Human Medicines Regulations 2012 Advisory Bodies

Annual Report 2017

Commission on Human Medicines

British Pharmacopoeia Commission

Medicines & Healthcare products Regulatory Agency

HUMAN MEDICINES REGULATIONS 2012
ADVISORY BODIES ANNUAL REPORT 2017

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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 2017 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.

Lord O'Shaughnessy

COMMISSION ON HUMAN MEDICINES ANNUAL REPORT 2017

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 Social Care and the Northern Ireland Minister, who act as 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 Angela Thomas**, vice-chair of the Commission on Human Medicines and Chair of the Clinical Trials, Biological and Vaccines Expert Advisory Group, on receiving an OBE for services to the Regulation of Public Health in the New Year's Honours List 2018.

5. The Commission paid tribute this year to **Professor Derek Calam CBE**, who sadly passed away on 24th September 2017.

6. The Commission wishes to record its gratitude and appreciation of the valuable work of its Expert Advisory Groups and Working Groups listed below that met in 2017. Members' details are listed at **Appendix II**.

Expert Advisory Groups 2017

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)
Chaired by **Professor Jonathan Friedland**

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**

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

Working Groups 2017

Chronic Liver Disease Working Group
Chaired by **Professor Kevin Moore**

Dovonex Ad Hoc Stakeholder Group
Chaired by **Professor Kevin Taylor**

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

Independent Prescribing Ad Hoc Group
Chaired by **Dr J Colin Forfar**

Sodium Valproate Working Group
Chaired by **Professor Sir Munir Pirmohamed**

Tamoxifen Ad Hoc Group
Chaired by **Professor Martin Gore**

7. 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:

   - Dr J Colin Forfar (Cardiovascular Issues SAG)
   - Professor Robert Read (Anti-Infectives SAG)
   - Dr Richard Gilson (HIV/Viral Diseases SAG)
   - Professor Martin Gore (Oncology SAG)
   - Professor Nigel Klein (HIV/Viral Diseases SAG)
   - Dr Anthony Johnson (Neurology SAG)
   - Professor Malcom Macleod (Neurology SAG)
   - Professor David G C Owens (Psychiatry SAG)
   - Professor Elizabeth Miller (Vaccines SAG)
   - Professor Andrew Pollard (Vaccines SAG - **Chair**)

8. 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 year. Members' details are listed at the end of this report at **Appendix III**.

MEETINGS

9. The Commission held 11 meetings during 2017. Two day meetings were held in January, February, March, July, October, November and December. 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

10. 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

11. 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

12. The Commission considered and advised on a total of 91 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	**3**	**36**
Abridged Applications	**1**	**39**

13. The Commission was extensively involved in applications made through the European Centralised Procedure. The Commission considered 35 new active substances, or new combinations of active substances, via the Centralised Procedure.

14. The Commission considered 12 papers under the Early Access to Medicines Scheme.

15. The Commission considered an average of eight marketing authorisation applications at each of its 11 meetings in 2017, in addition to clinical trial applications, appeals, reclassifications, pharmacovigilance issues and other matters.

APPEALS

16. The Commission conducted two oral hearings, which covered two Abridged applications. The Commission advised against the grant of a marketing authorisation for both applications.

17. The Commission considered a total of ten written representations covering ten applications. Of these, the Commission advised that marketing authorisations could be granted, subject to the resolution of the outstanding concerns for six representations. For the remaining four written representations, the Commission advised against the grant of marketing authorisations.

EXTERNAL STAKEHOLDERS

18. The Commission received the following as observers:

Mr Robert Fernley
Programme Manager – Early Access to Medicines Scheme, Specialised Commissioning, NHS England

Professor Mike Kelly PhD, Hon FRCP, FRCPE, FFPH
Senior Visiting Fellow, Primary Care Unit, Institute of Public Health, University of Cambridge and former Director of the Public Health Excellence Centre at the National Institute for Health and Care Excellence (NICE)

Professor Theresa McDonagh BSc (Hons), MB ChB (Hons) MD (Distinction) FRCP FESC FHFA
Consultant Cardiologist, King's College Hospital, London & Professor of Heart Failure King's College, London
Member of the Cardiovascular, Diabetes, Renal, Respiratory and Allergy EAG

Dr Krithika Murali
Clinical Research Fellow – Gynaecology
The Royal Marsden NHS Foundation Trust

Dr Anna Olsson-Brown MBChB (Hons) BSc (Hons) MRCP (UK)
MRC Clinical Research Fellow
Department of Molecular and Clinical Pharmacology

Dr Veli-Pekka Parkkinen
Post-Doctoral Fellow in Philosophy, Centre for Reasoning, University of Kent

Dr Richard Turner MA(Cantab), MB BChir(Cantab), MRCP(UK)
MRC Clinical Research Fellow in Clinical Pharmacology & Therapeutics

CONSIDERATION OF OTHER MATTERS

19. 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 PARAMEDICS AND DIAGNOSTICS RADIOGRAPHERS

20. In October 2015, CHM advised on proposals by NHS England to amend the Human Medicines Regulations 2012 to allow independent prescribing by appropriately trained registered paramedics and radiographers (diagnostic and therapeutic). The Commission was unable to recommend independent prescribing for paramedics and diagnostic radiographers. In the case of paramedics, who could potentially encounter a very wide range of conditions, it was unclear if they would have adequate training to assess these conditions and prescribe appropriate treatment. For diagnostic radiographers, there was insufficient information about the range of conditions and how they would be trained in the assessment and diagnosis of these conditions.

21. In June 2016, the Commission agreed to set up a CHM led ad-hoc group with additional expertise from the relevant Royal Colleges to consider the options for independent prescribing by paramedics and diagnostic radiographers in more detail. The group met twice in December 2016 and July 2017.

22. At their meeting in September 2017, CHM considered and discussed feedback from the ad-hoc group. The Commission endorsed the ad-hoc group's recommendations to support independent prescribing for paramedics. They also endorsed the group's recommendation that independent prescribing for diagnostic radiographers could not be supported at this time.

SAFETY OF MARKETED MEDICINES

Meningococcal group B vaccine (Bexsero) – safety update

23. The Commission considered a routine update on the safety data relating to Bexsero (meningococcal group B (Men B)) vaccine since it was offered to all children aged 2, 4 and 12 months in September 2015. The Commission noted that the vaccine uptake was around 95%, with 2.5 million doses given and at least 1 million children vaccinated. As expected, the vast majority of suspected adverse drug reactions (ADRs) relate to acute febrile reactions and local reactions, as well as other events that are common with other routine infant vaccines. The Commission advised that the only unexpected observation had been that many of the reported local reactions described a persistent subcutaneous nodule at the injection site, which had since been reflected in the product information. The Commission advised that reports of seizures were consistent with the expected background rate and should remain under review. The Commission advised that analysis of vaccination usage had found no adverse impact of the addition of Bexsero to the schedule on the timing or uptake of other routine infant vaccines.

Assessment of the efficacy and safety of Cardioxane (dexrazoxane) use in children

24. The Commission considered an assessment of the efficacy and safety of dexrazoxane in children in the context of an EU wide review. Dexrazoxane is indicated for the prevention of cardiotoxicity caused by anthracycline anti-cancer agents and was contraindicated for use in children and adolescents in 20111 following review of studies which reported an increase in malignancies and other toxicity associated with its use. In the current review, the Commission noted that uncertainties remained about the long-term efficacy and safety in children, however the data presented allowed better characterisation of the risk of the short to medium term safety. The Commission concluded that there was a small group of children treated with high doses of anthracyclines for rare cancers who were at high risk of cardiotoxicity which limited their therapeutic options. The Commission advised that with higher cumulative doses of anthracyclines, dexrazoxane can reduce cardiotoxicity, however the Commission advised that with lower doses of anthracycline, dexrazoxane's cardioprotective effect in children was not demonstrated. The Commission advised that the available data do not support an indication in paediatric patients, however the available evidence supported the partial lifting of the contraindication in paediatric patients receiving high cumulative doses of anthracyclines. The Commission supported the need to closely monitor dexrazoxane's use in children and the proposal to utilise existing paediatric cancer registries to collect data.

Cardiovascular Safety of Celecoxib, naproxen, or Ibuprofen for arthritis; the PRECISION trial

25. The Commission considered the results of the PRECISION trial published in the New England Journal of Medicine (NEJM) in December 20162 . This trial was designed to assess, in particular, the risk of adverse cardiovascular and gastrointestinal events in patients prescribed a low dose of the COX-2 selective non-steroidal anti-inflammatory drug (NSAID) celecoxib for the treatment of pain associated with rheumatoid arthritis or osteoarthritis compared to those prescribed the other (non-selective) NSAIDs, ibuprofen or naproxen. In addition, the Commission considered the results of a recent large population-based observational study from Denmark3 which reported an association between out-of-hospital cardiac arrest and use of non-selective NSAIDs. Overall the Commission advised that both studies had methodological limitations and did not warrant any immediate regulatory action in relation to celecoxib or other NSAIDs.

[1] https://www.gov.uk/drug-safety-update/dexrazoxane-cardioxane-restriction-of-use
[2] Nissen et al 2016
[3] Sondergaard et al 2017

Alteplase (Actilyse) and updated review of concerns

26. The Commission considered further concerns raised following the review of the Expert Working Group (EWG) on alteplase and its use in the treatment of acute ischaemic stroke, published in July 2015, which concluded that the benefit risk balance of alteplase remained positive in its licensed indications. The Commission carefully considered the further concerns raised and heard presentations from visiting experts. Having listened carefully to the arguments put forward and explored each issue in detail in light of the supporting data, the Commission concluded that the concerns raised did not cast doubt on the positive balance of benefits and risks of alteplase in the treatment of acute ischaemic stroke, and there were no grounds to alter the conclusions and recommendations of the EWG for alteplase.

Hormonal Pregnancy Tests (HPT) Working Group Report

27. The Commission considered the report of the Expert Working Group on Hormone Pregnancy Tests and adverse effects relating to its use in pregnancy including possible birth defects. The Commission advised that, taking all aspects into consideration, the available evidence did not support a causal association between the use of hormone pregnancy tests during early pregnancy and birth defects or miscarriage. The Commission endorsed the recommendations of the Expert Working Group to further strengthen the scientific evidence which supports safety monitoring of medicines in pregnancy.

MEDICINES AVAILABLE WITHOUT PRESCRIPTION

28. The Commission considered 5 applications for change of legal status during the year. Four applications were for medicines for Pharmacy (P) availability. The Commission advised that three of the applications might be approvable and these have since been granted:
    - Maloff Protect 250mg/100mg Tablets containing Atovaquone 250mg /Proguanil 100mg for the prevention of malaria in adults weighing more than 40kg, at a maximum dose and daily dose of 250mg/100mg and a maximum pack size of 36 tablets (total number of tablets dispensed dependent on duration of travel with maximum of 93 tablets for 12 weeks' travel).
    - Dovonex Psoriasis 50mcg/g cream and ointment containing 50micrograms/g calcipitriol for the treatment of mild to moderate plaque psoriasis which has been previously diagnosed by a doctor in adults aged 18 years and over, at a maximum application of once per day, a maximum weekly dose of 60g, a maximum duration of use of 12 weeks and a maximum pack size of 60g
    - Viagra Connect 50mg tablets containing sildenafil 50mg for the treatment of erectile dysfunction in men aged 18 years and over, at a maximum dose and daily dose of 50mg and a maximum pack size of 8 tablets

29. The Commission advised against the fourth application for P availability and considered that the fifth application, which was for GSL availability might be approvable subject to further consideration of specific aspects.

Ad Hoc Reclassification Stakeholder Groups

30. Reclassification Stakeholder Groups are established by the CHM to consider certain major applications to reclassify a medicine from prescription only (POM) to P. The role of a stakeholder group is to consider the practical aspects of the supply and use of a proposed reclassified medicine. The views of the group are provided to the Commission when the MHRA seeks its advice on the reclassification application. The feedback from the stakeholder group is taken into account by the Commission when it considers all the evidence provided by the company and the MHRA's assessment of the application. A Reclassification Stakeholder Group meets on one occasion and comprises representatives from: the medical, pharmacy and nursing professional organisations, practising healthcare professionals, patients, and patient representatives.

31. In 2017 an ad hoc stakeholder group met to consider the application to reclassify from POM to P, Dovonex Psoriasis 50mcg/g cream and ointment containing calcipitriol, 50micrograms/g for the treatment of mild to moderate plaque psoriasis which has been previously diagnosed by a doctor in adults aged 18 years and over.

Review of the OTC availability of stimulant laxatives

32. CHM agreed to a proposal to set up an external ad hoc expert group to inform its review of the over the counter (OTC) availability of stimulant laxatives.

