care Professions Council (Attended September and October)

Ms Alison Culkin
Advanced Practitioner / Research Dietician, North West London Hospitals NHS Trust (Attended September)

Mrs Christina Freeman
Professional Officer, The Society and College of Radiographers (Attended October)

Mr Will Flower
Stakeholder Strategy Lead, NHS England (Attended September and October)

Mr Dylan Griffin
Advanced Clinical Practitioner, Royal Derby Hospital (Attended October)

Ms Sarah Griffiths
Consultant Therapeutic Radiographer, University Hospitals Bristol NHS Trust (Attended in October)

Mrs Sharon Harrison
National Programmes Manager, Directorate of Education and Quality, Health Education England (Attended October)

Ms Fiona Henderson
Diagnostic Strategy & Development Manager, University College London Hospitals (Attended in October)

Ms Dianne Hogg

Non-Medical Prescribing Lead, East Lancashire Hospitals NHS Trust (Attended September and October)

Professor John Lawrenson
Professor of Optometry, City University (Attended September)

Ms Helen Marriott
Allied Health Professions Medicines Project Lead, NHS England (Attended September and October)

Ms Shelagh Morris
Deputy Chief Allied Health Professions Officer, NHS England (Attended September and October)

Ms Naija Qureshi
Professional Officer / Prescribing Lead, British Dietetic Association (Attended September)

Ms Suzanne Rastrick
Chief Allied Health Professions Officer, NHS England (Attended September and October)

Ms Claire Saha
Medicines Project Lead, British and Irish Orthoptic Society (Attended September)

Mr Andy Sharman
Project Officer, College of Paramedics (Attended October)

MEMBERSHIP OF THE CARDIOVASCULAR, DIABETES, RENAL, RESPIRATORY & 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[17] BSc (Hons) MBChB PhD MD MA FRCP FRCP (Edin)
Consultant Physician and Cardiologist, John Radcliffe Hospital, Oxford

Members

Dr Amanda Adler[18] MD PhD FRCP
Consultant Physician, Diabetes, Addenbrooke's Hospital, Cambridge University Hospitals

Professor Houman Ashrafian[19] BA MA BM BCh MRCP DPhil
Associate Professor of Medicine, Head of Experimental Therapeutics, Honorary Consultant Cardiologist, Radcliffe Department of Medicine, University of Oxford

Professor Richard Donnelly[20] 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
Deputy Medical Director, Cambridge University Hospitals FT, 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 MD FRCP
Professor of Diabetes & Endocrinology, Head of Service Diabetes, University Hospital Birmingham

[17] Reappointed 01 January 2016 – 31 December 2018
[18] Appointed 10 December 2015 – 11 December 2019
[19] Resigned 01 April 2015
[20] Resigned 26 May 2015

Professor Richard IG Holt[21] 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 Respiratory and General Physician, Adjunct Reader NHLI, Imperial College School of Medicine

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

Professor Ann Millar MBChB MD FRCP **(Vice Chair)**
Emeritus 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[22] 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. Shadow Governor of the Surrey and Sussex Hospital

Mr Phil Willan MSc
Lay Representative. Member of MHRA Pharmacovigilance EAG, Cardiovascular, Diabetes, Renal, Respiratory and Allergy EAG, Patient and Public Engagement EAG (acting Chair), 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, and Patient Safety Committee. Member of the NHS England Clinical Reference Group for Renal Transplantation

[21] Resigned 10 November 2015
[22] Reappointed 17 September 2015 – 16 September 2019

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[23] BPharm PhD FRPharmS
Chair of the British Pharmacopoeia Commission and Professor of Clinical Pharmaceutics, UCL School of Pharmacy, London

Members

Professor Michael E Aulton[24] BPharm PhD FRPharmS FAAPS FSP
Emeritus Professor, De Montfort University, Leicester

Professor Graham Buckton[25] BPharm PhD DSc FRPharmS FRSC
Professor of Pharmaceutics, UCL School of Pharmacy

Professor Derek H Calam[26] 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[27] BSc PhD CChem FRSC FRPharmS **(Vice Chair)**
Professor of Pharmaceutics, Strathclyde University

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

Professor Geoffrey W Hanlon[28] BSc PhD
Emeritus Professor of Pharmaceutical Microbiology, School of Pharmacy & Bio-Molecular Sciences, University of Brighton

[23] Reappointed 01 January 2016 – 31 December 2018
[24] Reappointed 17 September 2015 – 16 September 2017
[25] Reappointed 17 September 2015 – 16 September 2019
[26] Reappointed 12 November 2015 – 11 November 2017
[27] End of appointment 11 November 2015
[28] Reappointed 17 September 2015 – 16 September 2017

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

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

Dr Majella Lane[29] BSc PhD
Senior Lecturer in Pharmaceutics, University College London - School of Pharmacy

Mr Robert Lowe BPharmS MRPharmS
Practising Hospital Pharmacist, Specialist Pharmacy Services - East of England

Professor Christopher Marriott[30] 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 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

[29] Appointed 12 November 2015 – 11 November 2019
[30] Reappointed 17 September 2015 – 16 September 2018

MEMBERSHIP OF THE CLINICAL TRIALS AND 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

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

Members

Professor Andrew J T George MA PhD DSc FRCPath FHEA FRSA FRSB
Deputy Vice Chancellor (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 FRCPath **(Vice Chair)**
Reader and Honorary Consultant in Amyloidosis and Renal Medicine, University College London

Professor Elizabeth Miller OBE BSc MBBS FRCPath FMedSci
Consultant Epidemiologist, Immunisation Hepatitis and Blood Safety Department, Public Health England

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

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 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

Dr Peter F Searle BA PhD
Institute of Clinical Sciences, University of Birmingham

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

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

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 MB BCH BAO DCH PhD FRCP
Professor of Rheumatology, Medical School, University of Sheffield

Members

Dr Michael Ardern-Jones[31] BSc MBBS DPhil FRCP
Associate Professor, University of Southampton and Consultant Dermatologist

Dr Ian Barrison[32] BSc MB FRCP FEBGH
President European Board of Gastroenterology and Hepatology; Associate Dean, Postgraduate Medicine, School of Life and Medical Sciences, University of Hertfordshire

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

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

Professor Kevin Moore 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

[31] Appointed 17 September 2015 – 16 September 2019
[32] Reappointed 17 September 2015 – 16 September 2019

MEMBERSHIP OF THE INFECTION EXPERT ADVISORY GROUP (FORMERLY THE ANTI-INFECTIVES, HIV & HEPATOLOGY EXPERT ADVISORY GROUP)

Remit

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

Chair

Professor Jonathan S Friedland[33] 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

Members

Dr Sanjay Bhagani[34] BSc MB ChB FRCP
Consultant Physician and Honorary Senior Lecturer, Department of Infectious Diseases/HIV Medicine, Royal Free London Foundation Trust

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

Dr Andrew Freedman[35] B.A M.B,B.Chir M.A M.D FRCP FRCP
Reader in Infectious Diseases, Cardiff University School of Medicine/
Hon. Consultant Physician, University Hospital of Wales

Dr Richard Gilson[36] MD FRCP
Reader in Sexual Health and HIV; Director, Centre for Sexual Health & HIV Research and Head, Research Department of Infection and Population Health, University College London

Dr Richard Hobson MBBS MRCP FRCPath PhD LLM
Consultant Microbiologist and Honorary Senior Lecturer, Harrogate and District NHS Foundation Trust/University of Leeds

Dr Susan Hopkins BA MB BCh BAO (Hons) MSc FCRPI FCRP
Consultant in Infectious Diseases and Microbiology, Royal Free London NHS Trust, Healthcare Epidemiologist, Public Health England, Honorary Senior Lecturer, University College London

Professor Martin Lombard[37] MD MSc FRCP (Lond)
Consultant Hepatologist & Gastroenterologist, Royal Liverpool University Hospitals NHS Trust

[33] Appointed 17 July 2015 – 31 March 2018
[34] Resigned 21 November 2015
[35] Appointed 10 December 2015 – 11 December 2019
[36] Appointed 15 December 2014 – 14 December 2018
[37] Appointed 10 December 2015 – 11 December 2019

Dr Hermione Lyall[38] 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[39] MB ChB FFPH
Consultant in Health Protection, Public Health England, East Midlands Centre, Leicester

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

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

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

[38] Re-appointment 17 November 2015 – 16 September 2017
[39] Resigned 08 July 2015

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 Director of the Clinical Effectiveness Unit of the Faculty of Sexual and Reproductive Health, Chalmers Centre, Edinburgh

Members

Professor Juliet Compston[40] OBE MD FRCP FRCPath FMedSci
Professor of Bone Medicine & Honorary Consultant Physician, School of Clinical Medicine, Cambridge University

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

Ms Linda Pepper[41] BA MA (Education)
Independent Consultant: patient and public involvement in healthcare

Professor Philip Hannaford[42] MB ChB DRCOG DCH MD FRCGP FFSRH FFPH
Professor of Epidemiology, University of Aberdeen

Dr Sally Hope[43] 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 Siobhan Quenby MBBS BSc MD FRCOG
Professor of Obstetrics, Warwick University

[40] End of appointment 14 September 2015
[41] Appointed 17 July 2015 – 16 July 2019
[42] Reappointed 17 September 2015 – 16 September 2019
[43] End of appointment 11 November 2015

Carolyn, Lady Roberts[44] RGN RHV MSc DUniv
Member of The Ethox Foundation - Oxford Foundation for Ethics and Communication in Healthcare Practice. Health Visitor

Mrs Margaret V Shotter[45] BSc MSc
Lay Member

Dr Clare Spencer[46] MA MB BCHIR DM MRCOG MRCGP DFFPRHC
GP Partner

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

[44] Appointed 01 November 2015 – 31 November 2016
[45] End of appointment 13 March 2015
[46] Appointed 15 January 2015 – 14 January 2019

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

Professor John Duncan[47] 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

Mr Michael J Harnor[48] 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[49] BA MA BMBCh DM FRCPsych
Professor of Old Age Psychiatry, University of Cambridge

Dr Waqar Rashid[50] MBBS BSc MRCP(UK) PhD
Consultant and Honorary Clinical Senior Lecturer in Neurology, Brighton and Sussex University Hospitals NHS Trust, member of the Multiple Sclerosis Society

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

[47] Resigned 13 March 2015
[48] End of appointment 11 November 2015
[49] Reappointed 12 November 2015 – 11 November 2019
[50] Appointed 10 December 2015 - 11 December 2019

Dr Catherine F Stannard MB ChB FRCA FFPMRCA
Consultant in Pain Medicine, Pain Clinic, Southmead 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 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[51] MB BS MRCP MSc (Immuno) MD FRCP
Consultant Neurologist, Queen Elizabeth Hospital, Birmingham

[51] Resigned 31 August 2015

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

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

Members

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

Professor Mark D Bower[52] MA MB BChir PhD FRCP FRCPath
Consultant Medical Oncologist, Chelsea & Westminster Hospital, London

Professor Stephen Devereux PhD FRCP FRCPath
Consultant Haematologist and Professor of Lymphoma Biology, Kings College Hospital

Dr Chris Gallagher[53] BSc PhD FRCP
Consultant Medical Oncologist, St Bartholomew's Hospital, Barts and the London NHS Trust

Professor Charlie Gourley[54] BSc (Hons) MB ChB PhD MRCP FRCP
Professor and Honorary Consultant in Medical Oncology, University of Edinburgh Cancer Research Centre

Professor Angela E Thomas[55] MB BS PhD FRCPE FRCPath FRCPCH **(Vice Chair)**
Consultant Paediatric Haematologist, Royal Hospital for Sick Children, Edinburgh

[52] Reappointed 17 September 2015 – 16 September 2019
[53] Reappointed 17 September 2015 – 16 September 2019
[54] End of appointment 09 November 2015
[55] Reappointed 01 January 2016 – 31 December 2018

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 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 MB ChB MRCP FRCA
Consultant Anaesthetist, Tunbridge Wells Hospital

Professor J Helen Cross[56] OBE MB ChB PhD FRCP FRCPCH
The Prince of Wales's Chair of Childhood Epilepsy, Deputy Head of Developmental Neurosciences Programme, UCL Institute of Child Health

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

Professor Peter C Hindmarsh BSc MD FRCP FRCPCH
Consultant Paediatric Endocrinologist, UCL Institute of Child Health

Dr Meriel E M Jenney MD MRCP FRCPCH
Consultant Paediatric Oncologist/Assistant Medical Director (Cancer Services)

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[57] BSc (Hons) MSc RCN
Paediatric Intensive Care Unit Nurse Consultant, Evelina Children's Hospital

Dr Rubin Minhas 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

[56] Appointed 14 May 2015 – 13 May 2019
[57] End of appointment 09 November 2015

Professor Anthony Nunn 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[58] BA CPE LPC
Lay Representative. Solicitor

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

Dr Beverly Tsai-Goodman 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 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 PhD FRCPath FBTS FRSC FRSB FBPhS European Registered Toxicologist
Professor of Biochemical Pharmacology and Toxicology, College of Life Science and Medicine, University of Aberdeen

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

Dr Mark Whiting[59] BNursing MSc PhD
Consultant Nurse, Children's Community and Specialist Nursing, Peace Children's Centre, Hertfordshire Community NHS Trust

Dr Morris Zwi MB BCh FRCPsych
Consultant Child & Adolescent Psychiatrist, Richmond Royal Hospital, Clinical Lead for Islington Child & Adolescent Mental Health Services

[58] Reappointed 10 March 2015 – 09 March 2019
[59] Reappointed 10 November 2015 – 09 November 2019

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[60] CBE
Lay Member. Chief Executive, Professional Standards Authority for Health and Social Care, London

Mr Phil Willan[61] MSc
Lay Representative. Member of MHRA Pharmacovigilance EAG, Cardiovascular, Diabetes, Renal, Respiratory and Allergy EAG, Patient and Public Engagement EAG (acting Chair), 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, and Patient Safety Committee. Member of the NHS England Clinical Reference Group for Renal Transplantation

[60] Resigned 29 January 2015
[61] Vice Chair 1 January 2015 – 29 January; Chair *Pro Tem* from 30 January 2015

Members

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

Mrs Alison Bowser[62]
Lay Representative. Patient and Public Involvement Officer, Research Design Service, Southampton University & National Institute for Health Research

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
Former Director of the Foundation for the Study of Infant Deaths. Member of NICE accreditation committee and NSPCC research ethics committee. Former member of Kings College research ethics committee (psychiatry, nursing and midwifery). Former member of local authority standards committee. Member of the Trial Steering Committee of the RCT of Comprehensive Geriatric Assessment in a Hospital at Home Setting of the Nuffield Dept of Primary Care Health Sciences at Oxford University

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

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

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

Dr Bella Starling PhD BSc Hons Dip
Lay Member. Director of Public Programmes, Research & Innovation, Central Manchester University Hospitals NHS Foundation Trust

Mr Paddy Storrie MA (Oxon) NPQH
Lay Member. Deputy Headmaster, St. George's School, Hertfordshire and Chair, NICE Technology Appraisals Appeals Committee

Mr Phil Willan MSc **(Vice-Chair)**
Lay Representative. Member of MHRA Pharmacovigilance EAG, Cardiovascular, Diabetes, Renal, Respiratory and Allergy EAG, Patient and Public Engagement EAG (acting Chair), 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, and Patient Safety Committee.