THE COMMISSION'S EXPERT ADVISORY GROUPS (EAGs)

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

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

34. In 2017, the CDRRAEAG met once and convened four times via teleconference and provided advice by written correspondence on five occasions.

35. In January, the EAG convened via teleconference and made recommendations on the following applications:
    - A medicine indicated for the treatment of neonatal diabetes, for use in newborns, infants and children.

- A medicine indicated for the reduction in the risk or delay of the onset of type 2 diabetes in adults with prediabetic hyperglycaemia.

36. Also in January, the respiratory experts in the EAG provided written comments on a medicine indicated for the symptomatic treatment and reduction of exacerbations in adult patients with chronic obstructive pulmonary disease (COPD), and those who are at risk of exacerbations despite regular therapy.

37. In March, the EAG provided written comments on a medicine indicated for the treatment of Duchenne muscular dystrophy (DMD), a genetic disorder characterized by progressive muscle degeneration and weakness.

38. In May, the EAG convened via teleconference and discussed a medicine for the treatment of Duchenne muscular dystrophy (DMD), a genetic disorder characterized by progressive muscle degeneration and weakness. This was discussed in the context of the Early Access to Medicines Scheme (EAMS)

39. Also in May, the EAG provided written comments on a review of a medicine indicated for weight loss in overweight adults.

40. In July, the EAG provided written comments on a medicine indicated for the treatment of asthma in patients under the age of twelve months.

41. In September, the EAG convened via teleconference and discussed and made recommendations on:
    - A medicine indicated for the treatment of asthma and Chronic Obstructive Pulmonary Disease (COPD).
    - The use of home nebulisers for the treatment of paediatric asthma following the report of a child fatality.

42. In October, the EAG met and made recommendations on the following applications:
    - A variation application to extend the use of a medicine indicated for the reduction of cholesterol in adults, to children and adolescents 6 years or older.
    - A medicine for the treatment (sclerotherapy) of varicose veins. The EAG considered the submitted evidence based on the extensive use of the medicine over the last 50 years in liquid form and more recently in foamed form.
    - A medicine to be used for diagnosis of bronchial airway hyper-reactivity in patients who do not have clinically apparent asthma.

43. In December, the EAG convened via teleconference and made recommendations on the following applications:
    - A medicine used for the treatment of cystic fibrosis in patients 12 years and older.

- A medicine used for the treatment of patients with familial chylomicronaemia syndrome (FCS), a rare genetic disease that is characterised by very high levels of triglycerides and a high risk of episodes of acute pancreatitis (inflammation of pancreas).

44. Also in December, the EAG provided written comments on a medicine used to prevent transplant rejection.

Chemistry, Pharmacy and Standards Expert Advisory Group (CPSEAG)

45. In 2017, the CPSEAG met 11 times and provided advice by written correspondence on three occasions.

46. In January, the EAG considered and made recommendations on the following:
    - A medicine indicated for the treatment of Spinal Muscular Atrophy (SMA)
    - A medicine indicated for the short-term treatment of impetigo in adults, adolescents, infants and children aged two months and above. Impetigo is a bacterial skin infection forming pustules and yellow crusty sores.

47. The EAG also considered and made recommendations on:
    - A paper on the proposed quality standards, including microbiological requirements and their presentation and labelling for skin antiseptic medicinal products used prior to invasive procedures both for new applications and proposed corrective actions for currently authorised products.
    - An update on the development of the ICH Q11 Question and Answer (Q&A) document which is currently subject to public consultation.

48. Also in January, the EAG also considered two company responses to questions and advised the Commission on the following:
    - An application involving a medicine indicated for a wide variety of disorders amenable to glucocorticoid therapy, as well as an adjunct in the control of cerebral oedema. This is where excess fluid accumulates in the brain.
    - An application involving a medicine indicated for the treatment of coma of myxedema, resulting from longstanding low levels of thyroid hormone; management of severe chronic thyroid deficiency, where the immune system attacks a patient's thyroid gland; and hypothyroid states occurring after treatment of thyrotoxicosis.

49. In February, the EAG considered and made recommendations on the following:
    - A medicine indicated for the treatment of moderate dry eye disease in adults.

- A medicine indicated for the treatment of advanced ovarian cancer in adult patients with deleterious germline BRCA and somatic BRCA mutations, who have been treated with two of more prior lines of chemotherapy.
- A medicine indicated for the treatment of adult patients with advanced breast cancer with brain metastases and / or a history of brain metastases who have completed local treatment for brain metastases, with anthracycline, taxane, and capecitabine therapy unless patients were not suitable for any of these treatments.
- A medicine indicated for the reduction of elevated intraocular pressure in chronic open-angle glaucoma and ocular hypertension in adults (as monotherapy or as adjunctive therapy to beta-blockers).
- A medicine indicated for the treatment of and prophylaxis against acute or recurrent, uncomplicated lower urinary tract infections or pyelitis either spontaneous or following surgical procedures.

50. Also in February, the EAG considered a company's response to questions and advised the Commission on a medicine indicated for topical treatment of mild to moderate scalp psoriasis.

51. Also in February, the EAG provided written comments on a medicine indicated for the treatment of vitamin K deficiency bleeding in neonates and infants.

52. In March, the EAG considered and made recommendations on the following:
    - An application for the treatment of chronic hepatitis C (HCV) infection in adults with specific criteria.
    - A medicine indicated for the symptomatic treatment and reduction of exacerbations in adult patients with chronic obstructive pulmonary disease (COPD)
    - A medicine indicated for the reduction of subcutaneous fat below the chin in adults.
    - A medicine indicated for the prevention and treatment of nausea and vomiting.

53. The EAG also considered and made recommendations on the European Medicines Agency (EMA) concept paper on developing a guideline on Quality requirements of medicinal products containing a device component for delivery or use of the medicinal product.

54. In April, the EAG considered and made recommendations on the following:
    - A medicine indicated in adults 18 years and older with symptoms typical of influenza, when influenza virus is circulating in the community.
    - A medicine indicated for the treatment of hepatitis C virus (HCV) infection in adults.

- A medicine indicated for extended prophylaxis of venous thromboembolism (VTE) in adults with acute medical illness and risk factors for VTE. This is when blood clots form in the deep veins that can travel in the circulatory system and lodge in the lungs.
- A medicine indicated for testosterone replacement therapy.
- A medicine indicated for the treatment of asthma and COPD.
- A medicine indicated for cutaneous peri-ocular and conjunctival antisepsis pre-operatively in ophthalmic surgery.

55. The EAG also considered a company's response to questions and advised the Commission on a medicine indicated for severe extensive psoriasis that is resistant to other forms of therapy. Additionally, the EAG considered and made recommendations on the development of a Question and Answer (Q&A) document on Administration of Medicines via Enteral Feeding Tubes.

56. Also in April, the EAG provided written comments on the validity of the protocol for proposed investigation of in vitro skin permeation of sodium cromoglicate from different formulations.

57. In May, the EAG considered and made recommendations on the following:
    - A medicine indicated for the treatment of urea cycle disorders or non ketotic hyperglycinemia.
    - A medicine indicated in the treatment of fungal infections.
    - A medicine indicated for short-term treatment of severe insomnia (sleeping problems) which is interfering with normal daily life.

58. The EAG also considered a company's response to questions and advised the Commission on a medicine indicated for prevention and treatment of candidal infections of the oral cavity, oesophagus and intestinal tract.

59. In June, the EAG considered and made recommendations on the following:
    - A medicine indicated to treat adult patients with advanced stages of non-small cell lung cancer
    - A medicine indicated for the treatment of schizophrenia, a severe long-term mental health condition that may cause a range of different psychological symptoms, in adult patients
    - A radiopharmaceutical product for diagnostic use only.
    - A medicine for the treatment of Human Immunodeficiency Virus (HIV-1) infection in adults
    - A medicine indicated for the treatment of primary hypercholesterolaemia, a condition in which there are increased levels of cholesterol in the blood
    - A medicine for the treatment of ocular signs and symptoms of seasonal allergic conjunctivitis, an allergic reaction to a substance

such as pollen or dust mites resulting in itching, redness as well as swelling of the surface of the eye
- Two medicines for the treatment of bacterial infections
- A medicine indicated to treat various illnesses involving inflammation and a number of different diseases of the immune system
- A medicine indicated for use in adults as add-on therapy in the treatment of peptic ulcer
- An electrolyte replacement solution to help maintain the right balance of water and salts
- A medicine for the treatment of overactive thyroid gland
- A medicine used in the treatment of type 2 diabetes mellitus

60. The EAG also considered a company's response to questions and advised the Commission on an application for a medicine for the treatment of serious bacterial infections.

61. In July, the EAG considered and made recommendations on the following:
    - A medicine indicated for the first-line treatment of adult patients with ALK-positive, advanced non-small cell lung cancer.
    - A medicine for the treatment of thyroid hormone deficiency
    - A medicine indicated for the treatment of serious bacterial infections.
    - A medicine indicated for use in combination with other medicines for the treatment of malignant pleural mesothelioma, a form of cancer that affects the lining of the lung and for the initial treatment of patients with advanced stage lung cancer.
    - A medicine used in the treatment of type 2 diabetes mellitus.
    - A medicine indicated for the treatment of nausea and vomiting during pregnancy when changes in diet or other non-medicine treatments have not worked.
    - The EAG considered and made recommendations on the application of parametric release in lieu of sterility testing for six sterile products.

62. The EAG also considered a company's response to questions and advised the Commission on an application for a medicine for the treatment of thyroid hormone deficiency.

63. In September, the EAG considered and made recommendations on the following:
    - Three medicines indicated for the treatment of bacterial infections
    - A medicine indicated for the treatment of asthma and Chronic Obstructive Pulmonary Disease (COPD)
    - A medicine to treat men with an enlarged prostate (benign prostatic hyperplasia (BPH)) - a non-cancerous growth of the prostate gland.

64. Also in September, the EAG provided written comments on a medicine indicated for relapsing forms of multiple sclerosis.

65. In October, the EAG met twice and considered and made recommendations on the following:
    - A medicine indicated to treat pneumonia, infection of the lung, and other infections of the urinary tract and stomach.
    - A medicine for measuring lung function and for diagnosing asthma.
    - A medicine for the treatment of adult patients with colon cancer and metastatic colorectal cancer (colon or rectal cancer that has spread to other parts of the body).
    - A medicine for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and children above 6 years of age.
    - A medicine used for the treatment of primary biliary cirrhosis (PBC), a long-term liver disease in which the bile ducts in the liver become damaged; to dissolve gallstones caused by excess cholesterol in the gall bladder and for the treatment of disorders of the liver, bile ducts and gallbladder associated with cystic fibrosis (a genetic condition in which the lungs and digestive system become clogged with thick sticky mucus
    - A medicine for the treatment of varicose veins
    - A medicine indicated to treat the signs and symptoms of dry eye disease in adults.
    - A medicine for the treatment of adult patients with unresectable or metastatic melanoma, a type of skin cancer that cannot be removed by surgery or has spread to other parts of the body
    - A medicine to prevent HIV-1 infection.
    - A medicine used for pain relief after major surgery and during labour.
    - A medicine for the treatment of epilepsy.

66. The EAG also considered and advised the Commission on histamine contamination in gentamicin injections.

67. In December, the EAG considered and made recommendations on the following:
    - A medicine indicated for use in combination with another medicine for the treatment of cystic fibrosis (CF) of patients aged 12 years and older.
    - A medicine indicated for the treatment of breast cancer that has spread to other parts of the body.
    - A medicine indicated for the treatment of adult patients with familial chylomicronemia syndrome (FCS), a rare genetic disease that causes the build-up of lipoprotein responsible for transporting dietary fat and cholesterol.
    - A medicine indicated for the treatment of opioid dependence.

- A medicine used to assist the primary treatment of respiratory tract disorders.
- A medicine indicated to treat and control hypothyroidism, thyroid hormone deficiency
- A medicine indicated to be used in children with medical conditions that cause drooling and to help treat peptic (stomach) ulcers in adults.
- A medicine indicated to treat coronary heart disease, heart failure and coronary artery spasms
- The EAG discussed an application to treat adult patients with familial chylomicronemia syndrome (FCS). The product was discussed in the context of the UK Early Access to Medicines Scheme (EAMS).

68. The EAG also considered two company responses to questions and advised the Commission on the following:
    - A medicine indicated for the prevention and treatment of nausea and vomiting in adults.
    - Two medicines indicated for the treatment of acute or recurrent urinary tract infections.

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

69. In 2017, the CTVBEAG met nine times and convened twice via teleconference and provided advice by written correspondence on four occasions.