[62] Appointed 01 January 2015 to0 8 March 2016, retired 21 October 2015

Member of the NHS England Clinical Reference Group for Renal Transplantation

External Experts

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

Mrs Anne Joshua BPharm (Hons) MSc Pharm Dip MRPharmS
Head of Community Pharmacy Strategy, 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

Ms Amanda Hoey[63]
Lay Representative. Director, ConsumerHealth Consulting Ltd. Independent Health Policy and Strategy Consultant

Carolyn, Lady Roberts HV Cert. MSc D Univ
Member of The Ethox Foundation - Oxford Foundation for Ethics and Communication in Healthcare Practice

[63] Appointed 01 January 2015 to 08 March 2016

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 Sir Munir Pirmohamed[64] MB ChB (Hons) PhD FRCP FRCP (Edin) FMedSci
David Weatherall Chair of Medicine, University of Liverpool, NHS Chair of Pharmacogenetics, Director of the Wolfson Centre for Personalised Medicine, Director of the MRC Centre for Drug Safety Science

Members

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

Professor Jamie Coleman[65] MD MA (Med Ed) FRCP FBPhS
Professor in Medical Education / Consultant Clinical Pharmacologist, University of Birmingham

Dr William Dixon[66] MRCP PhD
Director, Arthritis Research UK Centre for Epidemiology and Honorary Consultant Rheumatologist, The University of Manchester

Dr Ian J Douglas[67] BSc MSc PhD
Senior Lecturer in Pharmacoepidemiology, London School of Hygiene & Tropical Medicine

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

[64] Reappointed 01 January 2016 – 31 December 2018
[65] Reappointed 15 September 2015 - 14 September 2019
[66] Reappointed 15 September 2015 – 14 September 2019
[67] Reappointed 15 September 2015 – 14 September 2019

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

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 FBPhS FHEA
Professor of Student Learning/Clinical Pharmacology, Western General Hospital, Edinburgh & University of Edinburgh

Dr Karen Miller[68] BSc MBBS DRCOG DCH DFFP FRCGP
GP Partner, Adelaide Medical Centre, London

Dr Nicholas J Plant BSc PhD
Reader in Systems Biology, University of Surrey

Professor Alan Silman[69] MRCP MSc MFCM MD FFPHM FRCP FMedSci
Former Medical Director of the Arthritis Research Campaign

Dr Ruben Thanacoody[70] 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. Shadow Governor of the Surrey and Sussex Hospital

Mr Phil Willan MSc
Lay Representative. Member of MHRA Pharmacovigilance EAG, Cardiovascular, Diabetes, Renal, Respiratory and Allergy EAG, Patient and Public Engagement EAG (acting Chair), 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, and Patient Safety Committee. Member of the NHS England Clinical Reference Group for Renal Transplantation

[68] Reappointed 15 September 2015 – 14 September 2019
[69] Resigned 02 November 2015
[70] Reappointed 15 September 2015 – 14 September 2019

THE COMMISSION'S WORKING GROUPS

MEMBERSHIP OF THE ALTEPLASE WORKING GROUP

Chair

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

Members

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The Yellow Card Roadmap

A new era for the Yellow Card Scheme

Edition 1: March 2015

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Chapter 1: Introduction to the Yellow Card Scheme Roadmap

The Yellow Card Scheme has for 50 years been the UK system for collecting information on suspected adverse drug reactions (ADRs) to medicines. The Scheme allows the safety of the medicines and vaccines that are on the market to be continually monitored in real world clinical use.

The Scheme was founded in 1964 after the thalidomide disaster. Sir Derrick Dunlop, then Chair of the Committee on the Safety of Drugs, wrote to all UK doctors urging them to send reports of suspected side effects with medicines so that another thalidomide disaster could be promptly detected and averted.

The Scheme is run by the Medicines and Healthcare products Regulatory Agency (MHRA) and the Commission on Human Medicines (CHM).

Suspected ADRs are collected on all licensed and unlicensed medicines and vaccines, from those issued on prescription to medicines bought over the counter from a pharmacist or supermarket. The Scheme also includes all herbal preparations and unlicensed medicines. Suspected ADRs can be reported by anyone including patients and carers.

In November 2014 the Scheme was extended to include submitting reports of incidents with medical devices, defective medicines and reports of suspected counterfeit medicinal products.

Chapter 2: The Yellow Card Roadmap

The Yellow Card Scheme now celebrates 50 years as the UK's system for the collection of reports of suspected adverse drug reaction (ADRs). It is therefore timely for the MHRA and CHM to review the Scheme and consider how it continues to adapt to the changing technical and cultural environment and to address more actively the issue of under-reporting. This will be done by a multi-faceted approach including: the platforms available for reporting; greater awareness of the public of the Scheme; embedding reporting to the Scheme within the UK national health services; repositioning the Scheme in health education; better feedback provided to reporters to encourage their continued engagement with the Scheme; and the use of Yellow Card data in academic research.

The MHRA, supported by the CHM have created a strategic roadmap for the Yellow Card Scheme, to ensure it continues to be the primary source of vital drug safety information. The overall aim is to ensure the Scheme is optimally fit for the future, fully integrated into the healthcare system and a vital source of safety information to stakeholders to inform their daily lives and support safe use of healthcare products. This first edition of the Roadmap sets out four strategic themes, each with four strategic objectives. To achieve these objectives a set of activities which are outlined below, have been identified.

Theme 1 - Improving patient safety through systematic and cultural change

The aim of theme 1 is to extend the Scheme to include the reporting of all incidents that have caused harm including medicines and devices and where the product has been used outside of its licensed use. It also aims to investigate how social media and other data sources can supplement Yellow Card reports to identify "signals". It will also be important that public awareness of the Scheme is increased so that under-reporting is addressed.

Theme 2 – Embedding Yellow Card into the healthcare system

The aim of theme 2 is to improve reporting from the NHS by integrating Yellow Card reporting into the IT systems that are used in day to day practice and looking at where professional education can be changed to ensure health professionals are knowledgeable about and confident in reporting. A "Good Vigilance Practice" guide for the NHS will be developed to support this and how the revalidation and appraisal process can also be used to support better reporting.

Theme 3 – Making the best scientific use of Yellow Card data

The aim of theme 3 is to ensure Yellow Card data is used optimally to detect signals and inform stakeholders about our vigilance activities through effective feedback. It will also look at how Yellow Card data can by best used by the academic community.

Theme 4 – Yellow Card Scheme sustainability into the future through collaboration

To achieve the objectives of the Roadmap and ensure they are sustained into the future MHRA needs to collaborate effectively with a wide range of organisations and stakeholders. These include professional bodies, other government agencies and NHS bodies as well as the five regional Yellow Card Centres.

Chapter 3: Theme 1: Improving patient safety through systematic and cultural change

Objective 1: Extending the Scheme to all healthcare products

In November 2014 MHRA launched an enhanced Yellow Card Scheme to include all incident reports it has responsibility for under the Yellow Card brand as a single reporting system. Adverse incidents for both medicines and medical devices, including defective and counterfeit medicines can now be reported via the Yellow Card website forms. The reasons for this were to make reporting easier. Feedback from stakeholders informed the agency that there was confusion about what to report to whom. By using the strong “brand” of Yellow Card this could reduce that confusion so simpler and more accessible reporting forms were developed to coincide with the launch of the new system. To maximise the benefits of the single reporting system the MHRA will identify ways to further promote the use of the system for all adverse incidents and seek to make further improvements to the web-forms and other Yellow Card reporting form.

Objective 2: Extending the Scheme to capture reports of incidents of all types of harm with healthcare products.

New European pharmacovigilance legislation has expanded the definition of adverse drug reaction to include all reactions in a patient that are “noxious and unintended”. This includes where the adverse effect was through error, misuse, or abuse. It also includes reports where a medicine is used outside its licensed condition i.e. off-label use. Because of this MHRA will be seeking to receive reports from other data collection systems including:

National Reporting and Learning System (NRLS). The NRLS is the English NHS system for reporting incidents. These may include ADRs and have historically included incidents of medication error. MHRA and NHS England have been working together to improve data exchange so that both parties get the data they need to investigate issues within their respective remits. A Patient Safety Alert was issued to the English NHS in March 2014 explaining this work and to emphasise the importance of reporting. The NRLS is to be redeveloped in the coming years and MHRA will be a key partner in ensuring the format and quality of reports for both medicine and medical device incidents meet the needs of the agency. This will include working with suppliers of local risk management systems where many cases of interest are initially recorded before transfer into NRLS.

National Poisons Information Service (NPIS). The MHRA and NPIS have been in discussions to establish links between the two systems to ensure that Yellow card reporting is promoted through the NPIS system and that reports of medicines overdose are shared with MHRA. This work will continue to ensure both systems benefit from access to greater information, leading to better understanding of drug toxicity and better advice on overdose management.

Objective 3: Utilising other data sources including social media to complement the Yellow Card Scheme

The MHRA is leading a large EU project through the Innovative Medicines Initiative called WEB-RADR (Recognising Adverse Drug Reactions). An element of the project is to investigate the utility of social media data for pharmacovigilance. This is an area of significant interest and debate. MHRA will develop a strategy to utilise social media data to complement the Yellow Card Scheme in response to the conclusions from research findings in the WEB-RADR project

Objective 4: Improving public awareness of the Yellow Card Scheme

Yellow Card Strategy. A strategy to improve public awareness of the Yellow Card Scheme has been in place for a number of years and promotional campaigns to raise awareness have taken place. Such campaigns have often been targeted to particular professions or patient group e.g. pharmacists, paediatrics etc. The MHRA will continue to develop awareness raising campaigns to raise awareness of the Scheme and encourage reporting. The comments and suggestions received from this first edition Roadmap will help inform the agency on where to target efforts and resources.

NHS111, NHS24 and Choices. The NHS111 and NHS24 telephone services and NHS Choices website are the main contact points for patients and the public regarding their healthcare. Both services already refer callers and visitors to the Yellow Card Scheme however this may not be as prominent or consistent as desirable. The MHRA will work with the service providers across the UK to maximise the public's awareness of the Yellow Card Scheme.

Chapter 4: Theme 2: Embedding Yellow Card into the healthcare system

To increase reporting from health professionals on all the incidents which the MHRA needs to receive to protect public health reporting must be part of the NHS system and culture. The Yellow Card Scheme is voluntary and relies upon the professional duty of the health professional to submit a report. Time constraints and competing priorities however are a major deterrent so the MHRA needs to ensure that reporting is easier and health professional are suitably motivated to report. The objectives for this theme aim to ensure Yellow Card reporting is firmly embedded in the healthcare system.

Objective 5: Integrate reporting forms into clinical IT systems

GP System of Choice. In 2014 an electronic version of the Yellow Card reporting form was adopted as an NHS information standard (ISB 1582). The implementation of this standard has been included as a requirement for all English general practice IT systems under GPSoC. The GP system providers are developing their software to include this electronic Yellow Card and will be rolling out to their live systems over the course of the 2015. This will have a significant impact on ADR reporting volumes and is a major step forward in addressing under-reporting. MHRA will keep under review the implementation of the Yellow Card standard and monitor the impact on reporting. The requirements of GPSoC cover England only. However the same IT providers cover the other UK countries, so the new functionalities will be available to all. The MHRA will monitor reporting to see if the benefits are realised in all UK territories. Further consideration will be given to how the standard can be widened to include incidents with medical devices and reports of defective and counterfeit medicinal products.

Electronic reporting. Initiatives with reporting from clinical systems are not limited to GP systems. The MHRA have been working with the suppliers of hospital system in Newcastle, London and Oxford (Cerner Millennium) to introduce an electronic Yellow Card. The Newcastle site went live in 2013 as a pilot site and will soon be rolled out to other Cerner sites in the coming year. The MHRA will build upon this work with other system providers to deliver wider electronic reporting in UK hospitals.
Electronic reporting has also been introduced across the UK medicines information network (UKMI), the MiDatabank system has an integrated Yellow card and MHRA work closely with UKMI to encourage the use of this from MI professionals.

Objective 6: Improve healthcare education on reporting

There is a pressing need to work with medical schools and other education providers to review how Yellow Card reporting is taught. The MHRA will aim to ensure that curricula and examinations cover key factors of Yellow Card reporting and pharmacovigilance and encourage testing in professional examinations. The MHRA will also investigate, with Health Education England, the potential for joining the Commission for Healthcare to ensure that the Scheme remains on the agenda for health professionals through their continuous education programme.

Objective 7: Develop “Good vigilance practice” for healthcare professionals

Following the introduction of new pharmacovigilance legislation in the EU in 2012 a series of Good Vigilance Practice guidance documents (GVP) have been produced so that regulators and pharmaceutical companies can operate to best practice. The MHRA will look to develop a “GVP for the NHS”, and will seek to publish in order to clearly identify roles and responsibilities, what and how to report, and the importance of good patient safety with regard to medicines and medical devices.

Objective 8: Investigate making incident reporting as part of revalidation

In order to impress upon medical professionals the importance of Yellow Card reporting the MHRA will develop, with the General Medical Council, updated guidance on reporting and investigate how this can be become part of the appraisal process. It is considered that by making Yellow Card part of revalidation the awareness amongst medical practitioners of the importance of reporting will be heightened and engagement will improve. The MHRA will investigate with other professional bodies how revalidation and appraisal can include incident reporting.

Chapter 5: Theme 3: Making the best scientific use of Yellow Card data

Objective 9: Optimise signal detection methodologies

The MHRA has a long history of leading the way with detection of drug safety signals. This leading role has been based upon optimising new technology together with sophisticated methodology and expert staff to ensure signals are detected and managed effectively. It will be vitally important moving forward that signal detection methodologies continue to develop in light of a growing database, different types of reports (e.g. overdose and error) and reports for medical devices. Through this roadmap we will work with academic and technical experts to ensure our signal detection capabilities continue to be optimal.

Objective 10: Integration of Yellow Card data with other data sources

Work has started with the **Clinical Practice Research Datalink (**CPRD**)** to investigate novel ways to integrate the Yellow Card Scheme with this important public health resource. Two key work streams have been identified. The first will look at how drug exposure and background adverse event data from CPRD could be made routinely available in order to contribute to both signal prioritisation and assessment by putting data from the Yellow Card Scheme into context. The second will explore how proactive cohort studies conducted within the CPRD data could monitor the rates of pre-specified adverse events for a particular product or drug substance.

Objective 11: Increased academic research to continually enhance the use of Yellow Card data in particular biological plausibility

The use of Yellow Card data for health research has been intermittent since it was first made available 10 years ago. An emerging area of interest is the identification of the genomic make-up of patients suffering particular ADRs. The establishing of a Yellow Card **Biobank** to help inform what patients may be more predisposed to a reaction will help inform prescribing in the future and have major benefits for patient safety.