70. In January, the EAG convened and made recommendations on:
    - The trial of a medicine for the treatment of various types of tumour that spread to other areas of the body.
    - A medicine for the treatment of a rare inherited storage disorder due to an abnormality of the CLN2 genes.
    - A medicine for the treatment of breast and gastric cancers.

71. In February, the EAG convened and made recommendations on:
    - A trial of two medicines for the treatment of Alzheimer's disease.
    - A trial of a medicine for the treatment of HIV.

72. Also in February, the EAG provided written comments on a trial of a medicine for the treatment of various types of metastatic tumours.

73. In March, the EAG convened and made recommendations on:
    - A medicine for the treatment of acute myeloid leukaemia (AML), a type of cancer in which the bone marrow makes abnormal white blood cells.
    - A medicine for the treatment of X-Linked Hypophosphataemia (XLH), a genetic disease where levels of phosphorus in the blood are lower than needed for healthy bones.

- A medicine to reduce the duration of neutropenia (low white blood cell count), caused by chemotherapy.
- A medicine for the treatment of various types of cancer.
- A medicine for the treatment of eosinophilic asthma, a type of asthma where patients have too many eosinophils in the blood or lungs.

74. In April, the EAG convened and made recommendations on:
    - A trial of medicine for the treatment of B cell acute lymphoblastic leukaemia.
    - A trial of medicine for the treatment of acute optic neuritis, an inflammatory condition that causes visual loss.
    - A trial of medicine for the treatment of Stage IIIb or Stage IV Non-Small Cell Lung Cancer (NSCLC).

75. The EAG also considered and advised on a medicine for the treatment of moderate or severe (corneal ulcer) neurotrophic keratitis in adults. This is a degenerative disease of corneal epithelium. This was discussed in the context of the Early Access to Medicines Scheme (EAMS).

76. In May, the EAG convened and made recommendations on:
    - A medicine indicated to treat the problems caused by not having enough natural leptin, which is a mediator of long-term regulation of energy balance, suppressing food intake and thereby inducing weight loss, in patients with congenital, familial or acquired lipodystrophy (partial or general), a condition characterised by complete or partial loss of fat.
    - A trial of medicine for the treatment of Hepatocellular carcinoma
    - A trial of medicine for the treatment of HIV infection
    - A trial of medicine for the treatment of Diffuse large B cell Lymphoma

77. The EAG also considered and advised on an application to amend the manufacturing process of a specific batch of an Anti-D (Rh) immunoglobulin.

78. Also in May, the EAG provided written comments the following:
    - A medicine indicated for the treatment of B cell acute lymphoblastic leukaemia.
    - A medicine indicated for the treatment of acute optic neuritis.
    - A medicine indicated for the treatment of Stage IIIb or Stage IV Non-Small Cell Lung Cancer (NSCLC).

79. In June, the EAG convened and made recommendations on:
    - A medicine indicated for the treatment of adults experiencing an episode of acquired thrombotic thrombocytopenic purpura, a rare disorder of the blood coagulation system.
    - A medicine indicated to help prevent the formation of blood clots, and to prevent existing blood clots from increasing in size.

- A trial for the medicine for the treatment of Stage IIIb or Stage IV Non-Small Cell Lung Cancer.

80. The EAG also considered and advised on the strain selection for annual influenza vaccine.

81. In July, the EAG convened via teleconference and considered and advised on the strain selection for annual influenza vaccine.

82. In September, the EAG convened via teleconference and considered and advised on a clinical trial application for the treatment of blood cancer.

83. In October, the EAG convened twice and made recommendations on:
    - A medicine for the treatment of patients who have haemophilia A (a bleeding condition).
    - A medicine used to treat patients with vision loss due to Leber congenital amaurosis, an eye disorder that primarily affects the retina, which is the specialized tissue at the back of the eye that detects light and colour.
    - A medicine indicated for the temporary improvement in the appearance of moderate to severe vertical lines between the eyebrows seen at maximum frown (glabellar lines) when these facial lines have an important psychological impact in adult patients.
    - A clinical trial application for the treatment of blood cancer.

84. The EAG also considered and advised on the following papers:
    - Administration of an Investigational Medicinal Product (IMP) to patients who were previously treated with advanced therapy medicinal products (ATMPs) for example CAR-T cells, cell therapy and tumour vaccines. CAR-T cells are genetically modified T cells where the T cell receptor is engineered to identify a specific antigen on the target cells enabling the T cell to mount an immune response. The modified T cell is called Chimeric Antigen Receptor-T cell.
    - A risk assessment for an albumin product for the treatment of patients with blood volume deficiency.

85. In December, the EAG convened and made recommendations on:
    - A medicine indicated for the treatment of some forms of lymphoma, a type of blood cancer, in adult patients.
    - A medicine indicated for the treatment and prophylaxis of bleeding in patients >12 years of age with haemophilia A, a genetic disorder caused by a missing or defective factor VIII, a clotting protein.
    - A clinical trial application for the treatment of Relapsed/Refractory Diffuse Large B Cell Lymphoma, a type of blood cancer.
    - A clinical trial application for the treatment of patients with relapsed or refractory CD19 positive B cell malignancies, different forms of blood cancer.

- A clinical trial application for treatment of Non-Hodgkin Lymphoma, a type of blood cancer with an investigational medicinal product.
- A clinical trial application for the treatment of patients with metastatic melanoma, a type of skin cancer with an investigational medicinal product.

86. The EAG also considered and discussed a risk assessment of plasma donations in a batch of intermediates for an albumin product for the treatment of patients with blood volume deficiency.

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

87. In 2017, the GRIDEAG convened once via teleconference and provided written comments on three occasions.

88. In January, the EAG provided written comments on a CHMP draft concept paper on Chronic Liver Disease.

89. In July, the EAG provided written comments on the following papers:
    - An EMA draft guideline for Crohn's Disease in adult and paediatric patients.
    - An EMA draft guideline for Ulcerative Colitis in adult and paediatric patients.

90. In October, the EAG convened via teleconference and made recommendations on:
    - A medicine indicated for the treatment of moderate to severe active ulcerative colitis (UC) in adults.
    - A medicine indicated for active psoriatic arthritis in adult patients with inadequate response or intolerance to prior DMARD (disease-modifying anti-rheumatic drugs).

Infection Expert Advisory Group (IEAG)

91. In 2017, the IEAG met three times and provided written comments on four occasions.

92. In January, the EAG discussed and made recommendations on an application for pharmacy supply of a product for the prevention of malaria in adults.

93. The EAG also considered and advised on a discussion paper on skin antiseptic medicinal products used prior to invasive procedures.

94. In March, the EAG discussed a medicine for the treatment of chronic hepatitis C (HCV) infection in certain adult patients.

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

- Two medicines indicated for the treatment of hepatitis C virus (HCV) infection in adults.
- A medicine indicated for the treatment of influenza in children from 2 years, adolescents and adults.
- A medicine indicated for prevention of HIV infection in adolescents and adults.

96. In June, the EAG provided written comments on a paper on the use of antibiotics during pregnancy and the risk of spontaneous abortion.

97. In August, the EAG provided written comments on a paper on the use of antibiotics during pregnancy and the risk of major congenital malformations.

98. In October, the EAG provided written comments on a medicine indicated for reducing the risk of HIV infection via vaginal intercourse in sexually active HIV-uninfected women aged 18 or older.

99. In November, the EAG provided written comments on the reclassification from Pharmacy to General Sales of a medicine indicated for mild cases of distal and lateral subungual onychomycoses (fungal nail infections) in up to 2 nails.

Medicines for Women's Health EAG (MWHEAG)

100. The MWHEAG met on two occasions during the year by teleconference and provided comments by written communication on 1 further occasion.

101. The MWHEAG considered the evidence and made recommendations on the following issues with marketed medicines:
    - the latest evidence on bone health and the risk of fracture with use of long acting medroxyprogesterone acetate injections
    - pregnancy outcomes following use of antibiotics during pregnancy

Neurology, Pain & Psychiatry Expert Advisory Group (NPPEAG)

102. In 2017, the NPPEAG met on three occasions and provided advice by written correspondence on ten occasions.

103. In January, the EAG provided written comments on a medicine indicated for the treatment of Spinal Muscular Atrophy (SMA).

104. In February, the EAG convened and provided recommendations on:
    - An application of a medicine for the treatment of relapsing and progressive multiple sclerosis.
    - A medicine used for the treatment of multiple sclerosis.
    - A paper in relation to the risk of medication errors with a medicine used for the treatment of epilepsy.

105. In March, the EAG provided written comments on:
    - A paper regarding the safety of a drug indicated for the treatment of epilepsy and bipolar disorder during pregnancy.
    - A medicine indicated for the treatment of multiple sclerosis.

106. In April, the EAG provided written comments on a medicine used for the treatment of multiple sclerosis.

107. In May, the EAG convened and provided recommendations on:
    - A medicine for the short-term treatment of severe insomnia.
    - A paper in relation to the risk of medication errors with a medicine used for the treatment of epilepsy.
    - A paper discussing a drug safety communication recently issued by the FDA relating to the use of general anaesthetics and sedatives in young children.

108. In June, the EAG provided written comments on the safety review of a medicine indicated for the treatment of relapsing forms of multiple sclerosis.

109. In July, the EAG provided written comments on:
    - A medicine indicated for the treatment of schizophrenia in adult patients.
    - A medicine indicated for the treatment of a medicine used to treat multiple sclerosis.

110. In August, the EAG provided written comments on:
    - A paper on the memory impairment side effects of medicines used to treat overactive bladder syndrome, allergies, psychosis, depression, irritable bowel syndrome and cardiac arrhythmias.
    - A medicine indicated for progressive multifocal leukoencephalopathy (PML), a rare demyelinating disease of the brain.

111. In November, the EAG convened and provided recommendations on:
    - A medicine for the treatment of peptic ulcer in adults, and for the management of chronic severe drooling associated with neurological conditions such as cerebral palsy in children.
    - A paper on the risk management of a medicine, indicated for the treatment of some types of haematological cancer, for a type of vasculitis (inflammation of the blood vessels) and for rheumatoid arthritis, a condition that causes pain, swelling and stiffness in the joins.

112. In December, the EAG provided written comments on a medicine indicated for the treatment of opioid addiction.

Oncology and Haematology Expert Advisory Group (OHEAG)

113. In 2017, the OHEAG convened seven times by teleconference and provided advice by written correspondence on twelve occasions.

114. In February, the EAG convened via teleconference and made recommendations on a product for the treatment of a type of ovarian cancer caused by changes in the BRCA gene. It is used after the cancer has responded to previous chemotherapy treatments.

115. In March, the EAG convened via teleconference and made recommendations on:
    - A product for the treatment of adult patients with de novo (a type of newly diagnosed) acute myeloid leukaemia (AML)
    - A variation application to add an indication to a currently licensed product for the primary reduction of breast cancer risk in women either at moderately increased or high risk.

116. Also in March, the EAG provided written comments on the following:
    - A variation application to include indication for first line treatment of anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC).
    - A medicine indicated for the treatment of breast cancer.

117. In April, the EAG provided written comments on a paper concerning a medicine indicated for the treatment of several types of blood cancer and its potential to cause Hepatitis B reactivation.

118. In May, the EAG provided written comments on the following:
    - A medicine indicated for the treatment of ALK-positive NSCLC.
    - A medicine indicated for the treatment of adults experiencing an episode of acquired thrombotic thrombocytopenic purpura (aTTP), a condition where blood clots form in small blood vessels which block blood flow to the body's organs.
    - A variation application to include the treatment of advanced melanoma in children and adolescents 12 years of age and older.
    - A medicine indicated for hepatocellular carcinoma, the most common type of primary liver cancer, often occurring in patients with chronic liver disease.
    - A medicine indicated for the treatment of NSCLC after failure of at least one round of chemotherapy.

119. In July, the EAG convened via teleconference and made recommendations on a medicine indicated for the treatment of breast cancer in people whose cancer has spread to the brain.

120. Also in July, the EAG provided written comments on a medicine proposed as monotherapy for the first-line treatment of adult patients with ALK-positive, advanced NSCLC.

121. In August, the EAG provided written comments on a variation application indicated as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer.

122. In September, the EAG convened via teleconference and made recommendations on:
    - A product indicated to treat patients with an enlarged spleen or with symptoms related to a disorder of the bone marrow, a form of blood cancer.
    - A product for use in patients that affects the thyroid gland, a small gland at the base of the neck that produces hormones and is also indicated for the use of liver cancer.

123. Also in September, the EAG provided written comments on a medicine indicated for patients with relapsed refractory myeloma, a type of blood cancer, after at least three prior treatment regimens.

124. In October, the EAG convened via teleconference and made recommendations on:
    - Three products to treat adult patients with a type of skin cancer called melanoma when it has spread to other parts of the body.
    - A medicine used to treat advanced stomach (gastric) cancer and cancer of the food pipe/ stomach junction in adults

125. In November, the EAG convened twice via teleconference and made recommendations on:
    - A product to treat adult patients with previously untreated, primary de novo CD33-positive acute myeloid leukaemia, a form of blood cancer, which affects the white blood cells.
    - A product to treat adult patients with breast cancer that has spread to other organs in the body.
    - A medicine indicated for the treatment of some forms of lymphoma, a type of cancer, in adult patients.

126. Also, in November, the EAG provided written comments on a medicine indicated for the treatment of adults with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastases.

Paediatric Medicines Expert Advisory Group (PMEAG)

127. The Paediatric Medicines Expert Advisory Group (PMEAG) advises the Commission on Human Medicines on the safety, quality and efficacy of medicines for paediatric use, including all matters relating to the implementation of the EU Paediatric Regulation. The PMEAG met 6 times in 2017 and provided advice through written correspondence for 22 papers.

Paediatric Investigation Plans

128. PMEAG advises on Paediatric Investigation Plans (PIPs) where UK is Rapporteur or Peer Reviewer. The PMEAG discussed 2 PIPs where the UK is Rapporteur and 10 where UK has acted as Peer Reviewer. In addition, EAG members commented through written procedures for 5 PIPs for which UK was Rapporteur. The advice given covered a range of therapeutic areas, including: oncology, neurology, bone diseases, psychiatry, infectious diseases and rare paediatric conditions.

129. The PMEAG reviewed the regulatory outcomes for psychotropic medications over the past 10 years (2007-2017).

Work-sharing Procedures

130. The PMEAG considered products being assessed under work-sharing procedures, (coordinated at European level by Member States) for which the UK was Rapporteur. These included 4 products with studies completed before the Regulation came into force (Article 45 procedure) and 1 product with studies completed afterwards (Article 46 procedure). The therapeutic areas for these procedures included drugs used for infectious diseases, and in neurology.

Marketing Authorisation Applications Supported by Paediatric Data

131. The PMEAG advised on 3 applications for new products. The products covered a range of indications including the treatment of metabolic diseases and paediatric asthma.

Safety of Medicines in Children

132. In 2017 the PMEAG reviewed monthly statistics on adverse drug reactions in paediatric patients reported to MHRA, and an overview of all identified paediatric signals. The Group advised on the updated data with regards to an ongoing review of the safety of topical products for infant teething. The PMEAG also advised on a safety review of a product used for the prevention of vitamin deficiencies in children and considered the impact of genetic variation on the use of opioids in paediatric patients. The PMEAG considered and advised on the availability of home devices for the treatment of asthma.

Other Advice Related to the Use of Medicines in the Paediatric Population

Regulatory guidance:

133. The PMEAG discussed and advised on a number of draft or revised guidance documents being developed at European or international level. The topics included the development of products indicated for the prophylaxis or treatment of respiratory syncytial virus (RSV) disease and the use of colourings in paediatric medicines. The PMEAG considered

the need for a paediatric addendum of the guideline on clinical investigation of medicinal products for the treatment of venous thromboembolic disease. The PMEAG heard an update on the European Commission consultation on the impact of the EU Paediatric Regulation.

Discontinuations of paediatric medicinal products:

134. In 2017, the PMEAG gave advice on the clinical implications of the proposed discontinuation of 3 medicinal products for children. This included an antibiotic used in children (including neonates).

Pharmacovigilance Expert Advisory Group (PEAG)

135. The Commission's Pharmacovigilance Expert Advisory Group (PEAG) membership includes expertise in pharmacovigilance, clinical pharmacology, toxicology, epidemiology, general practice, nursing, and pharmacy and includes lay representation. The PEAG met on 8 occasions during 2017 and provided advice by written procedure on a further five occasions. The PEAG considered papers on the following drug safety issues:

- Sodium valproate and the risk of neurodevelopmental disorders in children exposed to sodium valproate during pregnancy
- Daclizumab and risk of drug induced liver injury
- Use of antibiotics by women during pregnancy and risk of miscarriage
- Use of antibiotics by women during pregnancy and risk of major congenital malformation
- Fingolimod and risk of rebound multiple sclerosis
- Eluxadoline and risk of pancreatitis
- Anticholinergic drugs, cognitive dysfunction and cerebral atrophy in normal older adults
- Long-lasting, disabling and potentially irreversible adverse effects of quinolone and fluoroquinolone antibiotics for systemic and inhalational use
- Interferon beta and risk of thrombotic microangiopathy and new data on a dose-dependent toxic effect
- Mefloquine and psychiatric adverse effects
- Clinical implications of CYP2D6 polymorphisms in users of ethylmorphine, tramadol or oxycodone
- Finasteride and a signal of depression and suicide
- Cladribine and risk of progressive multifocal leukoencephalopathy
- Anaesthetics and sedatives and possible adverse effects in pregnant women and young children
- Intravenous and intramuscular methylprednisolone products containing lactose of bovine origin and risk of allergic reactions in patients allergic to cows' milk
- Intravenous fluids and the risk of hospital acquired hyponatraemia
- Medication errors with injectable phenytoin

- Rituximab and risk of progressive multifocal leukoencephalopathy

136. Where major regulatory action or restrictions on use were proposed, advice was also sought from the Commission on Human Medicines. The PEAG's advice on the majority of these issues was subsequently taken forward for further discussion within the European medicines regulatory system. The outcome of these European discussions can be found on the website of the European Medicines Agency.

137. The PEAG considered safety update reports on vaccines used in the current UK routine vaccination schedule – the Meningococcal groups A, C, W and Y vaccines and Meningococcal group B vaccine.

138. The PEAG gave advice on 10 Risk Management Plans (RMPs) including on the RMP for the first sildenafil product for erectile dysfunction to be authorised for use without a prescription in the UK and an RMP for a new product being considered under the UK Early Access to Medicines Scheme (EAMS). The PEAG also noted the results of a Clinical Practice Research Database (CPRD) study which examined prescribing trends of the antibiotic nitrofurantoin in UK primary care after the contraindication against use in individuals with kidney impairment was relaxed in 2014. In addition to the monthly Yellow Card reporting statistics, the PEAG also reviewed three applications for Type II Yellow Card Data.

139. 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).

Patient & Public Engagement Expert Advisory Group

140. The PPEEAG did not meet during the reporting period. The Commission and the secretariat have been considering a revision to the remit of the PPEEAG taking into account the current regulatory landscape and the need to consider an appointments exercise to the PPEEAG.

Chronic Liver Disease Expert Working Group

141. The remit of the group was to advise on the development of clear guidelines so that going forwards the MHRA can advise the pharmaceutical industry on the conduct of clinical trials in three disease conditions: Non-alcoholic steatohepatitis (NASH), Primary Biliary Cholangitis (PBC), Primary Sclerosing Cholangitis (PSC).

142. In 2017, the Chronic Liver Disease Working Group met twice.

143. In July, the group discussed the extent of the need for drug treatment regarding the three disease conditions including the definition of suitable

target patient population for study. The group also discussed the nature of the investigations which would be required to evaluate the effectiveness of treatments and the minimum duration of study period before efficacy can be established in each disease condition.

144. In December, the group discussed a variety of topics which included the following issues: the importance of describing the natural history of the particular disease condition which may need stratification in order to categorise the patient population where the need is greatest. The group also discussed the requirement to define the severity of the disease and existence of sub-types, co-morbidities and phenotypes including the need to identify non-responders during the course of the studies and that such particular patients should be followed up.

145. Also in December, the group discussed another issue surrounding situations where a consideration can be given to grant marketing authorisation for a drug which treats a particular symptom e.g. pruritus. In case of the indication for disease modification, the group discussed the minimum duration of study before efficacy can be established and when to make a decision for possible conditional approval. The group also deliberated on the importance of identifying adverse events given the potentially long-term use of drug therapy in these conditions.

Expert Working Group on Hormone Pregnancy Tests and Adverse Effects in Pregnancy

146. The CHM's Expert Working Group (EWG) on Hormone Pregnancy Tests (HPTs) and adverse effects in pregnancy, convened in 2015, met twice in 2017 to complete its evaluation of the remaining evidence. The Group had previously considered the social, medical and legal context from the time HPTs had been available in the UK (1950s-1970s); the pharmacology, pharmacokinetic and non-clinical data on the components of Primodos; vascular disruption as a potential mechanism for an adverse effect during pregnancy; and an initial assessment of the available epidemiological evidence.

147. In 2017 the Group considered a further analysis of the adverse effect data, a re-analysis of the epidemiological evidence using a specifically-developed quality scoring system, additional pharmacological considerations for a possible effect of HPTs on the developing fetus, and historical information submitted for the purpose of the review by individuals. The Group also considered how the approach to identifying, evaluating and communicating safety concerns with medicines in pregnancy had changed since HPTs were available. A visiting expert from Cambridge University presented historical considerations in relation to HPTs and members of the Group gave an overview on valproate and the risk in pregnancy, a proposal for a pregnancy pharmacovigilance system, and a perspective on the material from the Berlin archive.

148. Following discussion of the draft report of the Group at its meeting in October 2017, CHM endorsed the final report at the meeting in November 2017. The final report was published on 15 November 2017.

Independent Prescribing Ad Hoc Group

149. The Independent Prescribing Ad Hoc Group met for a second time in July 2017, following an initial meeting in December 2016. The group discussed proposals for independent prescribing by paramedics, and their conclusions were recommended to the Commission.

Sodium Valproate Expert Working Group

150. The Commission convened a new ad hoc expert working group (the sodium valproate expert working group: SV-EWG) to inform the UK position in a new European safety review initiated by France in March 2017, to review the effectiveness of risk minimisation measures implemented following completion of the previous European safety review in 2015 and to consider what further regulatory action might be required. The Terms of Reference for the SV-EWG agreed were:
    - To review the current risk minimisation measures in place and possible reasons for lack of effectiveness,
    - To consider further regulatory measures required to minimise the risk of valproate use in pregnancy including (but not limited to):
        - a contraindication for use in pregnancy or in girls and women without effective contraception
        - a formal pregnancy prevention program
    - To consider other measures required across the healthcare system to ensure compliance with the regulatory position in clinical practice (e.g. shared care agreements, registries) and
    - to advise the Commission.

151. The Commission noted the results of studies to monitor the effectiveness of the risk minimisation measures following previous regulatory action, which showed little change in prescribing in women of childbearing potential, or awareness of the latest evidence of harms in pregnancy by healthcare professionals and patients surveyed despite the wide communication of key messages in the Valproate Toolkit.

152. The Commission considered the advice from the two meetings of the SV-EWG held in August and October 2017 and the ongoing communications and stakeholder engagement. The Commission noted that pregnancy exposures to valproate continue despite repeated distribution of risk minimisation materials and communications.

153. The Commission welcomed the ongoing work that the MHRA was undertaking with the professional bodies, voluntary organisations, NHS Improvement, Department of Health, NICE and the BNF on this issue and advised on the need to continue to raise levels of awareness of the

risks. The Commission advised the need for continued close monitoring of progress following any additional regulatory action.

Tamoxifen Ad Hoc Expert Group

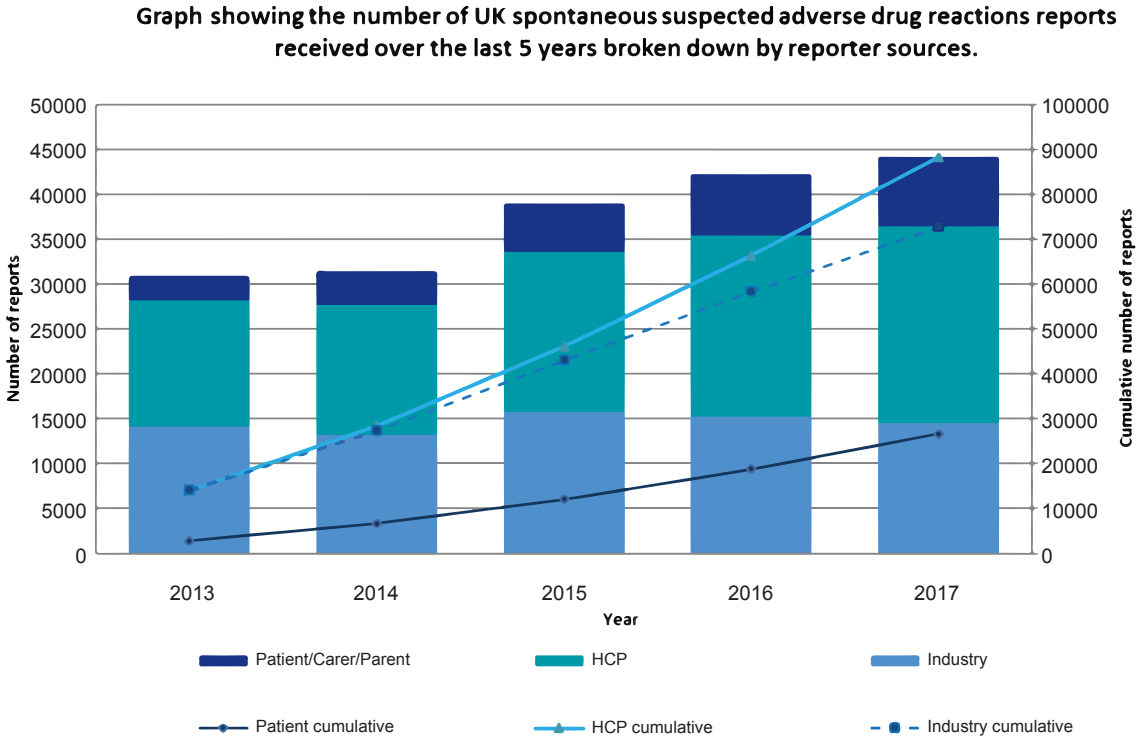
154. The Tamoxifen Ad Hoc Expert Group met in September 2017 and the Tamoxifen Patient Ad Hoc Group met in December, to discuss proposals for a chemopreventative indication for women at moderate to high risk of developing breast cancer.