Objective 12: Improved feedback to Yellow Card reporters using new technologies

The MHRA recognises that the feedback reporters receive upon submitting a Yellow Card needs to be improved. A number of activities are underway to address this. These include:

- Renewing the agency's business intelligence software to enable more user friendly data to be provided or signposted with acknowledgement letters. This may include information on the drug and reaction reported and in context of the demographics of the patients who have had reactions, and the time periods where reports have been received. Drug Analysis Prints (DAPs) list all ADRs reported to the MHRA. They are a very popular source of information with around 3,000 reports downloaded each month. A new format for the DAP is being developed and demonstrated at the Yellow Card 50th anniversary conference, and a separate consultation is being launched to seek stakeholder opinion.

- DAPs, patient information leaflets, the monthly Drug Safety Update bulletin and other drug safety information are available in different areas of the MHRA website. The MHRA will be considering moving all safety related information to the Yellow Card website in order to make it accessible to reporters in the same web based environment.

- The Yellow Card mobile reporting App (see WEB-RADR above) will include functionality to access relevant information via mobile devices and will also enable reporters to register for notifications should any new information on drugs of interest be published.

- The MHRA is working on makin available reporting data to Trusts and Care Commissioning Groups to enable them to see how what their reporting rates look like when compared to other comparator organisations. This will help raise reporting rates. This type of feedback has already been implemented through the five Yellow Card Centres (Scotland, Wales, West Midlands, Northern & Yorkshire, and North West).

- The MHRA will investigate how reporters can be recognised for submitting Yellow Cards of particular importance to drug safety. Areas the agency will investigate are:

    - Quality Outcome Framework (QoF). Whether QoF points could be awarded to GPs for submitting reports or reports of significant interest.

    - Continuous Professional Education (CPD) points. Whether CPD points could be awarded to reporters for Yellow Card reporting.

    - Regularly publishing in journals such as British Medical Journal (BMJ) Yellow Cards of significance

- The “Dunlop Award”, a periodic award for the Yellow Card reporter who was the first to identify a reaction caused by a drug. The first Dunlop Award will be awarded at the Yellow Card 50th Anniversary Conference on 20th March 2015.

Chapter 6: Theme 4: Yellow Card Scheme sustainability into the future through collaboration

The various activities/initiatives can only be achieved through effective collaboration with other organisations. The MHRA has been actively engaged in forming new partnerships with care organisations and will continue to do so to deliver this Roadmap

Objective 13: Ensure Yellow Card Centres feed in and communicate aims locally.

The five YCCs have a specific remit to undertake local training and promotion of the Scheme and this will continue. YCCs and MHRA will need to identify how the centres can support the wider role of the Scheme now it has been extended to include reports of incidents with medical devices, defective medicines and counterfeits.

Objective 14: Work with other healthcare bodies

NHS England. A partnership has been formed with NHS England and other partnerships are under development with Scotland, Northern Ireland and Wales. Through this the MHRA have improved data sharing on incident reports, established the network of MSOs and MDSOs and are actively engaged in the functional requirements for the redeveloped NRLS. It will be important to continue to work closely with NHS England and other regional partners as we collaborate with other organisations as there is a shared patient safety agenda.

Care Quality Commission (CQC). The MHRA will work with CQC to share reporting data from NHS organisations to help inform CQC audits. Yellow Card reporting can be an important indicator of the reporting culture of a Trust and therefore when viewed alongside other data sources may inform CQC on where to audit and where previously audited organisations have improved with regard to reporting.

Health Improvement Scotland (HIS). The MHRA has formed a good relationship with HIS and are working on developing a Memorandum of Understanding to ensure the sustainability of the collaboration.

Health Education England (HEE). In order to achieve the educational awareness objectives of the roadmap the MHRA will need to engage with HEE to identify how healthcare service staff training on drug and medical product safety through Yellow Card reporting can be established as part of the safer care agenda.

National Poisons Information Service (NPIS). The MHRA and NPIS have been in discussions to establish links between the two systems to ensure that Yellow card reporting is promoted through the NPIS system and that reports of medicines overdose are shared with the MHRA. This work will continue to ensure both systems benefit from access to greater information.

Devolved Administrations. The Yellow Card Scheme covers the whole of the UK and whilst many of the collaborative links mentioned above are for the English health system, parallel discussions continue to be held with the other governments to ensure the benefits of such collaborations can be mirrored across the UK.

Sign Up to Safety. The MHRA joined SU2S in November 2014. The campaign aims to save 6,000 lives a year and reduce avoidable harm by 50%. This will be achieved through healthcare provider organisations who are signed up to the campaign developing action plans to address safety issues. By joining the MHRA are to produce a plan to share with other signed up organisations to raise awareness of Yellow Card with a view to engaging better and improving reporting and feedback. The MHRA will produce an action plan and share with other organisations signed up to the campaign.

Objective 15: Work with the Regulatory Science Network

The MHRA has developed a strategic Regulatory Science Network (RSN), in particular the Centre for Drug safety Science and centres for epidemiology such as the London School of Hygiene and Tropical Medicine. Working with this RSN will strengthen the agency's pharmacovigilance capabilities.

The MHRA is leading a European Commission funded Joint Action project called SCOPE (Strengthening Collaborations to Operate Pharmacovigilance in Europe). This is a broad ranging 3 year programme that looks at all aspects of regulatory pharmacovigilance. One of the key areas in SCOPE is the management of ADR reporting systems. This area is being led by the Croatian national

medicines agency, HALMED. The MHRA is an active participant and will ensure that the activities in the UK are shared with colleagues. Similarly we will learn from other partners in the project to further develop the Yellow Card Scheme.

The MHRA is also an active participant in the collaboration of WHO ADR monitoring centres and exchange information on ADR reporting initiatives to strengthen the Yellow Card Scheme.

Objective 16: Work with professional regulatory bodies

The MHRA has engaged with the General Medical Council (GMC), the Royal Pharmaceutical Society, Royal Colleges and other regulatory bodies to ensure Yellow Card reporting is in the various codes of practice. MHRA will continue this engagement to discuss how Yellow Card reporting can be part of the appraisal process and reflected fully in current professional guidelines.

Chapter 7: Timeframe

Much of the work described above is already underway and will continue over the next two years. The MHRA aim to deliver all the objectives outlined above over this period. Some of the objectives will be in a maintenance, rather than delivery stage however it is important that all objectives in the roadmap are tracked to delivery and enhanced throughout and beyond 2017.

Chapter 8: Governance

To deliver all the objectives in this roadmap The MHRA will consult CHM and its Pharmacovigilance Expert Advisory Group and the independent advisory committees for medical devices. The delivery of the roadmap will be managed by the Vigilance and Risk Management of Medicines Division along with colleagues from Devices Division and other areas of the Agency as necessary. The Corporate Executive Team of the MHRA will provide management oversight and the MHRA Agency Board will provide strategic advice.

Chapter 9: Conclusion

The MHRA have set out an ambitious strategic roadmap for the Yellow Card Scheme to build upon 50 years of success in underpinning UK drug safety. As the Scheme moves forwards and collects additional data on medical devices, defective and counterfeit medicines and other reports due the

extended definition in law of adverse drug reaction it is essential that the Agency ensures it is well connected to the UK health systems to raise awareness of the extended Scheme. To achieve this roadmap good collaboration with other health bodies, educators and health providers is essential. The MHRA have identified a broad range of organisations to collaborate with and have set plans in motion to make these connections.

The use of new technologies is also an essential component of the roadmap. With increased pressure on health professionals it is essential that the MHRA provide accessible and user friendly ways to report. The introduction of mobile App technologies and the integration of Yellow Card into clinical IT systems will ensure reporting is easier than ever before. New technologies also offer the opportunity to provide better feedback to reporters. The MHRA have been told by stakeholders that in order to engage better more useful, timely and personalised feedback should be provided, this roadmap seeks to deliver on this.

Chapter 10: Next Steps

This is the first edition of the Yellow Card “Roadmap”. It will evolve over time in light of comments received. Comments should be addressed to yellow.card@mhra.gsi.gov.uk.

Glossary of Acronyms and Abbreviations

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

ALB: 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: Current Awareness 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 non-confidential 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 2015

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 2015, showing their terms of appointment, is shown in Appendix I.

3. A review of membership was carried out during the year by the Department of Health Public Appointments Team. Eight members were re-appointed for periods between 2 and 4 years and eight new members were appointed for a period of 4 years with effect from 1st January 2016.

4. A list of members of the supporting Expert Advisory Groups, Panels of Experts and Working Parties for 2015 is given in Appendix II. A new Working Party on Identification Techniques was established to progress work on the development of molecular methods for inclusion in the British Pharmacopoeia and the first meeting of the Working Party was held in January. In order to progress the joint BP-NIBSC Herbal Project, a Working Party on Microscopy was also established. The status of the Working Party on Excipients was changed to that of a Panel of Experts in view of the increased workload of the group.

CODE OF PRACTICE

5. 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

6. The British Pharmacopoeia Commission met three times during 2015. Sixteen meetings of the Expert Advisory Groups, Panels of Experts and Working Parties were also held during the year. These meetings were held at the Medicines and Healthcare products Regulatory Agency, 151, Buckingham Palace Road, London SW1W 9SZ.

7. 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 [https://www.pharmacopoeia.com/meeting-minutes].

TRIENNIAL REVIEW

8. The Department of Health carried out a Triennial Review of the British Pharmacopoeia Commission and the report was published on 30th March 2015. The review confirmed that the functions of the BP Commission were still required and that the Commission should be retained as an Advisory Non-Departmental Public Body. A number of recommendations were made regarding tendering for the next publication contract, appointments to the BP Commission and use and scope of the BP website. The Secretariat has taken steps towards implementing the various recommendations.

9. The recommendation that appointment dates should be spread over several years to ensure continuity of service had been acted upon during the campaign to appoint and re-appoint members of the Commission.

10. The report had recommended that draft monographs should be published to a specific, predictable timetable, including a deadline for comment. A formal process was agreed during the year.

SECRETARIAT

11. 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

12. 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

13. 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 2015

14. Following publication of the British Pharmacopoeia 2015 three electronic updates were issued providing users with the text of Supplements 8.3, 8.4 and 8.5 of the 8th edition of the European Pharmacopoeia.

British Pharmacopoeia 2016

15. The British Pharmacopoeia 2016 was published in August 2015. This new edition is now available as a package containing the five volumes of the British Pharmacopoeia 2016, the one volume of the British Pharmacopoeia (Veterinary) 2016 and access to the electronic versions of both publications (online BP and offline download format).

16. This new edition contains almost 4000 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 2016 is 1st January 2016.

17. All monographs published within the 8th Edition of the European Pharmacopoeia, as amended by Supplements 8.1 to 8.5, are included either in this edition of the British Pharmacopoeia or, where appropriate,

in the associated edition of the British Pharmacopoeia (Veterinary). Monographs of the European Pharmacopoeia are clearly distinguished from those of national origin by means of a chaplet of stars that appears alongside the monograph title. Where appropriate, statements of relevance to UK usage, such as Action and use and the list of BP preparations, have been added to the European Pharmacopoeia monographs.

18. The British Pharmacopoeia 2016 contains 37 new monographs of national origin which were not published in previous editions. These include three new monographs for Traditional Herbal Medicines and five new monographs for unlicensed formulations. Two new infrared reference spectra have been added to this edition.

19. Following publication of MHRA guidance on the non-interchangeability of certain categories of anti-epileptic drugs, statements that relevant products “are not interchangeable” or “may not be interchangeable” were added to a number of monographs for licensed oral dosage anti-epileptic formulations.

20. In line with recommendations from the Commission on Human Medicines and the British Pharmacopoeia Commission, reference to chloroform as an ingredient in licensed medicines was removed from affected monographs either by deleting the formula and/or method of preparation or omitting the monograph from the publication. The Supplementary Chapter on Unlicensed Medicines was similarly amended to recommend that the use of chloroform as an ingredient in unlicensed medicines should be avoided.

21. Two new Appendices were added to harmonise with the European Pharmacopoeia (VIII X: Methyl, Ethyl and Isopropyl Toluenesulfonate in Active Substances and XV K: Carrier Proteins for the Production of Conjugated Polysaccharide Vaccines for Human Use).

22. A new BP Appendix was added (XI V: Deoxyribonucleic Acid (DNA) Based Identification Techniques for Herbal Drugs). This included a sequence for Holy Basil, the subject of a new monograph in the British Pharmacopoeia 2016.

23. One new Supplementary Chapter was added to harmonise with the European Pharmacopoeia (VII C: Monographs on Herbal Drugs).

24. The previous Supplementary Chapter on Inhaled Products (I O) was updated to reflect the current policy on inhaled products and re-instated.

British Pharmacopoeia (Veterinary) 2016

25. The British Pharmacopoeia (Veterinary) 2016 was published as a companion volume to the British Pharmacopoeia 2016 in August 2015. 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) 2016 is 1st January 2016.

26. 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

27. Supplement No. 4 to British Approved Names 2012 was published in August 2015, adding 30 new names not previously published.

BP Online

28. Access to the online version of the publications (www.pharmacopoeia.com) was provided as a component of the British Pharmacopoeia 2016 package. The USB format, which has been available since publication of the 2015 edition, was replaced by provision of a single-user offline download. The benefit of the offline download is that it allows the offline product to be updated to include the European Pharmacopoeia Supplement updates at the same time as the online BP.

29. 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

30. Details of the prices and availability of the above-mentioned publications are shown in Appendix IV.

Future Publications

31. By the end of 2015 work was progressing on the preparation of the next editions of the British Pharmacopoeia and British Pharmacopoeia (Veterinary). These will be published during 2016 and will have an effective date of 1st January 2017.

32. An electronic update to the British Pharmacopoeia 2016 was issued in December 2015 providing users with the text of Supplement 8.6 to the 8th Edition of the European Pharmacopoeia which came into effect on 1st January 2016. Further updates will be issued to coincide with the implementation of Supplements 8.7 and 8.8 on 1st April and 1st July 2016 respectively. These updates will only be available via the online BP and the offline download. The texts will subsequently be included in the BP 2017 publications.

OTHER PHARMACOPOEIAL MATTERS

BP Website

33. The new BP website (www.pharmacopoeia.com) was launched in August. The updated website incorporates the functionality of both the old websites and includes new features and improved search capabilities. The contents of the website were fully reviewed and updated in line with Government guidelines and the new site has been favourably received by users.

34. In addition to accessing the current edition of the British Pharmacopoeia, users can view older versions of the publication via an archive facility. Information relating to monograph development and revision, together with information relating to the BP Commission and the Expert Advisory Groups, is easier to find and users benefit by being able to purchase British Pharmacopoeia Chemical Reference Substances directly from the website.

35. In line with the recommendation arising from the Triennial Review of the British Pharmacopoeia Commission, and in response to feedback from stakeholders, a schedule for reviewing draft text has been introduced. With effect from 1st January 2016 draft new and revised monographs will be posted on the BP website on specific dates and removed after a 3-month commenting period. This will allow greater visibility of the BP work programme and will facilitate stakeholder input into the development and revision of monographs.

Unlicensed Medicines

36. 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.

37. 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. Information

continues to be collected on widely used preparations for which there are currently no published standards.

Traditional Herbal Medicines

38. 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. The BP has continued to seek national and international collaborations to identify validated analytical methods and suitable standards.