REPORTING OF SUSPECTED ADVERSE DRUG REACTIONS 2017

155. Suspected adverse drug reactions (ADRs) to medicinal products and vaccines are reported to the CHM and MHRA on a voluntary basis by healthcare professionals and members of the public 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.

156. The total number of UK spontaneous suspected ADR reports received from all sources over the last five years is shown in Figure 1 below. The highest number of suspected ADRs was received since the Scheme was established over fifty years ago with over 44,000 suspected ADR reports received by the MHRA in 2017. The total number of UK spontaneous suspected ADR reports increased by 5% (2,009 reports) in 2017 when compared to the previous year.

Figure 1 – Graph showing the number of UK spontaneous suspected adverse drug reactions reports received over the last 5 years broken down by reporter sources.



Number of reports	30915	31441	38951	42130	44168

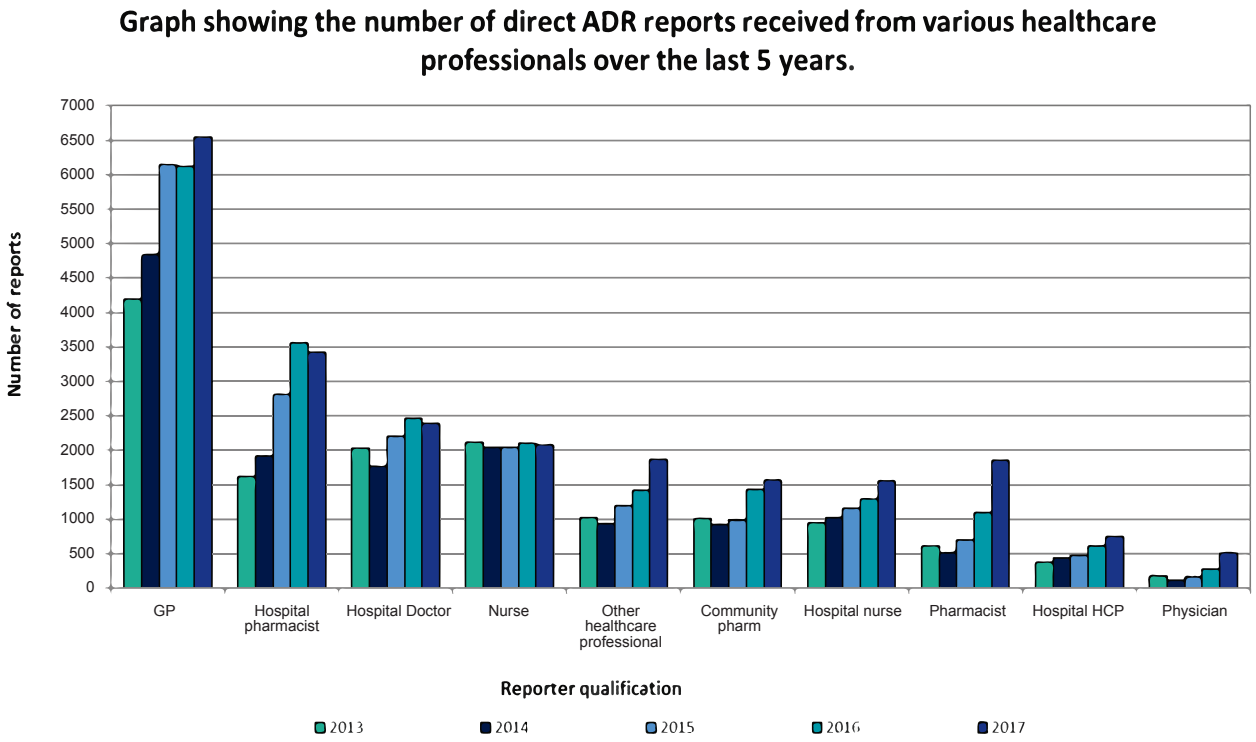
157. Over the last five years, reporting increased by 43% (13,253 reports). This increase corresponds to the increase in direct reports, 77%(12,873 reports), received from healthcare professionals and members of the public (including patients, parents and carers) as a result of many planned strategic efforts to improve the quantity and quality of reports.

158. In 2017 specifically, 49.6% (21,911) of all suspected ADR reports were received directly from healthcare professionals, 17.6% (7,783) from members of the public and 32.8% (14,501) from the pharmaceutical industry.

Healthcare Professional ADR Reporting

159. A breakdown of direct healthcare professional reports by reporter qualification between 2013 and 2017 is shown in Figure 2.

Figure 2 – Graph showing the number of direct ADR reports received from various healthcare professionals over the last 5 years.



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

160. As in previous years, GPs reported the highest number of suspected ADR reports (6,539) to the Yellow Card Scheme in 2017, accounting for 30% of all direct healthcare professional reports, with an increase of 7% (416 reports) compared to the previous year.

161. In line with previous campaigns and strategic work, the MHRA has worked collaboratively with a number of healthcare professional organisations such as medical Royal Colleges, to promote Yellow Card reporting to their membership, for example through promotional articles within their organisations' newsletters, as well as working with various pharmacy groups such as the Community Pharmacy Patient Safety Group, that launched its website in June 2017 to highlight the importance of reporting suspected ADRs, and the Centre for Pharmacy Postgraduate Education's new Foundation pharmacist training pathway to include information on ADRs and medicines safety. This supports the MHRA's ongoing work to encourage Yellow Card reporting in all trainee healthcare professionals, including medical students, pharmacy students and nursing students.

162. Adding to the existing Continuing Professional Development (CPD) accredited e-learning modules for pharmacists and nurses, the MHRA developed a new free e-learning module on ADR reporting for healthcare

professionals. The European Accreditation Council for Continuing Medical Education (EACCME), an institution of European Union of Medical Specialists (UEMS), gave the module the highest order of accreditation through awarding doctors 1 EACCME credit (1 hour CPD) on completion of the 45 minute ADR e-learning module. The e-learning module was developed as part of the European Commission Joint Action project, Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE). This was supported by a Drug Safety Update article and MHRA press release that was picked up by various health professional media such as the Pharmaceutical Journal. Feedback on the ADR e-learning module has been highly positive, with an optional survey showing over 6 months that 93% of learners who took the survey found the module helped them gain a clearer understanding about the importance of reporting suspected ADRs. Of those in training who took the survey 95% said they they would change their clinical practice as a result of the module and 94% would recommend the module to colleagues.

Patient ADR Reporting

163. 2017 saw the highest ever number of Yellow Card reports from members of the public (includes patients, parents and carers) since the launch of the Yellow Card Scheme, with 7,783 reports received, making up 26% of all direct reports in 2017. Overall there has been a 15% (1040 reports) increase in patient, parent and carer reports compared to 2016. Over recent years, the MHRA and its 5 Yellow Card Centres have made significant efforts to proactively encourage the reporting of suspected ADRs by this important reporter group via engagement to reach patients through their associations and organisations. The MHRA also worked with the Patient Information Forum to produce a blog for organisations providing health information for patients, to support them with material about the reporting of suspected side effects to the Yellow Card Scheme.

164. In 2017, as part of its ongoing commitment to strengthen paediatric pharmacovigilance, MHRA also made links with the Personal, Social, Health and Economic (PSHE) Association. This PSHE education gives pupils the knowledge, skills, and attributes they need to keep themselves healthy and safe and to prepare them for life and work. The curriculum that is designed to build knowledge for life now introduces side effects to children in primary school. This knowledge is built upon for secondary school children through the importance of discussing side effects to medicines with a GP or pharmacist and is complemented with a link to the Yellow Card Scheme for teachers to use in classrooms.

165. In November 2016 the MHRA led an award-winning social media campaign through the SCOPE project. Building on this success, in November 2017 the MHRA, together with the Uppsala Monitoring Centre, a collaborating centre of the World Health Organisation, led its second social media ADR awareness week campaign to raise general awareness of the Yellow Card Scheme with the public. The campaign

reached nearly 2.3 million people involving 19 medicines regulators from within the EU and a further 8 medicines regulators from outside the EU via the International Coalition of Medicines Regulatory Authorities (ICMRA) Pharmacovigilance project on Increasing Adverse Event Reporting (IAER), which is led by the MHRA. A month after the campaign launch saw a 16% increase in suspected ADR reports received directly from healthcare professionals and members of the public compared to the same time period the year before.

166. The campaign was supported by the release of an animation and other supporting infographics to promote reporting of suspected ADRs. The main message was that the reporting of suspected side effects helps the safe use of medicines to protect public health. The 2017 campaign focussed on over-the-counter medicines; the messages were applicable to those on general sale as well as Pharmacy medicines. This was supported by contacting over 250 UK stakeholders and networks, including via a Drug Safety Update article to raise awareness with healthcare professionals.

Electronic ADR Reporting

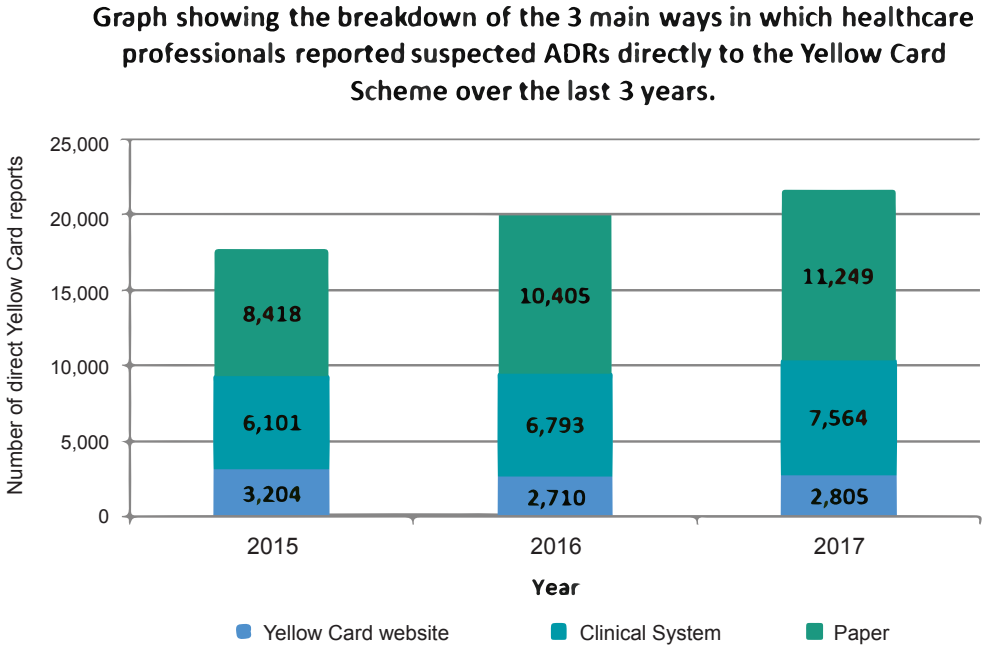
167. Throughout 2017, the MHRA continued its strong focus on making Yellow Card reporting easier and more accessible, especially through integration into clinical systems. To date, the MHRA have successfully integrated Yellow Card with the primary care GP systems SystmOne (2010) and Vision (2016), as well as the secondary care medicines information system for pharmacy MiDatabank (2011). Reports from clinical systems formed 35% (7,564 reports) of all direct reports from healthcare professionals. Further work continues with other clinical system providers such as EMIS and Ulysses to integrate Yellow Card reporting functionality and further extend this proven method of increasing reporting.