Liaison with Other Organisations

39. The BP has been developing links with academic institutions and is currently involved in projects with several universities. Lectures have been given to pharmacy and chemistry students on “Use of the British Pharmacopoeia” and “Pharmaceutical Analysis”, along with introductions to the BP and MHRA. A sponsored MSc project has also been completed on developing dissolution procedures for pharmacopoeial use.

40. A teleconference between representatives from the Veterinary Medicines Directorate (VMD) and the BP took place in May. 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.

Customer Insight Research

41. An in-depth customer insight research project, sponsored by the MHRA’s Corporate Executive Team, was undertaken during the year. The aim of the project had been to gain a deeper understanding of the customers of the British Pharmacopoeia and their needs. Overall the results had been very positive, showing that the BP had a very strong reputation and was highly valued.

BP Reference Materials

42. 41 new BP Reference Materials were established to support the British Pharmacopoeia and British Pharmacopoeia (Veterinary) publications, 66 were replaced and 133 were re-tested to ascertain their continued stability.

43. The demand for these reference materials remained high throughout the year. 22,550 vials were sold within the UK and to countries worldwide, representing an 8% increase in sales from the previous year. The number of vials sold has more than doubled in the past 10 years.

Nomenclature

44. 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 (73 and 74) were published by WHO during the year.

45. The BP Secretariat is also responsible for assessing proposed invented names for medicines in the UK and providing the UK input to the European Medicines Agency (EMA) Naming Review Group. During the year 985 proposed invented names were assessed on behalf of the MHRA and 470 on behalf of the EMA.

MHRA and NIBSC

46. The Secretariat has been working with colleagues from NIBSC in the area of Herbal Medicines as well as Biological Medicines. It is anticipated that work in these areas will continue and increase in the future.

47. Investigation of the feasibility of the BP providing biological reference preparations is continuing. A project is underway at NIBSC with a view to establishing reference materials to support new monographs.

48. Work undertaken by the BP-NIBSC Herbal team, and supported by the DNA Working Party, led to the production of an innovative nucleic acid reference material which is required to support the new Appendix on DNA-Based Identification Techniques for Herbal Drugs.

European Pharmacopoeia

49. The sixth and seventh Supplements to the 8th edition of the European Pharmacopoeia (Supplements 8.6 and 8.7) were published in July 2015 and October 2015 respectively. Supplement 8.6 came into effect on 1st January 2016 and Supplement 8.7 will come into effect on 1st April 2016. The eighth Supplement (8.8) was published in January 2016 and will come into effect on 1st July 2016.The text of these publications will be included in the next editions of the British Pharmacopoeia or British Pharmacopoeia (Veterinary), as appropriate.

50. 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 eight Working Parties and experts to all of the principal Expert Groups and Working Parties.

51. 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.

52. 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.

53. 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 2015, is included in Appendix V.

International Liaison and Collaboration

54. 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.

55. BP Staff attended the Fifth and Sixth International Meetings of World Pharmacopoeias which were organised by the World Health Organization. The Fifth Meeting was held at the headquarters of the United States Pharmacopeia, Rockville, USA (April) and the Sixth Meeting was held in Suzhou, China (September). The meetings focussed on the continuing development of the guidelines on "Good Pharmacopoeial Practices". Good progress was made towards completion of the guidelines, although a number of issues are still to be overcome to accommodate differences in medicines legislation amongst the participating countries. In addition to participating at the WHO meetings, the BP has fully reviewed the guidelines in order to ensure editorial accuracy.

56. 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. During the year BP staff visited WHO to discuss future projects and ways of working and identified areas of interest for possible future collaboration.

57. The BP participated in the WHO Consultation on Specifications for Medicines, Sampling and Technologies (April) and in the 50th Meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (October).

58. BP staff attended the 61st WHO Consultation on International Nonproprietary Names (October) during which Dr Patience Holland, a member of the Secretariat, was elected as Chair of the INN Committee.

59. BP and MHRA staff met with senior representatives from the United States Pharmacopeia (USP) in February to discuss areas of shared interest and future collaborative projects, including biological medicines.

60. Representatives from the BP attended the USP Convention in Washington DC during April. Mr James Pound, Editor-in-Chief, is the BPC Delegate to the Convention.The USP shared its key areas of work over the next five years, which included focussing on global harmonisation of standards, biological medicines and a major investment programme to update old monographs.

61. The project on informal prospective harmonisation with the USP continued to grow with the publication of two harmonised Rizatriptan finished product monographs in the British Pharmacopoeia 2016.

62. A teleconference was held with representatives from the USP in June to progress the informal harmonisation joint work programme for medicinal chemicals. A further teleconference was held with the USP in September to discusss opportunities to collaborate in the “USP-NF Up-to-Date” project aimed at modernising old monographs. The BP continues to collaborate with the USP in a range of other areas including biological medicines and Analytical Quality by Design.

63. A member of BP staff visited the head office of the Therapeutic Goods Administration, Australia, in May and discussed issues relating to the BP with TGA staff. TGA will assist in the development and revision of BP monographs of interest by acting as a second laboratory to assess the robustness of proposed methods.

64. A Collaboration Agreement between the MHRA and the Croatian Agency for Medicinal Products [HALMED] was signed in February. This agreement allows HALMED to reproduce BP texts relating to unlicensed medicines in the Croatian Pharmacopoeia.

65. During the year, BP staff met with representatives from the Chinese Pharmacopoeia, the Indian Pharmacopoeia, the Indonesian Pharmacopoeia, the State Pharmacopoeia of the Republic of Kazakhstan and the State Pharmacopoeia of Ukraine. The meetings focussed on current and future collaboration opportunities between the

BP and these organisations and provided the opportunity to learn of developments in the various pharmacopoeias. The BP also met with representatives from the Indian Ministry of Ayurveda, Yoga, Unani, Sidha and Homoeopathy with a view to identifying opportunities for future collaboration with the Ayurvedic Pharmacopoeia of India.

66. Two members of NIBSC-based staff, responsible for the DNA profiling of herbs, were seconded to the Institute of Chinese Materia Medica in Beijing during May. This provided an opportunity for training and an exchange of information in this new area of work, together with the chance to meet with representatives from the Chinese Pharmacopoeia and the Institute of Medicinal Plant Development.

67. The BP participated in a meeting with the Hong Kong Chinese Materia Medica Standards (HKCMMS) in October. Dr Samantha Atkinson, Secretary and Scientific Director of the British Pharmacopoeia Commission, was invited to become a member of the International Advisory Board of the HKCMMS.

68. A Memorandum of Understanding (MoU) between the MHRA and the Central Drugs Standard Control Organisation of India was signed in October. The MoU is aimed at increasing collaboration between the UK and India in the areas of medicines and medical devices and it is hoped that it will facilitate future interactions between the BP and the Indian Pharmacopoeia.

69. Along with representatives from the MHRA, the BP attended the 67th Indian Pharmaceutical Congress in Mysuru in December. Discussions were held with the Secretary/Scientific Director of the Indian Pharmacopoeia Commission with a view to identifying monographs of mutual interest that could be prepared jointly by the British and Indian Pharmacopoeias and regarding the provision of samples to enable the establishment of BP reference substances.

ACKNOWLEDGEMENTS

70. The Commission wishes to express its heartfelt thanks to those long-standing members who retired at the end of 2015, the majority of whom had served for the maximum allowable term of 10 years: Professor Donald Cairns, Mr Christopher Goddard, Dr Keith Helliwell, Dr Lincoln Tsang, Professor Elizabeth Williamson, Mr Barry Capon (lay member) and Mrs Josephine Turnbull (lay member). The Commission was pleased to learn that Professor Cairns, Mr Goddard, Dr Helliwell,
Dr Tsang and Professor Williamson would continue to serve on the Expert Advisory Groups, Panels of Experts and Working Parties to which they had been appointed.

71. 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.

72. The British Pharmacopoeia Commission also 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, the Information Management Division and the Communications Division of the Agency. 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.

73. The Commission wishes to acknowledge the advice of the publishing team at The Stationery Office in the production of the British Pharmacopoeia 2016 and the British Pharmacopoeia (Veterinary) 2016.

74. 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.

75. Mrs Matilda Vallender retired from the MHRA during the year. The Commission wishes to place on record its gratitude to Mrs Vallender for her 35 years of service to the BP, including 12 years as Editor-in-Chief.

MEMBERSHIP OF THE BRITISH PHARMACOPOEIA COMMISSION

Chair

Professor Kevin M G Taylor BPharm PhD FRPharmS
Professor of Clincial Pharmaceutics, UCL School Pharmacy

Members

Professor Donald Cairns[1] BSc PhD MRPharmS CSci CChem FRSC
Head: School of Pharmacy and Life Sciences, Robert Gordon University, Aberdeen

Mr Barry Capon[1] 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[1] BSc DIS CSci EurChem CChem FRSC
Quality Control Technical Manager, Recipharm Limited

Dr Keith Helliwell[1] 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[1] BPharm LLB PhD FRSC FIBiol FRSA FRPharmS Solicitor
Life Sciences Lawyer; Partner, Arnold & Porter LLP

Mrs Josephine Turnbull[1] 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[1] BPharm PhD MRPharmS
Former Professor of Pharmacy, University of Reading

Secretary and Scientific Director

Dr Samantha Atkinson BSc MSc PhD MRSC; Visiting Fellow, Reading University
Group Manager, British Pharmacopoeia and Laboratory Services, MHRA

[1] Retired, 31 December 2015.

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, E Flahive, A Gibson, V Jaitely, W Mann, J Miller, B White, I R Williams
BIO: Biological and Biotechnological Products	L Tsang (**Chair**), P Varley (**Vice-Chair**), L Bissett*, A F Bristow*, C Burns, D H Calam, K Chidwick*, A Cook*, J Cook*, L Findlay*, S Gill, E Griffiths, C Jones*, A Kippen*, B Patel, A M Pickett*, T Pronce, L Randon, I Rees*, S Schepelmann*, D Sesardic, P Sheppard, P Stickings*, W J Tarbit[1], A H Thomas, R Thorpe, M Wadhwa*
HCM: Herbal and Complementary Medicines	E Williamson (**Chair**), L A Anderson (**Vice-Chair**), P Anderson, A Bligh, S Gibbons, K Helliwell, C Leon, R Middleton, B Moore, M Pires, M Rowan, K Strohfeldt-Venables, J Sumal*, C Welham, 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, A James, V Loh[1], W J Lough, D J Malpas
MC2: Medicinal Chemicals	G Cook (**Chair**), C T Goddard (**Vice-Chair**), J Cowie, D Edwards, A Gibson, J Lim, J Miller, P Murray, A Ruggiero, M Turgoose, N Wynne (*Corresponding members* M Brits, W Sherwin)
MC3: Medicinal Chemicals	V Fenton-May (**Chair**), E Williamson (**Vice-Chair**), M Almond, S Arkle, J Beach, J Beaman, 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, B Granell-Villen, D Mehta, G P Moss, R Thorpe (*Corresponding members* R G Balocco Mattavelli, J S Robertson)

PCY: Pharmacy	R L Horder (**Chair**), B R Matthews (**Vice-Chair**), M Ahmed*, E Baker, J Beach, D Elder, B Granell-Villen, J Lim*, R A Lowe, J MacDonald, J F McGuire, T Purewal, L Randon, K M G Taylor, S Wicks (*Corresponding member* J Churchill)
ULM: Unlicensed Medicines	M G Lee (**Chair**), V Fenton-May (**Vice-Chair**), G Bennett, S Branch, D Caulfield, W Goddard, N Hussain, S Jones, J Rothwell[1], M Santillo, J Smith, A Sully, P Weir

PANELS OF EXPERTS

BLP: Blood Products	K Chidwick, A R Hubbard, J More, P Varley
CX: Excipients	B R Matthews (**Chair**), C Mroz (**Vice-Chair**), C Cable, R Cawthorne, W Cook, D Deutsch, N Hussain
IGC: Inorganic and General Chemicals	C T Goddard (**Chair**), M Almond, S Atherton, S Boland, D Caulfield, P Henrys, G Lay
MIC: Microbiology	V Fenton-May (**Chair**), B Alexander, S Denyer, P Hargreaves, B R Matthews, P Newby
RAD: Radioactive Materials	J Ballinger, J Brain, D Graham, G Inwards, R D Pickett, R Smith, S Waters
VET: Veterinary Medicines	E Williamson (**Chair**), A Coulson **(Vice-Chair**), A Cairns, S Cockbill, D Evans, E Flahive, B Ward
VIP: Veterinary Immunological Products	A-M Brady (**Chair**), R Banks, R Cooney, K Redhead, J Salt, R Woodland

WORKING PARTIES

AQbD: Analytical Quality by Design	G Cook (**Chair**), S Brown, S Ellison, M Hanna-Brown, S Jones, D Makohon, P Nethercote, E Razzano (*Corresponding membe*r K Barnett)
DNA: Identification Techniques	K Helliwell (**Chair**), I Feavers, J Hawkins, E Mee, A Slater, E Williamson
MCS: Microscopy	E Williamson (**Chair**), R Arroo, R Fleck, K Helliwell, K Maclellan Gibson

[1] Resigned during the year
* Specialist member

MEMBERS OF THE BRITISH PHARMACOPOEIA COMMISSION STAFF

SECRETARY AND SCIENTIFIC DIRECTOR

Dr S Atkinson

SECRETARIAT

Mrs M Vallender (*Editor-in-Chief, until 31st May)*
Mr J Pound (*Editor-in-Chief, from 1st June)*
Mr S Young (*Head of Analytical Science*)
Mrs M Barrett
Ms H Corns
Mr P Crowley
Mr A Evans
Ms J Francomb
Dr A Gardiner
Mr A Gibb
Dr P Holland
Ms G Li-Ship
Dr R A Pask-Hughes
Ms C Pitt
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, until 31st May)*
Mr J Pound (*Editor-in-Chief, BP, from 1st June)*
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 Services, LGC)*

ADMINISTRATIVE

Mr B Delahunty
Mr W Jeffries
Miss J Paine
Ms M-L Wall

BRITISH PHARMACOPOEIA COMMISSION PUBLICATIONS

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

British Pharmacopoeia 2016 package

Consisting of:-

British Pharmacopoeia 2016

British Pharmacopoeia (Veterinary) 2016

Online Access (single-user licence, allowing access to three in-year electronic updates)

BP Download Edition (single-user licence)

(Subscription price £1000; £875 for print and either online or download edition 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. 4

(Price £20)

EUROPEAN PHARMACOPOEIA COMMISSION

MEMBERS OF THE UNITED KINGDOM DELEGATION

Main: S Atkinson, A G Davidson, K M G Taylor
Alternates: R L Horder, M Vallender (*until 31st May*), J Pound (*from 1st June*)

MEMBERS OF GROUPS OF EXPERTS FROM THE UNITED KINGDOM DURING 2015

Group 1	Biological Methods and Statistical Analysis	V Fenton-May (***Chair***)
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 13B	Phytochemistry (B)	P Anderson
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, R Cooney (*Specialist*)

Group 16	Plastic Containers for Pharmaceutical Use	C O'Neill
Group P4	Procedure 4	S Young

MEMBERS OF WORKING PARTIES FROM THE UNITED KINGDOM:

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	A Davidson, 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
General Methods	A Davidson (***Chair***)
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 M G Taylor
Monoclonal Antibodies	R Thorpe (***Chair***), P Varley
Monocyte Activation Test	L Findlay

Nuclear Magnetic Resonance Spectroscopy	C Jones
Paediatric Formulary	N Hussain
Pharmaceutical Preparations	V Fenton-May (***Chair***), M G Lee
Procedure 4 for Biologicals	K Chidwick, M Wadhwa
Process Analytical Technology	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
Sutures	L Ferris
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 wider 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 or the EAG ch airmen to attend ev ents sponsored by t he phar maceutical industry (and accept the payment of their expenses) without recourse to the MHRA di scretionary f und. For ex ample, w here a l earned so ciety hol ds an international co nference t hat i s sponsored by a num ber o f di fferent pharmaceutical companies, it will generally be acceptable for the member to accept su ch an i nvitation and t o r eceive pay ment of ex penses, al though in such instances declaration of attendance and receipt of f unding m ust be declared in the normal way.