168. As part of a review to improve existing functionality, the MHRA worked with NHS Digital to develop the Data Coordination Board standard, DCB 1582 Electronic Yellow Card Reporting Standard which replaces the old ISB 1582 Electronic Yellow Card Reporting information standard. This standard can be used by IT providers to better integrate Yellow Card reporting into their systems.

169. Furthermore, in a bid to continue to support the integration of the Yellow Card into GP systems and improve reporting quality a meeting between the MHRA and SystmOne trainers was held in Newcastle. Further discussions and opportunities for engagement from this meeting will be pursued throughout 2018. MHRA would look to continue this collaboration with other clinical system suppliers.

170. Electronic reporting via both the Yellow Card website and clinical systems continues to increase in use amongst healthcare professionals as seen in Figure 3 below.

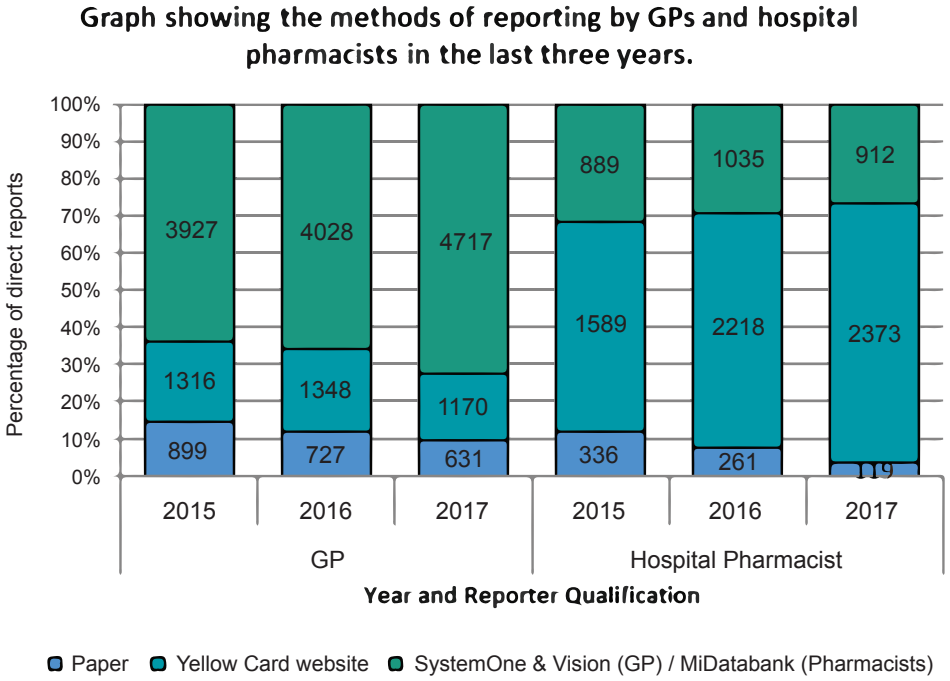
Figure 3 - Graph showing the breakdown of the 3 main ways in which healthcare professionals reported suspected ADRs directly to the Yellow Card Scheme over the last 3 years.



171. In 2017, 86% (18,926 reports) of all direct healthcare professional reports were received electronically, with 51% (11, 249 reports) through the Yellow Card website and 35% (7,564) via clinical systems. Paper reports formed the majority of the remaining 14% (2,805 reports) of direct healthcare professional reports (Figure 3).

172. Figure 4 shows the impact of electronic reporting on the number of suspected ADR reports received from GPs and hospital pharmacists over the last 3 years. There is a steady decreasing trend in the numbers of paper reports received from GPs and pharmacists compared to an increase in use of electronic methods to report a Yellow Card.

Figure 4 - Graph showing the methods of reporting by GPs and hospital pharmacists in the last three years.



173. In 2017 90% of all GP reports were received electronically, with GP reports via clinical systems accounting for 72% (4,717 reports) of all reports from GPs. Of this, SystmOne accounted for 63% (4,102 reports) of suspected ADR reports from GPs, an increase of 3% (106 reports) from 2016. Reports from Vision accounted for 9% (615 reports) of all GP reports in 2017, following its launch in 2016. Similarly, 97% (3,309 reports) of hospital pharmacist reports were received electronically, with 69% (2,373 reports) received via the Yellow Card website and 27% (913 reports) received via integrated clinical systems.

174. Electronic reporting is also the most popular method of reporting for members of the public. In 2017, 89% (6,960 reports) of all ADR reports from patients, parents and carers were reported electronically, with a 14% (822 reports) increase in reports via the Yellow Card website compared to 2016 and a 129% (81 reports) increase in reports via the Yellow Card app compared to 2016.

175. A new service provider was appointed for maintenance of the WEB-RADR mobile app. The developer has worked closely with MHRA to re-platform and unify the mobile app in both Android and Apple codes, enabling updates to be made more easily, as well as improving sustainability of the platform. WEB-RADR has been awarded a positive evaluation and full funding from the Innovative Medicines Initiative within the call for proposals for further exploitation of project outputs. This may provide the opportunity for extending its use to capturing adverse incidents for devices and defective medicine reports.

E-Cigarette Reporting

176. Since May 2016, the MHRA is the UK competent authority for the regulation of nicotine-containing e-cigarettes and refills under the terms of the Tobacco Products Directive. All nicotine containing products have had to be notified to the MHRA. During 2017 there have been 24 adverse reaction reports, 3 reports of product safety concerns and 6 reports of product quality concerns. We have also received notification of 3 product recalls from industry, all due to identified potential safety concerns. This rate of Yellow Card reporting is similar to the period in 2016 after the launch of the e-cigarette adverse reaction reporting form. We have been liaising with Trading Standards authorities to share the reports regarding product device-related safety and quality concerns. It is anticipated that there will be an increase in the number of reports in 2018 as further public communications about reporting via Yellow Cards for e-cigarettes is planned alongside a wider sustained communications campaign based on user research.

Report Illicit Drug Reactions (RIDR)

177. A pilot of a new national system for healthcare professionals to report the effects of New Psychoactive Substances (NPS) and other illicit drugs was set up jointly by Public Health England (PHE) and the MHRA in 2017. The NPS are substances designed to replicate the effects of 'traditional' illegal drugs and pose potentially serious risks to public health. There have been rapidly increasing numbers of new substances identified in recent years, with hospital admissions for poisoning by 'Psychostimulants with abuse potential' increasing by 44% in England and Wales from the period 2009-10 to 2014-15. At present, evidence is lacking about long-term harms to health associated with the use of NPS. The one-year pilot reporting website, titled Report Illicit Drug Reactions (RIDR), uses the architecture of the Yellow Card Scheme and was set up in response to the need to understand more about the effects of NPS, many of which are not well known, and associated reactions or problems do not have established methods for treatment. The overall aim of the project is to reduce the length of time between drug-related health harms emerging and developing effective treatment responses.

178. On 22nd March 2017 the RIDR web form was launched and over the first 9 months of the pilot 257 reports were received in total. Reports were received from across the UK, and in particular, a high number of reports were received from the East Midlands and the North-West regions. Healthcare professionals working in prisons were the most frequent reporters to RIDR, followed by those working in hospitals, drug treatment clinics, medical centres and hostels. Fifty-four different suspect substances have been reported in 2017 and these include New Psychoactive Substances (NPS) as well as well as 'traditional' drugs such as cocaine and heroin, and licensed medicines.

179. Reports received through RIDR are assessed in a similar manner to those received via the Yellow Card Scheme, with the MHRA's signalling processes being used to identify new harms. Any harms identified are discussed with experts from the Public Health England NPS Clinical Network group to determine appropriate actions. Information about identified harms is then published on the RIDR 'Dashboard', which is available on the RIDR website. The data received to date suggests that NPS can cause a wide range of harms, with nervous system disorders and psychiatric disorders being frequent presentations. New potential harms such as the development of eye disorders associated with synthetic cannabinoids and rhabdomyolysis associated with the NPS 'Red Ferrari' have been identified and discussed with the NPS clinical network group.

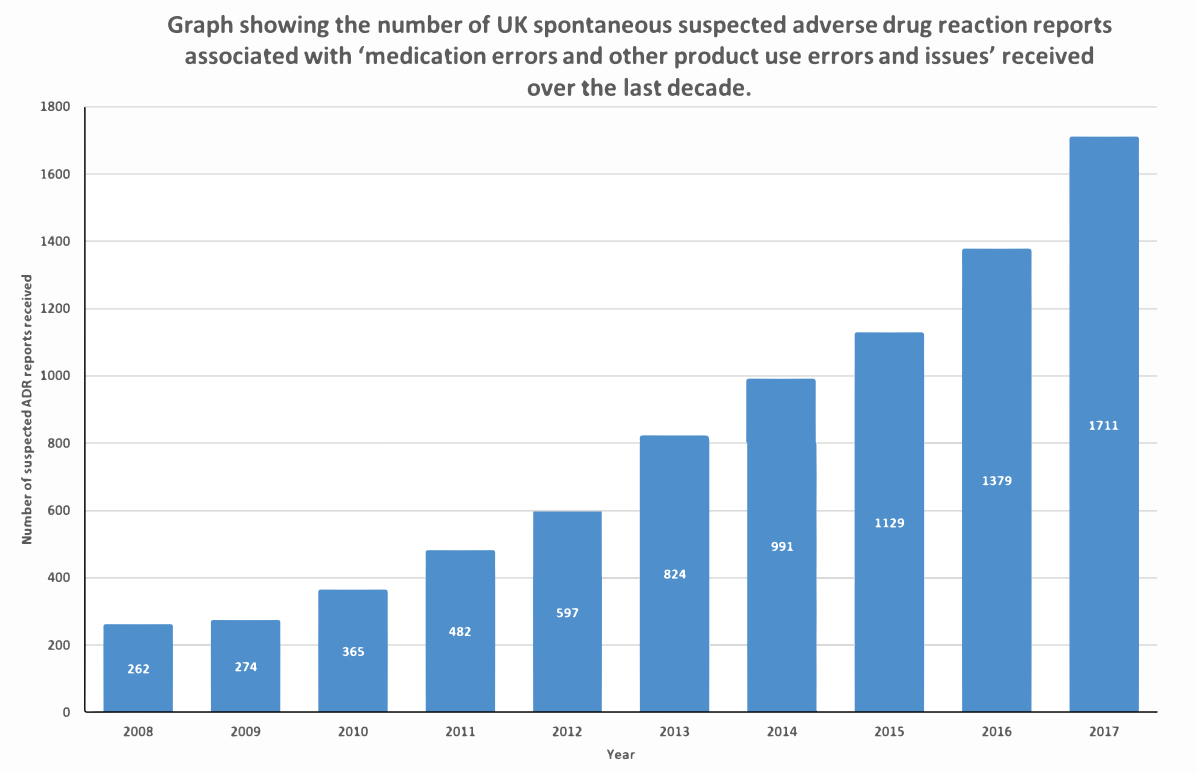
180. The identification of a range of potential harms via the RIDR scheme is encouraging and with more reports, it is anticipated that a greater number of signals will be detected. Fresh communication efforts are planned in 2018 to increase the promotion of the scheme and to encourage reporting, with the aim of continuing the progress made by RIDR so far.

Medication Safety Officers Network in England

181. Since 2014 the National Medication Safety Network, operating in partnership with NHS Improvement, has been in place and is intended as a forum for discussing potential and recognised safety issues as well as for identifying trends and actions to improve the safe use of medicines. As of September 2017, the National Medication Safety Network had a total of 500 registered Medication Safety Officers (MSOs). In England, the majority of MSOs are hospital pharmacists, and they continue to report as well as encourage reporting within their trusts. In addition to improving the quality of reporting, the MSOs serve as the essential link between the identification and implementation of local and national medication safety initiatives and the daily activities to improve patient safety with the use of medicines.

182. The main focus of the MSO network's activity is medication error. Figure 5 shows that over a ten-year period there has been a steady and clear increase in the number of UK spontaneous suspected ADRs received associated with medication errors and other product use errors. The dissemination of relevant research, information concerning new risks, best medication safety practice raised by the network, alongside the MHRA's signalling process has allowed the identification of new harms over the years.

Figure 5 – Graph showing the number of UK spontaneous suspected adverse drug reaction reports associated with 'medication errors and other product use errors and issues' received over the last decade.



183. Data from the National Reporting and Learning System (NRLS) is shared with the MHRA for analysis on a weekly basis. Of the 11,034 reports received between November 2016 and November 2017, 32.7% (3,606) were valid cases reporting a conventional suspected ADR or harm associated with a medication error. Efforts have been made through monthly web conferences and communication with the network to focus on increasing reporting and improving coding and quality of medication error reports.