4.12 If funding and /or ex penses are pai d sp ecifically f or an i ndividual's attendance but nev ertheless paid t o hi s department r ather than the individual hi mself, i t w ill not no rmally be acce ptable for t he i ndividual 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 co nference with a f amily member) must be decl ared as the i ndividual's own i nterest. H owever, there is no requirement to declare educational conferences and similar events attended by immediate family members.

4.14 If an i ndividual at tends an educa tional co nference or si milar, he o r she should av oid par ticipation i n, f or ex ample, " satellite" m eetings 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 a t 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 a ccept 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 pl ace. T his declaration m ay af fect an i ndividual'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 f rom t he MHRA S ecretariat i f they ar e i n any doubt about whether or not t hey sh ould attend, o r whether, h aving 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 av ailable or ca nnot par ticipate 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	Novartis	Zoledronic Acid - Consultancy to institution	Yes	None
			Amgen	Romosozumab - Investigator on clinical trial	Yes	
			Eli Lilly	Teriparatide and bisphosphonates - Research grant	Yes	
			Roche	Tocilizumab - Another consultant in our department was a local investigator on a clinical trial with this product	Yes	
			Bristol Myers Squibb	Abatacept - Another consultant in our department was a local investigator on clinical trials of this product	Yes	
			Menarini	Febuxostat & allopurinol - Investigator on a post-marketing safety study. (please note that the trial is sponsored by Dundee University)	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Tayside Pharmaceuticals	Alendronic acid - study. The alendronic and placebo were supplied by Tayside pharmaceuticals Dexamethasone - An investigator led research study is in progress run by Edinburgh Clinical Trials Unit. The dexamethasone and placebo were supplied by Tayside pharmaceuticals I have no direct involvement in the study.	Yes	
			Amgen	Denosumab - An investigator led research study is in progress run by Edinburgh Clinical Trials Unit in which denosumab is the IMP. I have no direct involvement in the study.	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Astrazeneca	Ticagrelor - An investigator led research study is in progress run by Edinburgh Clinical Trials Unit in which Ticagrelor is the IMP. I have no direct involvement in the study.	Yes	
			Genus Pharmaceuticals	Fluoxetine - An investigator led research study is in progress run by Edinburgh Clinical Trials Unit in which Fluoxetine is the IMP. I have no direct involvement in the study.	Yes	
			AMAG Pharma	Ferumoxytol - An investigator led research study is in progress run by Edinburgh Clinical Trials Unit in which Ferumoxytol is the IMP. I have no direct involvement in the study.	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Sanofi Aventis	Riluzole - Edinburgh Clinical Trials Unit is in charge of data management for a study involving this IMP. The sponsor is UCL. I have no direct involvement in the study	Yes	
			Actavis	Amiloride Fluoxetine - Edinburgh Clinical Trials Unit is in charge of data management for a study involving this IMP. The sponsor is UCL. I have no direct involvement in the study	Yes	
			PetNet solutions	[18F] Sodium Fluoride - An investigator led research study is in progress run by Edinburgh Clinical Trials Unit in which this is being used as an imaging agent. I have no direct involvement in the study.	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			No Specified Manufacturer	Aspirin, dipyridamole & clopidogrel - An investigator led research study is in progress run by Edinburgh Clinical Trials Unit in which these drugs (supplied by local pharmacies) are being used as IMP. I have no direct involvement in the study	Yes	
			Abbvie (infliximab) No specified manufacturer for other drugs	Infliximab, azathioprine, mercaptopurine and methotrexate - An investigator led research study An investigator led research study No specified mercaptopurine and is in progress run by Edinburgh Clinical Trials Unit in which these drugs (all supplied by local pharmacies) are being used as IMP.	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Pfizer	Celecoxib - Investigator on a post-marketing safety study. (please note that the trial is sponsored by Dundee University)	Yes	
Mrs Eileen J Barrett	Select Pharma Labs Ltd	Liothyronine Sodium 20 microgram tablets - Principle employer, Source Bioscience Plc, acquired select Pharma Labs Ltd in July 2015	Amgen Inc. Amgen Europe B.V. Pfizer Ltd Astrazeneca Exova UK Limited Royal Marsden Hospital Guys Hospital Cancer Research UK BioVex Ltd Boehringer Ingelheim Biogen Idec limited Boehringer Ingelheim Biogen Idec limited, King's College Hospital	The companies listed in the the non-personal interests, will have been a client of Source Bioscience Plc at the time of a given CHM meeting but the product of interest on the CHM agenda will not have been relevant to the services or products Source Bioscience Plc was providing to the companies at the time.	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Royal Free Hospital			
			Croyden University Hospital			
			UCB Pharma Limited			
			Teva UK Limited			
			Catalent Pharma Solutions LLC			
			Gilead Sciences International Limited			
			Patheon, Inc			
			Eurofins Lancaster Laboratories, Inc.			
			Bayer Icepharma hf.			
			Covance Central Laboratory Services Inc.			
			Central Hematology Laboratory			
			Radbound University			

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Sun Pharmaceuticals Industries			
			Boehringer Ingelheim Pharma GmbH			
			BASF			
			Sanofi Chimie			
			Prostrakan Limited			
			F- Hoffmann-LA roche LTD			
			Penn Pharmaceutical Sevices Ltd			
			Aptuit Ltd.			
			Lonza			
			Pfizer			
			Butterworth Laboratories Ltd			
			Actavis UK Limited			
			Shire Pharmaceuticals Limited			
			AstraZeneca AB			
			Bristol-Myers Squibb Pharma EEIG			
			Lilly			
			Roche			
			Takeda			

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Almac Pharma Services Ltd			
			Aventis Pharma Limited			
			Patheon UK Limited			
			GlaxoSmithKline UK Limited (GSK)			
			Novartis			
			Novartis Europharm Limited			
			Teva Pharmaceutical Industries Ltd			
			UCB Pharma Ltd			
			Merk-Serono Actavis			
			Merck Serono Ltd			
			Teva Amdipharm			
			Mercury Company Ltd			
			Goldshield and Mercury Pharma			
			Custom Pharmaceuticals Ltd.,			

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Glaxo Smith Kline			
			Trading			
			Glaxo Wellcome			
			S.A.			
			Novartis			
			Amgen			
			AstraZeneca			
			Bristol-Myers			
			Squibb Pharma			
			EEIG			
			Lonza Biologics			
			Inc			
			Cancer Research			
			UK			
			Great Ormond			
			Street Hospital			
			The Scottish			
			National Blood			
			Transfusion			
			Service			
			Lonza			
			Sera Laboratories			
			International Ltd			
			Life Technologies			
			I Invitrogen			
			HyClone			
			Sigma Aldrich			
			Sanofi Aventis			
			Roche			

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			University College London King's College Hospital Royal Free Hospital Patheon Manufacturing Services LLC F. Hoffmann-La Roche Ltd Bristol-Myers Squibb (BMS) Catalent Pharma Solutions Sanofi Simbec Research Ltd Wyeth Pfizer Generics (UK) Ltd trading as Mylan Pharmaserve (North West) Limited Napp GlaxoSmithKline (GSK) Pharmasol Ltd			

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Valeant Pharmaceutical International Inc. Minerva Scientific Limited ILS Limited Teva UK Limited Dr Reddy's Laboratories (Uk) Limited Sanofi Chimie Merck, Sharp & Dohme Ltd (MSD)			
Dr J Colin Forfar	None	None	Astra Zeneca	Ticagrelor - Advisory board	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	ViV	Antiretroviral therapies - collaborating site in clinical trials	Yes	None
			Pfizer	Maraviroc - Investigator-initiated study grant	Yes	
			Gilead Sciences	Antiretroviral therapies - collaborating site in clinical trials	Yes	
			Merck	Antiretroviral therapies - collaborating site in clinical trials	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Janssen	Antiretroviral therapies - collaborating site in clinical trials	Yes	
Professor Martin Gore	Bristol Myers Squibb	Ipilimumab - Trial costs to unit and institution	None	None	No	None
	Bristol Myers Squibb	Nivolumab - Trial costs to unit and institution Recruitment of melanoma patients into trials involving both drugs				
	Roche	Atezolizumab - Trial costs to unit and institution				
	Merck	Pembrolizumab - Trial costs to unit and institution				
	Pfizer	Avelumab - Trial costs to unit and institution				
Professor Malcolm Macleod	None	None	None	None	No	At the time that CHM Antiepileptic Drugs ad hoc expert group was convened I was in negotiation with epilepsy action regarding a small academic grant (~£10k) for a systematic review of epilepsy related deaths.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						On assuming Chairmanship of the EAG and following discussion with the office I withdrew from that grant. On 14th September 2015 I gave a talk to Janssen, at Beerse, Belgium. I received no fee or expenses from Jannsen for this meeting.
Dr Rebecca Mann	None	None	None	None	No	None
Professor Sarah Meredith	None	None	Abbott	Lopinavir, Ritonavir - grant & product donated for a trial. Financial support for a virology sub-study (no drug)	Yes	None
			Amgen	Neupogen/GM-CSF - product donated for a trial/grant	Yes	
			Astellas	Enzalutamide - grant & product donated for a trial	Yes	
			AstraZeneca	Cediranib/AZD 8931 - grant & product donated for a trial/product donated for a trial	Yes	
			Bayer	Sorafenib - grant & product donated for a trial. Aspirin - 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**
			Boehringer Ingelheim, Bristol-Myers Squibb	Efavirenz, Atripla - grant & product donated for a trial. Atazanavir - Product donated for a trial	Yes	
			Cipla	Albendazole, Azithromycin, Cotrimoxazole/Isoniazid/ Pyridoxine, Fluconazole, Efavirenz, Nevirapine, Lapimune minitabs, Zidovudine/Lamivudine, Aabacavir/Lamivudine, Stavudine/Lamivudine - products donated for a trial	Yes	
			Gilead Sciences	Tenofovir, Emitricitabine, Atripla - grant & product donated for a trial	Yes	
			Gilead Sciences	Truvada - Product donated for 4 trials;Grant for the Proud study. Efavirenz, Tenofovir (Viread) - product donated for a trial. Financial support for Resistance Database	Yes	

MEMBER	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS	WHETHER CURRENT	ADDITIONAL INFORMATION
			GlaxoSmithKline	Lapatinib, Abacavir, Zidovudine, Lamivudine - grant & product donated for a trial	Yes	
			GlaxoSmithKline	Abacavir, Lamivudine, Zidovudine, Lamivudine, Abacavir, Lamivudine, Combivir, Kivexa, HIV Conserve Vaccine - product donated for a trial	Yes	
			Janssen	Abiraterone and Bedaquiline - 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, Raltegravir, Virinostat - 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**
			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	
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	Yes	20% SCIg – IgPro20 Hizentra. Honorarium will be paid into departmental funds

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
				demyleinating polyneuropathy (CIDP) in patients completing study IgPro20_3003		
			Biotest		No	
				Participation in advisory board meeting titled: 'IgA and IgM replacement in PID'. Honorarium paid into departmental funds.		
			Biotest		No	
				Delivered talk on 'Iatrogenic immunodeficiency – from immunosuppressive agents to biologics' at Immunology forum, Royal College of Physicians. Honorarium paid into departmental funds.		
			Baxalta	Delivered talk at satellite symposium at biennial meeting of the United Kingdom Primary Immunodeficiency Network meeting titled: 'Drug-induced antibody deficiency –		

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
				from conventional immunosuppressive agents to biologics'. Honorarium 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	
Professor Munir Pirmohamed	None	None	GlaxoSmithKline	Research grant to support clinical training fellowships jointly with MRC	Yes	None
			Astra Zeneca	Research grant to support clinical training fellowships jointly with MRC	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Pfizer	Research grant to look at mechanisms of TKI-induced diarrhoea	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	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 Angela E Thomas (Vice Chair)	None	None	Novo Nordisk	Coagulation factor concentrates. Supporter of Haemophilia Academy Edinburgh (via a 3rd party)	No	PedNet meeting: travel and accommodation paid for individually. Impossible to pay for pre-ordered lunch and refreshments. Support for meeting as a whole was

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
				at which I lecture. Honoraria waived		through an unconditional educational grant Support for the Haernophilia was through an unconditional educational grant Academy
			Bayer	Coagulation factor concentrates. Meals at European Paediatric Haemophilia Network (PedNet) annual meeting	No	
Professor Simon H L Thomas	None	None	None	None	No	None
Dr Christopher Weir	None	None	Reneuron Ltd	DSMB membership resulting in income to my department	Yes	None
			Celgene	DSMB membership resulting in income to my department	Yes	
			Tayside Pharmaceuticals	Dexamethasone - supply for Edinburgh Clinical Trials Unit trial. Co-applicant on the grant that funds the trial	Yes	
			Sanofi Aventis	Riluzole - co-applicant on the grant that funds the trial	Yes	