184. The NRLS is currently being redeveloped through the Development of the Patient Safety Incident Management System (DPSIMS) project[4]. This project is aimed at developing a reporting and learning system that will help improve the ability of all healthcare associated organisations to report effectively and allow for greater transparency of patient safety data. The MHRA is working closely with NHS Improvement to integrate and better capture Yellow Cards fields within the new system.

[4]The future of the patient safety incident reporting: upgrading the NRLS: https://improvement.nhs.uk/news-alerts/development-patient-safety-incident-management-system-dpsims/ (Accessed on 17/01/18).

185. The MSO network has continued to improve learning at a local level, clarifying roles and improving communication between local and national levels. Monthly web conferences take place with approximately 100 attendees on each occasion. The network is supported by email discussion groups, an online information forum and by local or web events based on regions, clinical specialty or healthcare setting. The MHRA continues to work with the UK Devolved Administrations (Scotland, Northern Ireland and Wales) to share learnings from this initiative and to promote similar information sharing UK-wide.

Signal Detection

186. The MHRA signal management system is designed for the timely detection of new and changing drug safety issues. Changes in the frequency of ADRs already known to be associated with medicines are also closely monitored through the MHRA's signal detection process. The drug-event combinations from Yellow Card reports are assessed on a weekly basis to identify potential safety signals. In 2017, there were a total of 79 validated signals – potential signals that have been identified by a statistical algorithm or from external sources which subsequently require additional detailed investigation and review. Once evaluated, these validated signals result in appropriate regulatory action such as updates to product information, and may also contribute to wider reviews alongside other sources of data. Each signal is prioritised 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 1: Number of signals assessed in 2017

	Signal Priority		
	Top	**Increased**	**Standard**
Number of signals	2	13	64

187. In 2017, ADR reports received from members of the public contributed towards 5 signals being detected and ADR reports received from health care professionals contributed to 18 signals being detected. Some examples of signals which stimulated regulatory action include finasteride and depression/suicidal thoughts: warnings were added to strengthen the product information about depression and suicidal thoughts associated with finasteride. A Drug Safety Update was also published to advise healthcare professionals to be vigilant and stop the medicine if such reactions develop. Another signal example was miconazole and the drug interaction with warfarin which resulted in the contraindication of over the counter miconazole gel in patients on warfarin; warnings were also strengthened in the miconazole product information.

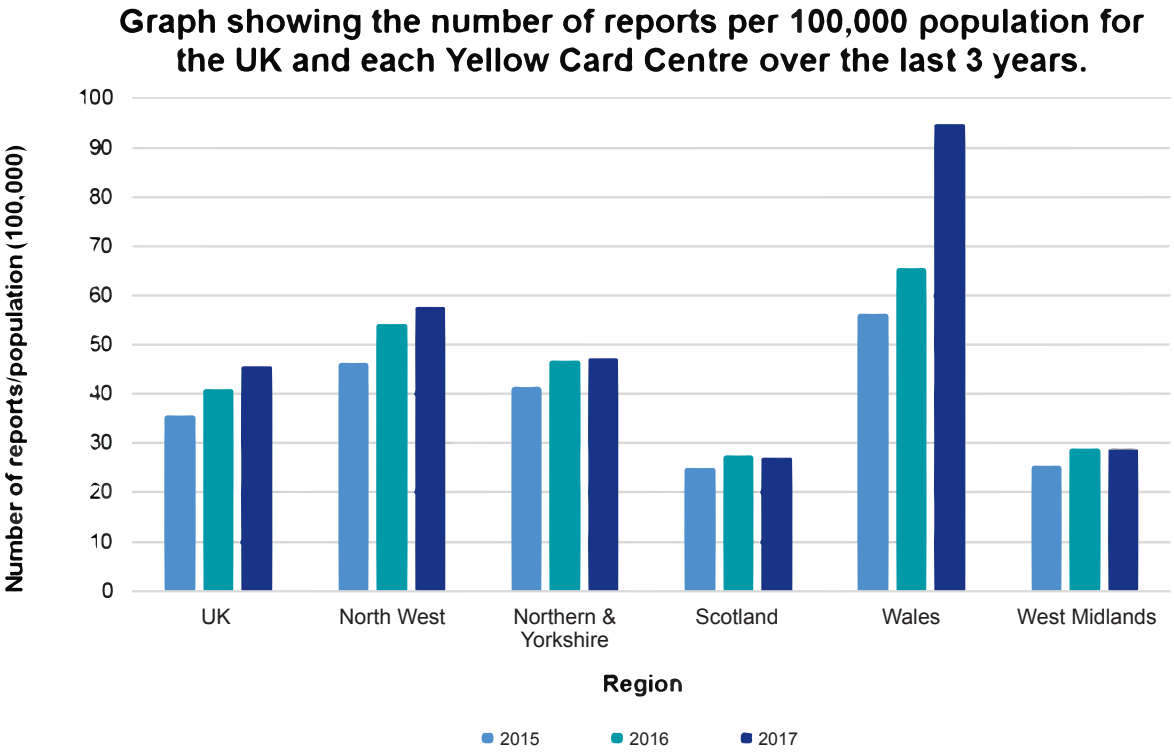
UK Yellow Card Centres

188. The Yellow Card Scheme operates throughout the United Kingdom. To strengthen reporting in certain regional areas, five Yellow Card Centres (YCCs) operate 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 locally.

189. The YCCs are involved in various programmes that aim to increase ADR reporting in their specific region, including the establishment of nominated hospital pharmacists or pharmacy technicians as 'ADR Champions'. The YCC Wales Champions Scheme, developed in 2013, has continued its success in promoting the Yellow Card Scheme. In 2017, YCC Wales extended the invitation to their Yellow Card Champion Training Day to practice-based pharmacists for the first time. Successful Yellow Card Champions Schemes have also been organised by YCC West Midlands and YCC North West. During 2017 YCC Scotland have engaged with the Community Pharmacy Champions network in Scotland and hope to expand collaborations in 2018.

190. The YCCs continue to provide valuable educational services for current healthcare professionals, as well as postgraduate and undergraduate students, local charities and support groups. The impact of the YCCs' efforts can be seen from the reporting rates from these regions in Figure 6. In 2017, 3 YCCs had a higher number of reports per 100,000 people than the UK average (46): Northern & Yorkshire (47), North West (58) and Wales (95). Of note, YCC Wales had a 46% increase in the number of reports per 100,000 population compared with the 2016 figure. YCC Wales have undertaken large-scale training events and trained new Yellow Card Champions within their region over the past year, increasing awareness of the scheme.

Figure 6 – Graph showing the number of reports per 100,000 population for the UK and each Yellow Card Centre over the last 3 years.



191. The Commission on Human Medicines encourages the reporting of suspected ADRs to the Yellow Card Scheme and is grateful for the co-operation of those healthcare professionals and patients who submit reports and thereby contribute to the protection of public health.

MEMBERSHIP OF THE COMMISSION ON HUMAN MEDICINES

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[5] Re-Appointed 12/02/2017
[6] Retired 10/02/2017

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

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University College Hospital; National Hospital for Neurology and Neurosurgery

Professor Ashok Soni OBE FFRPS FRPharmS
LPN Chair (Pharmacy), NHS England (London); English Pharmacy Board Member, Royal Pharmaceutical Society; Clinical Network Lead

(Pharmacy), NHS Lambeth CCG; and Past President, Royal Pharmaceutical Society of Great Britain

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

Visiting Experts to Commission Meetings

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

Sir Richard Thompson
Immediate Past President, Royal College of Physicians London

Dr Peter Wilmshurst
Consultant Cardiologist, University Hospital of North Staffordshire

En College Meeting – Invited Speakers to Commission Meetings

Dr Gregory Amos
Senior Scientist, Bacteriology, National Institute for Biological Standards and Control (NIBSC)

Professor Tim Spector MB MSc MD FRCP
Professor of Genetic Epidemiology and Director of the TwinsUK Registry at Kings College, London

Hormonal Pregnancy Tests Working Group (HPTWG) - Visiting Participants to Specific Items During Commission Meetings

Mr Nick Dobrik
HPTWG Invited Expert
Thalidomide Campaigner

Mrs Marie Lyon
HPTWG Observer
Chair of the Association for Children Damaged by Hormonal Pregnancy Tests

Observers of Commission Meetings

Mr Robert Fernley
Programme Manager – Early Access to Medicines Scheme, Specialised Commissioning, NHS England

Professor Mike Kelly PhD, Hon FRCP, FRCPE, FFPH
Senior Visiting Fellow, Primary Care Unit, Institute of Public Health, University of Cambridge and former Director of the Public Health Excellence Centre at the National Institute for Health and Care Excellence (NICE)

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Member of the Cardiovascular, Diabetes, Renal, Respiratory and Allergy EAG

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MRC Clinical Research Fellow
Department of Molecular and Clinical Pharmacology

Dr Veli-Pekka Parkkinen
Post-Doctoral Fellow in Philosophy, Centre for Reasoning, University of Kent

Dr Richard Turner MA(Cantab), MB BChir(Cantab), MRCP(UK)
MRC Clinical Research Fellow in Clinical Pharmacology & Therapeutics

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

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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

Professor Sarah Wild MB BChir MSc PhD FRCPE FFPH
Professor of Epidemiology, Honorary Consultant in Public Health, Usher Institute of Population Health Sciences and Informatics, University of Edinburgh

[7] Appointed 20/01/2017
[8] Re-appointed 15/02/2017

MEMBERSHIP OF THE CHEMISTRY, PHARMACY AND STANDARDS EXPERT ADVISORY GROUP

Remit

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

Chair

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

Members

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

Mr V'lain G Fenton-May[10] BPharm MIPharm FRPharmS
Pharmaceutical Microbiologist

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

[9] Passed away 26/09/2017
[10] Re-appointed 12/11/2017

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Academic Community Pharmacist, Visiting Fellow at University of Huddersfield & Past President of the RPSGB

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Mr Robert Lowe BPharmS MRPharmS
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Emeritus Professor of Pharmaceutics, King's College, London

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Chair in Drug Delivery, Strathclyde Institute of Pharmacy and Biomedical Sciences, University of Strathclyde, Glasgow. Scotland.

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

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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

[11] Re-appointed 24/01/2017
[12] Re-appointed 14/11/2017
[13] Re-appointed 14/11/2017

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

Remit

To advise the Commission on:

- First time in human (FTIM) studies with new compounds acting (directly or indirectly) via the immune system with a novel target or a novel mechanism of action or having a secondary potential effect on the immune system via a mechanism of action which currently is not well characterised
- FTIM studies with novel compounds acting via a possible or likely species specific mechanism
- Any FTIM studies which are otherwise seen as requiring expert advise
- 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 Farzin Farzaneh DPhil FRCPath FRSB
Professor of Molecular Medicine, King's College London
Honorary Consultant in Specialist Medicine, King's College Hospital NHS Trust

Professor Andrew J T George[14] MBE MA PhD DSc FRCPath FHEA FRSA FRSB
Vice Principal (Education and International), Brunel University, London

[14] Retired 04/04/2017

Dr Elwyn Griffiths[15] 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[16] MD FRCP FRCPath **(Vice Chair)**
Reader and Honorary Consultant in Amyloidosis and Renal Medicine, University College London

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Professor B Kevin Park BSc PhD FMedSci FRCP (Hon) FBTS
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Professor Andrew Pollard PhD FRCPCH FMedSci
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Dr Stephen Poole[18] PhD
Consultant: Biological Medicines and Vaccines

Dr Robin Thorpe[19] PhD FRCPath
Retired, Head, Division of Biotherapeutics, National Institute for Biological Standards and Control (NIBSC)

Professor Marc Turner MBBS PhD MBA FRCP FRCPath FHEA
Professor of Cellular Therapy; Medical Director Scottish National Blood Transfusion Service (SNBTS)

Mrs Madeleine Wang[20] BA (Hons)
Lay Representative. Patient Advocate

Professor Christopher Weir BSc (Hons) PhD MSc FRSS C.Stat C. Sci
Personal Chair in Medical Statistics and Clinical Trials, Usher Institute of Population Health Sciences and Informatics, University of Edinburgh

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[15] Retired 31/12/2017
[16] Re-appointed 12/11/2017
[17] Retired 16/10/2017
[18] Retired 04/04/2017
[19] Appointed 13/04/2017
[20] Re-appointed 12/11/2017

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, thaumatological, 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 BSc MBBS DPhil FRCP
Associate Professor, University of Southampton and Consultant Dermatologist

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

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

Dr Richard Groves[21] MB BS MRCP FRCP
Consultant Dermatologist, St John's Institute of Dermatology, Guy's and St Thomas Hospital