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)	None	None	None	None	No	None
Dr Amanda Adler						
Dr Houman Ashrafian	None	None	UCB (Union chimique belge)	Research grant	Yes	None
			SBI Pharamceuticals Ltd	Aminolevulinic acid - Research grant	Yes	
Professor Richard Donnelly	Janssen	Canagliflozin - Consultancy	None	None	No	None
	Astra Zeneca	Dapagliflozin - Speaker Fees				
Dr Iolo Doull	AstraZeneca	Symbicort - Educational lecture	None	None	No	None
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	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			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	
			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	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Andrew Grace	Xention Ltd	Consultancy, Options	None	None	No	None
Professor Wasim Hanif	Novo Nordisk	Liraglutide/Ideg Lira/Degludec - Research grants/Consultancy	None	None	No	
	Sanofi	Lixisenatide/Glargine 300 - Research grants/Consultancy	None	None	No	
	BI	Empagliflozin - Research grants/Consultancy	None	None	No	
	Jansen	Canagliflozin - Research grants/Consultancy	None	None	No	
	Astra Zeneca	Bydueron/Dapagliflozin - Research grants/Consultancy	None	None	No	
	MSD	Sitagliptin - Research grants/Consultancy	None	None	No	
	Eli Lilly	Dulaglutide - Research grants/Consultancy	None	None	No	
Professor Richard I G Holt	Otsuka	Aripiprazole - Fees for 8 lectures at academic meetings	None	None	No	I was the European Editor of Diabetic Medicine I was a member of the Diabetes UK governance committee
	Sanofi	Lantus and other insulin preparations, lixisenatide Duloxetine - Fees for 5 lectures at academic meetings				
	Janssen	Canigliflozin - Fees for 9 lectures at academic meetings and one advisory board				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Novo Nordisk	Novorapid, Novomix, Levemir, Tresiba, Xultophy, Liraglutide - Fees for 17 lectures at academic meetings and three advisory board				
	Novartis	Lucentis -Fees for two lectures at academic meetings				
	Sunovion	Lurisadone - Fees for a lecture at academic meetings				
Dr Philip Ind	Trinity-Chiesi	Fostair - Meeting registration (ERS) Chairing Meeting (sponsored Educational session) Speaker at meeting Hospitality Sponsored Departmental Breakfast Meeting	None	None	No	I have signed letters supporting the ban of smoking in cars. I have signed letters in support of the Junior Doctors (and strike action).
	Astra Zeneca	Symbicort Duaklir - Speaker at sponsored Educational Meeting				
	GlaxoSmithKline	Relvar Anoro - Hospitality Sponsored Departmental Breakfast Meeting (snack)				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Boehringer	Nintedanib - Hospitality Sponsored Departmental Breakfast Meeting (snack)				
Professor Alan Jardine	OPSONA Astellas	TLR-2 blockers - DMC Tacrolimus - lecture fees	None	None	No	None
	Roche	Antiviral drugs - lecture and consultancy fees				
	Bayer	Novel mineralocorticoid receptor blockers - DMC				
	Chimerix	Novel antiviral drugs - DMC				
Professor Ann Millar	None	None	None	None	No	None
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 that receives financial support from a number of pharmaceutical and respiratory device companies).
	Napp Pharmaceuticals					I am a member of the education sub- committee -some of the projects are supported by unrestricted educational grants from respiratory interested Pharmaceutical Companies
		Non-promotional presentation on self-management				
	Napp Pharmaceuticals	Chairing an educational meeting				International Primary Care Respiratory Group. (A registered charity that receives

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						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. 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
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
	PneumRX/BTG	RePneu lung volume reduction coils - Lecture/workshop/consultancy	ERBE, Cook medical, Immotech, Coveidien,	Sponsor Imperial college for bronchoscopy course	No	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Pulmonx	Endobronchial valves for emphysema (Zephyr) - Consultancy/lecture	Olympus, PneumRX, Pulmonx			
	Medtronic	iLogic Superdimension navigation bronchsocopy	Pulmonx	Zephyr valves - RCT with endobronchial valves Royal Brompton Hospital eimbursed for clinical trial expenses	No	
	Broncus	LungPoint - Consultancy	CSA medical	ReJuvinair (cryopspray) - RCT with cryospray Royal Brompton Hospital eimbursed for clinical trial expenses	No	
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	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	Actelion	Fees – patent advice	None	None	No	None
Professor Graham Buckton	Actavis	Consultancy	GlaxoSmithKline	Grant	Yes	None
	Teva	Consultancy	AstraZeneca	Grant	Yes	
	Apotex	Consultancy	Pfizer	Grant	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Perrigo	Consultancy	Alliance Boots	Grant	Yes	
			Pfizer	Grant	Yes	
Professor Derek H Calam	None	None	None	None	No	None
Professor Brian J Clark	None	None	None	None	No	None
Professor Ruth Duncan	None	None	None	None	No	None
Professor Gillian M Eccleston						
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 International Inc	Common shares - Shares bought whilst an employee 1982 to 1993 and dividend re-investment	None	None	No	None
	Baxalta Incorporated	Common Shares - Share alloction from Baxter, spin-off				
Dr Majella Lane	None	None	None	None	No	I have established a consultancy company called Melderm Ltd. The company provides expert witness services for patent litigation cases in the United States.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Mr Robert A Lowe	B Braun	Travel sponsorship and hospitality for a visit to a B Braun factory in Melsingen, Germany in 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
	MedPharm Limited	Shares				
	Remedica Limited	Directorship, Fees				
	Halation Limited	Directorship, Fees, Shares				
Professor Yvonne Perrie	None	None	Diagenode	Grant	Yes	None
			Izon	Grant	Yes	
			GSK (formallyNovartis)	Grant	Yes	
			Colorcon	Grant	Yes	
			Mologics	Grant	Yes	
			Roche	Possible 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	Takeda	Funded project at CrystecPharma	Yes	None
	CrystecPharma	Director, Shares	Anovex	Funded project at CrystecPharma		
	Lena Nanoceutics	Director	AstraZeneca	Funded project at CrystecPharma		
	Pfizer	Director	Skye Pharma	Funded project at CrystecPharma		

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**
Professor Angela E Thomas (Chair)	None	None	Novo Nordisk	Coagulation factor concentrates. Supporter of Haemophilia Academy Edinburgh (via a 3rd party) at which I lecture. Honoraria waived	No	PedNet meeting: travel and accommodation paid for individually. Impossible to pay for pre-ordered lunch and refreshments. Support for meeting as a whole was through an unconditional educational grant Support for the Haernophilia was through an unconditional educational grant Academy
			Bayer	Coagulation factor concentrates. Meals at European Paediatric Haemophilia Network (PedNet) annual meeting	No	
Professor Andrew J T George	Smart Targeting	Shares	Action Medical Research	Trustee	No	My wife is employed by Imperial Healthcare NHS Trust. She does act as a consultant for somepharmaceutical companies on an occasional basis.
			Imperial College Health Partners	Director	Yes	She is Chair of West London REC.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			National Research Ethics Advisors' Panel	Chair	Yes	I am employed by Brunei University London. The University has strong links with industry and much of its research is funded by industry. If I have specific knowledge of any such funding related to a study I would declare it. I am Chair of the National Research Ethics Advisors' Panel. I therefore might see some proposals or hold discussions with stakeholders in medical research. I am a member of a number of learned or professional societies that may receive funding from pharmaceutical companies.
Dr Elwyn Griffiths	None	None	None	None	No	I am a Member of the WHO Expert Advisory Panel on Biological Standardization and current Chair of the WHO Expert Committee on Biological Standardization. I am a member of a Special Advisory Board of the Korean Ministry of Food and Drug Safety, the regulatory agency in South Korea. I am also a member of the Board of the International Alliance for Biologicals (IABS) which has membership drawn

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						from regulatory agencies, academia and industry (unpaid). My daughter, Nia Wyn Voase, is Clinical Guidance Manager , Respiratory Biomedical Research Unit, Imperial College and Royal Brompton Hospital, London. She has no personal interest in the pharmaceutcal industry.
Dr Helen J Lachmann	Novartis	Ilaris - Fees, consultancy	None	None	No	None
	SOBI	Anakinra - Part funding of travel for meetings, consensus group meetings, Fees				
	Takeda	TAK-475 - Consultancy fees				
	Ionis Pharmaceuticals	ISIS 420915 - Data monitoring committee				
Professor Elizabeth Miller	None	None	None	None	No	None
Dr Siraj Misbah	None	None	CSL Behring	20% SCIg – IgPro20 Hizentra - UK National Co-ordinator for multicenter,open-label extension study of IgPro20 in maintenance treatment of chronic inflammatory demyelinating polyneuropathy (CIDP)	Yes	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
				in patients completing study IgPro20_3003 Honorarium will be paid into departmental funds		
			Biotest	Participation in advisory board meeting titled: 'IgA and IgM replacement in PID'. Honorarium paid into departmental funds.	No	
			Biotest	Delivered talk on 'Iatrogenic immunodeficiency – from immunosuppressive agents to biologics' at Immunology forum, Royal College of Physicians. Honorarium paid into departmental funds.	No	
			Baxalta	Delivered talk at satellite symposium at biennial meeting of the United Kingdom Primary Immunodeficiency Network meeting titled: 'Drug-induced antibody deficiency – from conventional immunosuppressive	No	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
				agents to biologics'. Honorarium paid into departmental funds.		
Professor B Kevin Park	None	None	Janssen Pharmaceutica N.V.	Project grant on the role of the Nrf2 system in DILI	No	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	
Professor Andrew Pollard	None	None	Pfizer	Grant to Oxford University (pneumococcal carriage study)	No	Chair of the Department of Health's Joint Committee on Vaccination and Immunisation.
			Pfizer	Grant to Oxford University (epidemiological study of meningitis in children)	Yes	I have not initiated any new projects with funding from vaccine manufacturers since 2013.
			Pfizer	Meningococcal vaccine (TruMenBa) - Grant to Oxford University	No	The following are academic trials or publicly funded research which

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS	WHETHER CURRENT	ADDITIONAL INFORMATION
			GlaxoSmithKline, Novartis, Astra Zeneca	Unrestricted educational funding - Grant to Oxford University	No	I lead where the research is not funded by pharmaceutical companies: • European Commission grant (EBOVAC) to study an Ebola vaccine which has been developed by Janssen (2015-current). • European Commission grant (EUCLIDS; funding 2011-2016) to study the cause of fever with Bexsero (vaccine provided for the study under a supply agreement with University by Novartis/GSK). • Grant from the Bill and Melinda Gates Foundation to study the efficacy of a typhoid vaccine (Tybar-CV) produced by Bharat Biotech, India (2013-2016). • European Commission grant (ADITEC, 2011-2016) to study the genes expressed in children when they receive an adjuvanted influenza vaccine (FluAd, Novartis). • Grant from the National Institute for Health Research (2015-2020) to study treatment of encephalitis in children with intravenous immunoglobulin

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						Other investigators in the same academic department as me undertake research funded by vaccine manufacturers and this research is listed under non-personal interests above for transparency although I am not involved in those projects.
Dr Stephen Poole	Debiopharm International S.A.	Monoclonal antibodies - Consultancy	None	None	No	None
Dr Peter F Searle	None	None	None	None	No	I have worked, and have a continuing interest, in the field of cancer gene therapy. My group has conducted gene therapy clinical trials in collaboration with biotech/pharmaceutical companies, and we have an ongoing clinical trial in prostate cancer. 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 have been 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.
Mrs Madeleine Wang	None	None	None	None	No	Abvie - Non -specific Interest held by an immediate family member
Dr Christopher Weir	None	None	Reneuron Ltd	DSMB membership, resulting in income to my department	Yes	None
			Celgene	DSMB membership, resulting in income to 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**
			Tayside Pharmaceuticals	Dexamethasone - supply for Edinburgh Clinical Trials Unit trial. Co-applicant on the grant that funds the trial	Yes	
			Sanofi Aventis	Riluzole - co-applicant on the grant that funds the trial	Yes	

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)	Bristol-Myers Squibb	Travel and accommodation support to attend EULAR AGM, Rome.	Hospira	Support for external speaker travel to Rheumatology Dept seminar series	No	None
	Hospira	Speaker fees	UCB	Certulizumab - Research funding to University of Sheffield	No	
	Abbvie	Travel and accommodation support to attend EULAR AGM, San Francisco.				
	Merck	Travel and accommodation support to attend Biologics Medicine Conference, Cleveland Clinic, Ohio, USA.				
	Epirus Biopharmaceuticals	Advisory Board on use of biosimilars				
Dr Michael Ardern-Jones	None	None	GlaxoSmithKline	Consultancy	No	None
Dr Ian Barrison			Unilever	Consultancy	No	

	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.
Dr Richard Groves Professor Kevin Moore	Servier	Valdoxan/Agomelatine - Consultancy on hepatotoxicity	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**
	NOORIK	Endothelin antagonist for clinical trials in HRS - Research or clinical studies	None	None	No	None
Dr Frances Williams	None	None	None	None	No	None

INFECTION 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 Jonathan Friedland (Chair) Dr Sanjay Bhagani	None	None	None	None	No	None
Professor David Dockrell	Bristol-Myers Squibb	Atazanavir - Advisory Board	None	None	No	None
	JACG	Darunavir - Speaker fees	None	None	No	None
	GlaxoSmithKline	Research grant for work on macrophage host defence against bacteria during COPD and receipt of joint University –GSK funded PhD studentship	None	None	No	None
Dr Andrew Freedman	Gilead Sciences Inc	Tenofovir Alafenamide - two advisory boards	None	None	No	I am currently a local investigator for two multicentre, international trials, run by Gilead Sciences Inc, of Tenofovir Alafenamide in patients with HIV (No personal or departmental payment).
	MedImmune	Advisor on research project	None	None	No	None
Dr Richard Gilson	None	None	ViiV	Antiretroviral therapies - My department is a collaborating site in clinical trials	Yes	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Pfizer	Maraviroc - UK chief investigator for one commercial trial – now completed. Chief investigator on one investigator-initiated study grant now completed and pending publication	Yes	None
			Gilead Sciences	Antiretroviral therapies - My department is a collaborating site in clinical trials.	Yes	None
			Merck	Antiretroviral therapies - My department is a collaborating site in clinical trials.	Yes	None
			Janssen	Antiretroviral therapies - My department is a collaborating site in clinical trials.	Yes	None
Dr Richard Hobson	None	None	None	None	No	None
Dr Susan M Hopkins	None	None	None	None	No	None
Professor Martin Lombard	None	None	None	None	No	None
Dr Hermione Lyall	None	None	None	None	No	None

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						
Dr E Jane Dickson	None	None	None	None	No	None
Ms Linda Pepper	None	None	None	None	No	None
Professor Philip Hannaford	None	None	None	None	No	None
Dr Sally Hope	Amgen	Denosumab - Gave two GP lectures on the general subject of Osteoporosis (Education) Sponsored by Amgen	None	None	No	I am a medical Primary Care advisor (unpaid) to the National Osteoporosis Society. Over the last year we have written an ‘Advanced Diploma’ on line module (unpaid). I have been the RCGP representative on the Menopause NICE guidelines group (2013-2015) unpaid. Deputy Editor of Maturitas Journal (Elservier) paid
	Consilient Health	InvitaD3 - Did paid lecture to new recruits to Consilient health on why Vit D was so important (education)				
Professor Mary Lumsden (Vice-Chair)	None	None	NeRRe Biotechnology Company	Advisor (development potential new molecules)	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 Siobhan Quenby						
Carolyn, Lady Roberts	None	None	None	None	No	Member of Council, University of Hull
Mrs Margaret V Shotter	None	None	None	None	No	None
Dr Claire Spencer	None	None	None	None	No	None
Professor Jonathan Tobias	None	None	None	None	No	None

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)	None	None	None	None	No	None
Professor John Duncan	Ervitech	Apnoea detector - Founder shareholder	Medtronic	Neuronavigation systems - Research collaboration	Yes	None
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.
	AstraZeneca	Shares				
	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.				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. 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 also an ordinary member of Headway - the Brain Injury charity which supports research. 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).

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
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	Throughout 2015 I was a member of the: - Azheimer's Society Research Advisory Committee - The Alzheimer's Research UK Scientific Board - The Lewy body Society Medical Advisory Board Since September 2015 I have been a member of the NICE Dementia Guideline Update Committee. Since July 2015 I have been NIHR National Specialty Lead for Dementia.
	TauRx	Methylthioninium - Consultancy				
	Lilly	Flurbetapir - Advisory board meeting and lecture fees				
	Piramal	Flurbetaben - Scientific collaboration				
Dr Waqar Rashid	Novartis	Advisory board discussing health modeling in MS	None	None	no	I on an ad hoc basis advise pharmaceutical companies on the MS treatment landscape and occasionally on specific products (as declared above). This is usually in a grouped advisory board environment.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Biogen	Pegylated beta-interferon - Invited talk at MS nurse meeting				All meetings are fully compliant with ABPI regulations. I and my family hold not position or financial interest in any pharmaceutical company.
	Roche	Advisory board to discuss MS treatment landscape				
	Biogen	Advisory board on MS service models				
	Roche	Ocrelizumab - Advisory board				
	Biogen	Travel grant to attend an international MS conference				
Professor Peter A G Sandercock	Ever Pharmaceutical	Cerebrolysin - Lecture fee and travel expenses for giving a lecture	Medtronic	Intermittent Pneumatic compression device - Lecture fee paid to Department	No	None
Dr Catherine F Stannard	None	None	None	None	No	None
Professor Eric A Taylor	None	None	None	None	No	None
Dr Christopher Weir	None	None	Reneuron Ltd	DSMB membership resulting in income to my department	Yes	None
			Celgene	DSMB membership resulting in income to 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**
			Tayside Pharmaceuticals	Dexamethasone - supply for Edinburgh Clinical Trials Unit trial. Co-applicant on the grant that funds the trial	Yes	
			Sanofi Aventis	Riluzole - co-applicant on the grant that funds the trial	Yes	
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	

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)	Bristol Myers Squibb	Ipilimumab - Trial costs to unit and institution	None	None	No	None
	Bristol Myers Squibb	Nivolumab - Trial costs to unit and institution Recruitment of melanoma patients into trials involving both drugs				
	Roche	Atezolizumab - Trial costs to unit and institution				
	Merck	Pembrolizumab - Trial costs to unit and institution				
	Pfizer	Avelumab - Trial costs to unit and institution				
Professor Angela E Thomas (Vice Chair)	None	None	Novo Nordisk	Coagulation factor concentrates. Supporter of Haemophilia Academy Edinburgh (via a 3rd party) at which I lecture.	No	PedNet meeting: travel and accommodation paid for individually. Impossible to pay for pre-ordered lunch and refreshments.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
				Honoraria waived	No	Support for meeting as a whole was through an unconditional educational grant Support for the Haernophilia was through an unconditional educational grant Academy
			Bayer	Coagulation factor concentrates. Meals at European Paediatric Haemophilia Network (PedNet) annual meeting	No	
Mrs Eileen J Barrett	None	None	Amgen Inc. Amgen Europe B.V. Pfizer Ltd Astrazeneca Exova UK Limited Royal Marsden Hospital Guys Hospital Cancer Research UK BioVex Ltd Boehringer Ingelheim Biogen Idec limited King’s College Hospital	The companies listed in the the non-personal interests, will have been a client of Source Bioscience Plc at the time of a given CHM meeting but the product of interest on the CHM agenda will not have been relevant to the services or products Source Bioscience Plc was providing to the companies at the time.	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Royal Free Hospital			
			Croyden University Hospital			
			UCB Pharma Limited			
			Teva UK Limited			
			Catalent Pharma Solutions LLC			
			Gilead Sciences International Limited			
			Patheon, Inc			
			Eurofins Lancaster Laboratories, Inc.			
			Bayer			
			Icepharma hf.			
			Covance Central Laboratory Services Inc.			
			Central Hematology Laboratory			
			Radbound University			
			Sun Pharmaceuticals Industries			

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Boehringer Ingelheim Pharma GmbH			
			BASF			
			Sanofi Chimie			
			Prostrakan Limited			
			F- Hoffmann-LA roche LTD			
			Penn Pharmaceutical Sevices Ltd			
			Aptuit Ltd.			
			Lonza			
			Pfizer			
			Butterworth Laboratories Ltd			
			Actavis UK Limited			
			Shire Pharmaceuticals Limited			
			AstraZeneca AB			
			Bristol-Myers Squibb Pharma EEIG			
			Lilly			
			Roche			
			Takeda			
			Almac Pharma Services Ltd			

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Aventis Pharma Limited Patheon UK Limited GlaxoSmithKline UK Limited (GSK) Novartis Novartis Europharm Limited Teva Pharmaceutical Industries Ltd UCB Pharma Ltd Merk-Serono Actavis Merck Serono Ltd Teva Amdipharm Mercury Company Ltd Goldshield and Mercury Pharma Custom Pharmaceuticals Ltd., Glaxo Smith Kline Trading Glaxo Wellcome S.A.			

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Novartis			
			Amgen			
			AstraZeneca			
			Bristol-Myers Squibb Pharma EEIG			
			Lonza Biologics Inc			
			Cancer Research UK			
			Great Ormond Street Hospital			
			The Scottish National Blood Transfusion Service			
			Lonza Sera Laboratories International Ltd			
			Life Technologies I Invitrogen			
			HyClone			
			Sigma Aldrich			
			Sanofi Aventis			
			Roche			
			University College London			
			King’s College Hospital			
			Royal Free Hospital			

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Patheon Manufacturing Services LLC			
			F. Hoffmann-La Roche Ltd			
			Bristol-Myers Squibb (BMS)			
			Catalent Pharma Solutions			
			Sanofi			
			Simbec Research Ltd			
			Wyeth			
			Pfizer			
			Generics (UK) Ltd trading as Mylan			
			Pharmaserve (North West) Limited			
			Napp			
			GlaxoSmithKline (GSK)			
			Pharmasol Ltd			
			Valeant Pharmaceutical International Inc.			
			Minerva Scientific Limited			
			ILS Limited			
			Teva UK Limited			

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Dr Reddy's Laboratories (Uk) Limited Sanofi Chimie Merck, Sharp & Dohme Ltd (MSD)			
Professor Mark D Bower	ViiV	Advisory Board	None	None	No	None
	ViiV	Speaker fees				
	BMS	Speaker fees				
	Gilead	Speaker fees				
	Janssen	Speaker fees				
Professor Stephen Devereux	Janssen	Ibrutinib - Speaker fee, advisory board	None	None	No	None
	Janssen	Ibrutinib - Speaker fee				
	Janssen	Ibrutinib - Speaker fee				
	Novartis	Ofatumumb - Conference travel, Speaker fee				
	Janssen	Ibrutinib - Conference travel				
	Gilead	Idelalisib - Advisory board				
	Roche	Obinutuzumab - Advisory board				
	Abbvie	Venetoclax - Advisory board				
	Janssen	Ibrutinib - Conference travel				
Dr Chris Gallagher						
Dr Charlie Gourley						
Professor Hilary Calvert						

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	Bayer	Riociguat - Small consultancy fee and travel to Expert Advisory Group meeting	Merck	Odanacatib - I am PI for ongoing drug trial in the department	Yes	None
	Pfizer	Etanercept - Small educational grant for conference fees to attend American College of Rheumatology 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	
Dr Helen Burdett	None	None	Vitaflo	Betashot - Salary for research coordinator paid to department	Yes	None
			UCB	Bivetiracetam - Advisory Board; honorarium paid to department	No	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Nutricia	Ketocal - Speaker fee paid to department	No	
			GW Pharma	Cannabidiol - Participation in clinical trials; fee paid to hospital	Yes	
			Zogenix	Fenfluramine - Participation in clinical trials, advisory board x 2; fees paid to department	Yes	
Dr Steven Cunningham	None	None	Ablynx	ALX-0171 - International Coordinating Investigator and PI for studies of ALX-0171. Consultancy fees paid to NHS Lothian for ICI duties	Yes	None
			Alios	ALS-8176 - PI for studies of ALS-8176	Yes	
			Vertex	Ivacaftor - PI for studies of Ivacaftor in children with CF	Yes	
Professor Peter C Hindmarsh	Medtronic Diabetes	Medtronic Insulin Pump - Consultancy for Product Development	None	None	No	None
Dr Meriel Jenney	None	None	None	None	No	None
Professor Nigel Klein	None	None	None	None	No	None
Ms Fiona Lynch						
Dr Rubin Minhas	None	None	None	None	No	I am an unpaid member of the following committees at this time: BMJ Ethics Committee

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						Dr Foster Ethics Committee NICE Quality Standards Committee
Professor Marie-Louise Newell	Crucell BVm a Janssen pharmaceutical company of Johnson & Johnson	A new Ebola vaccine - Member of the DSMB of the phase 2 trial	None	None	No	None
Professor Anthony Nunn	None	None	None	None	No	I am a registered scientific expert with EMA and a member of the EMA PDCO Formulation Working Group. I am a PDCO nominee to the EMA excipients working group and the EDQM advisory group on a pan-European Paediatric Formulary. I am a member of the European Paediatric Formulations Initiative (EuPFI, www.eupfi.org). I am a member of a research steering group for a project funded by Wellcome Trust and UK Department of Health concerning reformulation of a medicine for children with cancer. Nova Laboratories is an industry partner in the project and administers the grant.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						Through my company 'Tony Nunn Consulting Ltd' I work with University of Liverpool (for coordination of research and advice to academic researchers about paediatric formulations) and Alder Hey Children's NHS Foundation Trust, Liverpool (research in paediatric pharmacy and pharmacology - not product specific).
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
Dr Jane Tizard	GlaxoSmithKline	Shares	None	None	No	None
Dr Beverly Tsai-Goodman	None	None	None	None	No	None
Dr Catherine L C Tuleu	None	None	Novartis, Roche, Sanofi, Abbvie, Boehringer Ingelheim Pharma Gmbh, GlaxoSmithKline, Merck Sharp & Dohme, Janssen, Pfizer, Sanofi, Lilly, Piramal	These company contributes in membership to the European Paediatric Formulation Initiative (EuPFI) which is a consortium working in a pre-competitive way on paediatric drug formulations.	Yes	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
				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. 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	Grants to support a PhD studenships	Yes	
Professor Heather M Wallace	Novabiotics (University spin out company) Antoxis (University spin out company) Precious Cells	Shares less than 0.1% of company shares Shares less than 0.1% of company shares Shares less than 1% of company shares	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**
Mrs Madeleine Wang	Cell ProTx None	Shares and director 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)						
Ms Hellen Adom	None	None	None	None	No	None
Mrs Alison Bowser 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. My wife also works for the same charity, and the above also applies to her.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						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	None	None	Pfizer Inc USA	Corporate sponsor of annual meeting of an organisation where I am on the board (US Society for Adolescent Health and Medicine), And development of an App for the Organisation	Yes	My husband was contracted to provide a system to gsk for collection of data in A community pharmacy project until February 2015.
Mrs Farrah Pradhan	None	None	None	None	No	None
Mrs June Rogers	None	None	Norgine	£500 sponsorship of "Promocon Bowel Care Award" paid to winning entry	No	
			Norgine	Consultancy fee paid directly to charity Disabled Living	No	
			Ferring	unrestricted core funding grant to Disabled Living	Yes	
Dr Bella Starling	None	None	Innovative Medicines Joint Undertaking	European Patient Academy on Therapeutic Innovations EUPATI -	Yes	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			(European Commission and European Federation of Pharmaceutical Industries and Associations)	Grant Beneficiary is University of Manchester. Dr Starling is Workpackage leader/principal investigator for University of Manchester		
Mr Paddy Storrie	None	None	None	None	No	None
Mr Phil Willan	None	None	None	None	No	None
Professor Theo Raynor	None	None	Abbott	Duphalac - Advice on wording and layout of patient leaflet	No	I co-founded a University spin-out company, Luto Research in 2004. The company provides health information development and testing services to pharmaceutical companies, health authorities, charities and other health information providers.
			AbbVie	Norvir, Venetoclax - Advice on wording and layout of IFU; patient leaflet	No	The company was sold in 2009 and I remain academic advisor. I provide research-based input into the work of the company.
			AstraZeneca	Zurampic; Tagrisso; Cediranib; Brilique - Advice on wording and layout of patient leaflets	No	This includes providing advice on specific leaflets before and after testing. Sometimes this is minor input – for example advising on the wording of a particular point of information or section.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Boehringer Ingelheim	Buscopan - Advice on wording and layout of patient leaflet	No	Other times it is more major – if it is a particularly complex leaflet. I have listed under 'non-personal interests' those leaflets where I have provided significant levels of advice on layout and wording
			GE	Xperscan - Advice on wording and layout of patient leaflet	No	I have no shareholding in the company. My main profile remains as an academic at the University of Leeds.
			GSK Biologicals	Twinrix - Advice on wording and layout of patient leaflet	No	At meetings I will declare a 'specific non-personal interest' if a particular leaflet on which I have given advice is on the agenda. I will also declare a 'non-specific non-personal interest' if I have provided advice through my role at Luto to other leaflets of the company concerned.
			Janssen-Cliag	Zytiga - Advice on wording and layout of patient leaflet	No	
			Maxwellia	Aquiette - Advice on wording and layout of patient leaflet	No	
			Merck	MK-3102 - Advice on wording and layout of patient leaflet and carton	No	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Molteni	Oxycodone - Advice on wording and layout of patient leaflet	No	
			MSD	Emend; MK5127A; MK-1293 - Advice on wording and layout of patient leaflet	No	
			Novartis	Riamet;Exjade; Cosentyx; Farydak; - Advice on wording and layout of IFU, patient leaflets, educational materials	No	
			Novo Nordisk	NovoThirteen; Template work - Advice on wording and layout of educational materials for patients and professionals; clinical trial public summaries; clinical trial patient information	No	
			NPS Pharma	Natpar - Advice on wording and layout of patient leaflet	No	
			Puma Biotech	Nerlynx - Advice on drafting patient leaflet from SmPC	No	
			Roche	MabThera, Cymevene; Atezolizumab; Ocrelizumab	No	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
				Advice on wording and layout of patient educational materials; patient leaflet		
			Sanofi Aventis	Tadalafil; Multaq - Advice on wording and layout of patient leaflet; educational materials for professionals	No	
			Santhera	Raxone - Advice on wording and layout of patient leaflet	No	
			Taiho Pharma	Lonsurf - Advice on wording and layout of patient leaflet	No	
			Turnkey	Opsiria - Advice on wording and layout of patient leaflet	No	
			UCB	Neupro; Briviact - Advice on educational materials for patients; wording and layout of patient leaflet	No	
			Vivus	Qysmia - Advice on educational materials for patients	No	
Mrs Anne Joshua	None	None	None	None	No	Husband is Director of a market research company that provides services to the biopharmaceutical global industry
Professor Angus Mackay	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 freelance consultant. Through 2015, I held contracts with the University of Cambridge to research the UK pricing and reimbursement for innovative drugs, with a focus on sofosbuvir for hepatitis C. This research involved interviewing clinicians, patients and senior executives from pharmaceutical companies. The research was funded entirely by the University's Department of Sociology. Through 2015, my husband was an Executive Director of BMJ. He led 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.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						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.
Carolyn, Lady Roberts	None	None	None	None	No	Member of Council, University of Hull

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	Research grant to support clinical training fellowships jointly with MRC	Yes	None
			Astra Zeneca	Research grant to support clinical training fellowships jointly with MRC	Yes	
			Pfizer	Bosutinib - Research grant to look at mechanisms of TKI-induced diarrhoea	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	GlaxoSmithKline	Funding for Non-Communicable Disease Epidemiology Group (salary for IJD and 2 PhD studentships)	No	None
	GlaxoSmithKline	HIV portfolio Paroxetine (2012 only) - Consultancy				
	Gilead	HIV portfolio - Consultancy				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Alison B Ewing	Leo	Sponsored a chief pharmacists regional meeting with no direct product information £30	None	None	No	None
	Merck	Sponsored a chief pharmacists regional meeting with no direct product information £30				
Ms Amanda Lee	None	None	None	None	No	None
Professor Glyn Lewis	GlaxoSmithKline	Paroxetine - I have been appointed as an expert to a court proceeding concerning a claim of adverse events related to paroxetine withdrawal. I have been asked by the claimants' solicitor.	None	None	No	None
Professor Simon R J Maxwell	GlaxoSmithKline	Shares	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	GlaxoSmithKline	BBSRC-CASE funded PhD student	Yes	
			Breast Cancer Now	PhD Student	Yes	
Professor Alan Silman						
Dr Ruben Thanacoody	None	None	None	None	No	None
Dr Caroline Vaughan	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				
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.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						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
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	
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 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
			Ansys	Ansys have supplied several licences as part of an MRC infrastructure grant I am a co-investigator on	Yes	
			Philips Medical Systems	Department has research agreement in place	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
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 Robert Pickard	None	None	None	None	No	None
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	Paediatric cardiology related balloons and stents - Consultancy	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**
	Medtronic Inc	Melody valve - Proctor on an ad hoc basis				
	Abbott Inc	Cardiovascular products - Shares				
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:
	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	
Dr Neil Soni			Vertex	Kalydeco (Ivacaftor) & Lumacaftor - Payment for trial participation	Yes	
Professor Paul Stewart	None	None	None	None	No	None
Professor Roger Sturrock	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 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				
	Nutriticia	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**
	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				
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
Professor Paul N Bishop			Allergan	Fellowship - funding	Yes	
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.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**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 Sir 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	None	None	Merck & Co	ezetimibe, niacin/laropiprant, anacetrapib - I am Deputy Director of the CTSU, which has received funding from Merck for the conduct of randomized trials which are designed and run independently of the company and are sponsored by the University of Oxford.	Yes	
			Pfizer	Sirolimus - I am a co-PI for the 3C trial, which is part-funded by Pfizer. As for all other trials conducted by CTSU, it is designed and run independently of the company and is sponsored by the University of Oxford.		
			Novartis	LCZ696 - I am a co-PI for the UK-HARP-3 trial, which is funded by Novartis.		

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
				As for all other trials conducted by CTSU, it is designed and run independently of the company and is sponsored by the University of Oxford.		
Dr Dennis Briley						
Dr David Collas	Pfizer	Fee for facilitating a discussion seminar during the Masterclass on Anticoagulation event in Rome	Pfizer	NOAC and Anticoagulation - Fees for service and consultancy	No	
	Bayer	Support for travel, accommodation and registration fee to attend International Stroke Conference				
Dr Jeremy Dwight						
Professor Stephen Evans	None	None	None	None	No	LSHTM and the Medical Statistics department receive grant funding from various companies, but I am neither funded by, nor responsible for, any of this funding. It does not fund my research. I am not responsible for anyone funded by any such grants.
Dr Jeff Keep						
Mr Joe Korner						
Professor Peter Langhorne						
Professor Mike Laffan	Bicycle	Consultancy fees				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Clifford Mann Professor Keith Muir	Boehringer-Ingelheim	Alteplase - Travel expenses for speaking about ongoing thrombolysis trials at advisory board meeting; fee paid to University research account	Boehringer-Ingelheim	Tenecteplase - Agreement to provide tenecteplase for a clinical trial funded by the Stroke Association and British Heart Foundation (ATTEST 2) through a grant to the University of Glasgow	Yes	I am chief investigator of a clinical trial (ATTEST-2) funded by the Stroke ssociation and BHF to compare alteplase with tenecteplase as thrombolytic agents in acute stroke. Funding for this was agreed Sept 2015. There was no input from Boehringer Ingelheim (BI) into any aspect of the trial proposal but after funding was obtained, they agreed to provide tenecteplase to participating hospitals for no cost. My involvement of the advisory meeting arranged by BI to consider the outcome of the CHM alteplase report was to describe ongoing research in thrombolysis in stroke due to involvement in a number of academic trials, including ATTEST-2.
Dr Martin Punter	None	None	None	None	No	In 2008 I received a bursary from Boehringer Ingelheim to assist with costs of attending a conference. I have received no further funds from the pharmaceutical industry. .

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						I previously recruited patients to acute stroke trials including IST-3 when I was working as a registrar in St George's Hospital but held no responsibility for the trial there
Professor Liam Smeeth						
Dr David Werring						
Mr Phil Willan	None	None	None	None	No	None
Dr Peter Wilmshurst	None	None	None	None	No	None
Dr H Bart van der Worp						

ANTI-EPILEPTICS 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 Malcolm R Macleod	None	None	None	None	No	At the time that CHM Antiepileptic Drugs ad hoc expert group was convened I was in negotiation with epilepsy action regarding a small academic grant (~£10k) for a systematic review of epilepsy related deaths. On assuming Chairmanship of the EAG and following discussion with the office I withdrew from that grant. On 14th September 2015 I gave a talk to Janssen, at Beerse, Belgium. I received no fee or expenses from Jannsen for this meeting.
Mrs Eileen J Barrett	Select Pharma Labs Ltd	Liothyronine Sodium 20 microgram tablets - Principle employer Source Bioscience Plc, acquired Select Pharma Labs Ltd in July 2015	Amgen Inc. Amgen Europe B.V. Pfizer Ltd Astrazeneca Exova UK Limited Royal Marsden Hospital	The companies listed in the the non-personal interests, will have been a client of Source Bioscience Plc at the time of a given CHM meeting but the product of interest on the CHM	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Guys Hospital Cancer Research UK BioVex Ltd Boehringer Ingelheim Biogen Idec limited Boehringer Ingelheim Biogen Idec limited, King's College Hospital Royal Free Hospital Croyden University Hospital UCB Pharma Limited Teva UK Limited Catalent Pharma Solutions LLC Gilead Sciences International Limited Patheon, Inc Eurofins Lancaster Laboratories, Inc.	agenda will not have been relevant to the services or products Source Bioscience Plc was providing to the companies at the time.		

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Bayer Icepharma hf.			
			Covance Central Laboratory Services Inc.			
			Central Hematology Laboratory Radbound University			
			Almac Pharma Services Ltd			
			Aventis Pharma Limited			
			Patheon UK Limited			
			GlaxoSmithKline UK Limited (GSK)			
			Novartis			
			Novartis Europharm Limited			
			Teva Pharmaceutical Industries Ltd			
			UCB Pharma Ltd			
			Merk-Serono			
			Actavis			
			Merck Serono Ltd			
			Teva			

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Amdipharm Mercury Company Ltd			
			Goldshield and Mercury Pharma Custom Pharmaceuticals Ltd.,			
			Glaxo Smith Kline Trading			
			Glaxo Wellcome S.A.			
			Novartis			
			Amgen			
			AstraZeneca			
			Bristol-Myers Squibb Pharma EEIG			
			Lonza Biologics Inc			
			Cancer Research UK			
			Great Ormond Street Hospital			
			The Scottish National Blood Transfusion Service Lonza			
			Sera Laboratories International Ltd			

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Life Technologies I Invitrogen HyClone Sigma Aldrich Sanofi Aventis Roche			
			University College London King's College Hospital Royal Free Hospital Patheon Manufacturing Services LLC F. Hoffmann-La Roche Ltd Bristol-Myers Squibb (BMS) Catalent Pharma Solutions Sanofi Simbec Research Ltd Wyeth Pfizer Generics (UK) Ltd trading as Mylan Pharmaserve (North West)			

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Limited Napp GlaxoSmithKline (GSK) Valeant Pharmaceutical International Inc. Minerva Scientific Limited ILS Limited Teva UK Limited Dr Reddy's Laboratories (Uk) Limited Sanofi Chimie Merck, Sharp & Dohme Ltd (MSD)			
Professor J Helen Cross	None	None	Vitaflo	Betashot - Salary for research coordinator paid to department	Yes	None
			UCB	Bivetiracetam Advisory Board; honorarium paid to department	No	
			Nutricia	Ketocal - Speaker fee paid to department	No	
			GW Pharma	Cannabidiol - Participation in clinical trials; fee paid to hospital	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Zogenix	Fenfluramine - Participation in clinical trials, advisory board x 2; fees paid to department	Yes	
Dr Christopher Derry						
Dr Fergus Rugg-Gunn						
Mrs Michael J Harnor	Smith and Nephew AstraZeneca Glaxo Smith Kline Worldwide Healthcare Trust	197 ordinary shares 37 ordinary shares 56 ordinary shares 528 ordinary shares ordinary shares (listed investment trust) All the above 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.	None	None	No	None
Dr Gillian M Hawksworth	None	None	None	None	No	None
Dr Richard Hills						
Professor Sir Munir Pirmohamed	None	None	Pfizer	Bosutinib - Research grant to look at mechanisms of TKI-induced diarrhoea	Yes	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Glaxo Smith Kline	Research grant to support clinical training fellowships jointly with MRC		
			Astra Zeneca	Research grant to support clinical training fellowships jointly with MRC		
Mr Sid Dajani						

HORMONAL PREGNANCY TEST 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**
Dr Ailsa Gebbie	None	None	None	None	No	None
Dr Anne Connolly	Bayer	Mirena - Consultancy and Lecture fee	None	None	No	None
	Pfizer	Sayana Press - Lecture fee				
	Mylan	Femoston - Lecture fee				
	MSD	Nexplanon - Lecture fee				
Mr Ian Currie	None	None	None	None	No	None
Mr Nick Dobrik						
Professor Helen Dolk						
Professor Pat Doyle	None	None	None	None	No	None
Mrs Joyce Epstein	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, but I am neither funded by, nor responsible for, any of this funding. It does not fund my research. I am not responsible for anyone funded by any such grants.
Professor Joyce Harper						
Professor Dr Axel Heep						
Professor Stephen Hillier	None	None	None	None	No	None
Mrs Marie Lyon						

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Alison Macfarlane						
Professor Kay Marshall	None	None	None	None	No	None
Ms Sara Payne	None	None	None	None	No	My husband (Richard Meade QC) represents pharmaceutical and medical device companies in patent law, both UK and non UK.
Dr Irene Petersen						
Mrs Farrah Pradhan	None	None	None	None	No	None
Professor Shirley Price	None	None	None	None	No	I am currently a member of the Executive Committee for an Education and Training Programme, SafeSciMet, funded through the EU Innovative Medicines Initiative (IMI). The Innovative Medicines Initiative (IMI) is Europe's largest public-private initiative aiming to speed up the development of better and safer medicines for patients. IMI supports collaborative research projects and builds networks of industrial and academic experts in order to boost pharmaceutical innovation in Europe. IMI is a joint undertaking between the European Union and the pharmaceutical industry association EFPIA

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS	WHETHER CURRENT	ADDITIONAL INFORMATION
						SafeSciMet itself is a new and unique pan-European network, which aims to develop and establish a comprehensive modular education and training programme in safety sciences for medicines. The network brings together eighteen top institutes for drug safety education and research and fifteen pharmaceutical industry leaders. The SafeSciMET courses are open to all scientists from industry, academia and regulatory agencies and encompass the safety, ethical, regulatory and societal aspects of drug discovery and development. On the 24/25th September 2015 the SafeSciMet Executive Committee held its annual Steering Committee meeting where the outcomes of the year were discussed and future objectives for education and training in safety sciences were planned. This year the Steering Committee met at Bayer, Wuppertal.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS	WHETHER CURRENT	ADDITIONAL INFORMATION
						There were 24 participants at the Steering Committee meeting from both academic institutions and industry. In attending this meeting I paid for travel and hotel accommodation through my IMI grant administered through the University of Surrey. However unbeknown to me at the time of the meeting the following were paid for by the host company, Bayer: Dinner on the evening of the 24th September: The full Steering Committee had dinner together on the evening of the 24th September in a pub restaurant in Wuppertal and the bill for the meal for all those present was paid for by Bayer. Taxi Fare: My return taxi fare to Dusseldorf airport which I shared with a colleague from the University of Liverpool on the 25th September 2015 was paid for by Bayer. Neither of us had any idea of this arrangement until we went to pay the fare on our arrival to the airport

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS	WHETHER CURRENT	ADDITIONAL INFORMATION
						and was told by the driver that the fare had been paid for by Bayer. I reported these incidents to the MRHA on the 8th October 2015 by phone as soon as I realised the implications and made amends to have both the taxi bill and my share of the meal paid for from my grant. An invoice for payment of €90 to the VU University account 2887412 (SafeSciMET), the lead University of the IMI Executive, was raised and this invoice was paid by the University of Surrey. VU University then paid the costs back to Bayer. The total time taken for the invoice to be raised (13TH October 2015) and sent for payment to the University of Surrey was 6 days from the date of informing the MHRA of this issue by telephone. I can confirm that all other expenses incurred for this meeting including the hotel bill and airfare were paid by myself and these expenses are covered by the

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						EU Grant funding the IMI initiative and claimed via the University of Surrey who manages my funding.
Professor Siobhan Quenby						
Dr Richard Quinton	None	None	None	None	No	I received £500 honorarium and travel expenses in 2015 from Amgen for speaking on vitamin D physiology, a therapeutic area in which they have no products.
PD Dr Elke Röhrdanz	None	None	None	None	No	None
Professor Dr med Christof Schaefer	None	None	None	None	No	None
Dr Connie Smith						
Dr Diana Wellesley						
Professor Faith Williams						
Dr Laura M Yates						

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	
			Equazen	Hospitality for speakers	Yes	
Mr Barry Capon	None	None	None	None	No	None
Dr Graham D Cook	Pfizer	Salary, Shares	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**
Mr Andrew Coulson	Pfizer (formerly Upjohn) LabCorp (formerly Covance Ltd) Veterinary Medicines Directorate	Pension Pension Non-Executive Director, meeting fees	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 AbbVie	Shares Shares	None	None	No	None
Dr Gerard Lee	None	None	None	None	No	None
Dr Brian R Matthews	Alcon Eye Care UK Ltd Association of Contact Lens Manufacturers CTS Ltd Pharmaceutical Development Services	Consultancy (medical devices) Provision of information (medical devices) Consultancy (Pharmaceuticals) Consultancy (devices and pharmaceuticals)	None	None	No	None
Professor John Miller	None	None	World Health Organisation	Member of the Advisory Panel of the Expert Committee on Specifications for Pharmaceutical Preparations	Yes	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			World Anti-Doping Agency	Chair of Laboratory Expert Group; Member of Health, Medical & Science Committee	Yes	
			European Pharmacopoeia	Member of the Reference Standard Influence Group	Yes	
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	None	None	None	None	No	None
Dr Paul Varley	AstraZeneca (Medimmune)	Salary, Shares	None	None	No	None
Professor Elizabeth Williamson	None	None	None	None	No	None

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