Professor Kevin Moore[22] BSc MB BS PhD FRCP
Professor of Hepatology, Royal Free Hospital, London

Dr Frances MK Williams PhD FRCP(E)
Reader and Hon Consultant, Dept Twin Research and Genetic Epidemiology
King's College London

[21] Retired 13/10/2017
[22] Re-appointed 03/11/2017

MEMBERSHIP OF THE INFECTION 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 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

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

Dr Andrew Freedman 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 JC Gilson MD FRCP
Reader in Sexual Health and HIV and Honorary Consultant Pysician Director, UCL Centre for Sexual Health and HIV Research Head, Research Department of Infection and Population Health University College London

Dr Richard Hobson[23] MB BS MRCP (UK) FRCPath PhD
Consultant Microbiologist and Honorary Senior Lecturer, Harrogate and District NHS Foundation Trust/University of Leeds

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

Dr Katie Jeffery FRCP FRCPath
Consultant Microbiologist (Clinical Lead), Oxford University Hospitals NHS Foundation Trust

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

[23] Re-appointed 18/04/2017

Dr Hermione Lyall[24] BSc Hons MB ChB Hons MD FRCPCH
Consultant in Paediatric Infectious Diseases, St Mary's Hospital, Imperial College Healthcare NHS Trust, London

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

Dr Matthias Schmid MD FRCP DTMH
Consultant Physician & Honorary Clinical Senior Lecturer, Head of Department of Infection & Tropical Medicine, Royal Victoria Infirmary

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

[24] Re-appointed 17/09/2017

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

Professor Mary Lumsden[25] BSc MB BS MD FRCOG **(Vice Chair)**
Professor of Medical Education & Gynaecology, University of Glasgow

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

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

Dr Clare Spencer 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

[25] Retired 11/11/2017

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 Thomas R. E. Barnes MD FRCPsych DSc
Emeritus Professor of Clinical Psychiatry, Imperial College London

Professor Naomi Fineberg BA Hons MB BS MA MRCPsych
Consultant in General Adult Psychiatry, Hertfordshire Partnership NHS

Dr Anthony L Johnson[26] BSc PhD CStat
Honorary Senior Research Associate, MRC Clinical Trials Unit at University College London

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

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

Dr Waqar Rashid 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

Dr Fergus Rugg-Gunn MB BS MRCP PhD
Consultant Neurologist, National Hospital for Neurology and Neurosurgery, Queen Square, London

Dr Aditya Sharma MBBS MD MRCPsych PhD
Clinical Senior Lecturer and Honorary Consultant in Child and Adolescent Psychiatry at Newcastle University

[26] Retired 06/10/2017

Dr Catherine F Stannard MB ChB FRCA FFPMRCA
Consultant in Complex Pain/Pain Transformation Programme Clinical Lead
NHS Gloucestershire CCG, Senior Research Fellowship at the Institute of Psychiatry, Psychology and Neurosciences at King's College London.

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

MEMBERSHIP OF THE ONCOLOGY & 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
Consultant Medical Oncologist, The Royal Marsden NHS Foundation Trust and Professor of Cancer Medicine, Institute of Cancer Research

Members

Professor David Bowen[27] MA MB Bchir MD MRCP FRCPath
Consultant Haematologist, Leeds Teaching Hospitals and Honorary Professor of Myeloid Leukaemia Studies, University of Leeds

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

Dr Hugo Ford MA MB BChir MD FRCP
Director of Cancer Services, Cambridge University Hospitals Foundation Trust

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

Dr Geoff Shenton[28] FRCPath MRCP MBChB (Distinction) BMedSci
Consultant & Associate Clinical Lecturer in Paediatric and Adolescent Haematology & BMT, Great North Children's Hospital, Newcastle upon Tyne

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

[27] Appointed 16/06/2017
[28] Appointed 13/04/2017

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 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, Consultant Paediatric Endocrinologist, UCL Institute of Child Health

Professor Peter C Hindmarsh[29] BSc MD FRCP FRCPCH
Consultant Paediatric Endocrinologist, Royal Free and University College Medical School

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

Dr Caroline Jones[30] MB ChB FRCPCH MD
Consultant Paediatric Nephrologist, Alder Hey Children's NHS Foundation Trust

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

[29] Retired 11/11/2017
[30] Appointed 17/02/2017

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

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 BA CPE LPC
Lay Representative. Solicitor

Dr Beverly Tsai-Goodman[31] MD FRCP PG Cert Med Ed
Consultant Paediatric and Fetal Cardiologist, Royal Brompton Hospital

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 FRSC FSB FBPharmacolS FBTS European Registered Toxicologist
Professor of Biochemical Pharmacology and Toxicology, College of Life Science and Medicine, University of Aberdeen

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

Dr Morris Zwi MBBCh, FRCPsych
Consultant Child & Adolescent Psychiatrist & Clinical Lead, Child & Adolescent Mental Health Services, Whittington Health, Clinical Lead for Islington Child & Adolescent Mental Health Services

[31] Retired 08/02/2017

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.
- Review and advise the MHRA on applications for Type II Yellow Card data, which fall outside of Freedom of Information provisions.

Chair

Professor Sir Munir Pirmohamed MB ChB (Hons) PhD FRCP FRCP (Edin) FMedSci
David Weatherall Chair of Medicine, University of Liverpool, NHS Chair of Pharmacogenetics, Associate Executive Pro Vice Chancellor, Director of the Wolfson Centre for Personalised Medicine, Director of the MRC Centre for Drug Safety Science

Members

Professor Darren Ashcroft[32] BPharm, MSc, PhD, FRPharmS
Professor of Pharmacoepidemiology, University of Manchester

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

Professor Ann Daly[33] BA PhD FBPhS
Professor of Pharmacogenetics and Associate Dean for Internationalisation (Faculty of Medical Sciences)

Professor William Dixon[34] MRCP PhD
Director, Arthritis Research UK Centre for Epidemiology and Honorary Consultant Rheumatologist, The University of Manchester

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

[32] Appointed 11/12/2017
[33] Appointed 11/12/2017
[34] Retired 24/08/2017

Dr Daniel Hawcutt[35] BSc (Hons), MB ChB (Hons), MD, MRCPCH
Senior Lecturer Paediatric Clinical Pharmacology, University of Liverpool

Ms Susan Hunneyball[36] BSc (Hons)
Senior Associate, for and on behalf of Charles Russell Speechlys

Ms Amanda Lee[37] 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[38] 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 BSc MBBS DRCOG DCH DFFP FRCGP
GP Partner, Adelaide Medical Centre, London

Dr Rupert Payne[39] MB ChB MRCP PhD MRCGP FRCP
Consultant Senior Lecturer in Primary Care, University of Bristol

Dr Nicholas J Plant[40] BSc PhD
Reader in Molecular Toxicology, University of Surrey

Ms Christine Randall BPharm MRPharmS
Assistant Director, North West Medicines Information Centre

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

Dr Caroline Vaughan[41] PhD
Lay Representative of MHRA EAGS. Governor of the Surrey and Sussex Healthcare NHS Trust

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

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[35] Appointed 11/12/2017
[36] Appointed 11/12/2017
[37] Retired 23/03/2017
[38] Retired 01/03/2017
[39] Appointed 14/07/2017
[40] Retired 09/12/2017
[41] Retired 11/11/2017

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

THE COMMISSION'S WORKING GROUPS

MEMBERSHIP OF THE CHRONIC LIVER DISEASE WORKING GROUP

Chair

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

Members

Professor Guru Aithal
Head of Division, Faculty of Medicine & Health Science, University of Nottingham

Professor Quentin Anstee
Professor of Experimental Hepatology & Consultant Hepatologist , Newcastle University

Professor Chris Byrne
Professor of Endocrinology and Metabolism, Honorary Consultant Diabetologist & Metabolic Physician, University of Southampton

Dr Roger Chapman
Group Head / PI, Consultant Physician, Hepatology Research Group, John Ratcliffe Hospital

Professor Mike Heneghan
Consultant Hepatologist, King's College Hospital

Dr Gideon Hirschfield
Senior Lecturer/Honorary Consultant Transplant Hepatologist, University of Birmingham

Professor David Jones
Professor of Liver Immunology, Newcastle University

Dr George Mells
Clinical Lecture in Gastroenterology, University of Cambridge

Professor Phil Newsome
Director of the Centre for Liver Research, University of Birmingham

Dr Emmanuel Tsochatzis
Senior Clinical Lecturer Honorary Consultant Inst for Liver and Digestive Hlth, UCL

MEMBERSHIP OF THE DOVONEX AD HOC STAKEHOLDER GROUP

The main objective of the meeting was to receive views from all participating stakeholders affected by a reclassification on key aspects of a proposed reclassification as identified during assessment of the application. The group did not reach a consensus view or make recommendations. For this reason, it was ruled that any interests held did not debar the members and invited experts from taking part in proceedings. The views captured at the meeting, alongside the assessment report, were provided to CHM to advise the Licensing Authority on the reclassification application. Patient representatives' names have not been included in the report to protect their anonymity.

Chair

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

Members

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

Dr Martin Duerden RCGP
Member of National Stakeholder Platform, Senior Clinical Lecturer, Centre for Health Economics and Medicines Evaluation, Bangor University

Ms Carla Renton
Psoriasis Association Representative

Ms Ruth Wakeman RPS
Member of National Stakeholder Platform

Invited Experts

Ms Nicola Broad
Community Dermatology Specialist Nurse, Bridgewater Community Healthcare NHS Trust, Wigan Health Centre

Dr George Moncrieff FRCP FRCGP
Chair Dermatology Council for England,
GP partner at Bicester Health Centre, Oxon

Mr Ade Williams
Superintendent Pharmacist - Bedminster Pharmacy in Bristol

MEMBERSHIP OF THE HORMONE PREGNANCY TESTS WORKING GROUP

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

Mr Ian Currie
Vice President of UK Affairs, Royal College of Obstetricians and Gynaecologists

Professor Pat Doyle BSc MSc PhD
Department of Non-Communicable Disease Epidemiology, London School of Hygiene & Tropical Medicine

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 **(Lay Representative)**

Professor Joyce Harper
Professor in Human Genetics and Embryology, University College London

Professor Stephen Hillier OBE DSc FRCPath FRCOG
Emeritus Professor of Reproductive Endocrinology, University of Edinburgh

Professor Alison MacFarlane
Professor of Perinatal Health, School of Health Sciences, City University London

Ms Sara Payne BA CPE LPC
Solicitor **(Lay Representative)**

Mrs Farrah Pradhan
Invited Reviews Coordinator at the Royal College of Obstetricians and Gynaecologists **(Lay Representative)**

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

Dr Richard Quinton MB BChir
Consultant Endocrinologist, Endocrine Unit Royal Victoria Infirmary

Dr Connie Smith MB BS MFSRH
Retired Consultant in Sexual and Reproductive Health Care, Westminster PCT

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

Dr Diana Wellesley FRCP
Head of Prenatal Genetics, Consultant and Honorary Senior Lecturer in Clinical Genetics, Wessex Clinical Genetics Service, Princess Anne Hospital Southampton

Invited Experts

Dr Anne Connolly MB ChB DRCOG MRCGP
GPSI gynae; Clinical lead for maternity, women's and sexual health. Bradford City, Bradford Districts and AWC CCGs and chair of the Primary Care Women's Health Forum

Mr Nick Dobrik
Thalidomide Campaigner

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

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

Professor Kay Marshall
Head of the Manchester Pharmacy School, University of Manchester

Dr Irene Petersen
Reader in Epidemiology and Statistics, University College London

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

Professor Faith Williams
Emeritus Professor of Toxicology, Medical Toxicology Centre and Institute of Cellular Medicine, Newcastle University

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

Visiting Experts

Professor David Healy MD FRCPsych
Professor of Psychiatry, Dept of Psychological Medicine, University Health Board, Wales

Observers

Mrs Marie Lyon
Chair of the Association for Children Damaged by Hormonal Pregnancy Tests

PD Dr Elke Röhrdanz
EUROTOX registered Toxicologist; Head of the Unit Reproductive and Genetic Toxicology, Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices), Germany

MEMBERSHIP OF THE INDEPENDENT PRESCRIBING AD HOC GROUP

Chair

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

Members

Dr John Black QHP(C) MBBS (Lond) DCH FRCSEd FIMCRCSEd FRCEM
Medical Director, South Central Ambulance Service NHS Foundation Trust
Lecturer in Clinical Medicine, University of Oxford and Consultant in Emergency Medicine, John Radcliffe Hospital

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

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

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

Dr Clifford Mann FRCP FRCEM
Consultant in Emergency Medicine, Taunton and Somerset NHS Foundation Trust and Past President, Royal College of Emergency Medicine

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

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

Dr John Reynolds
Consultant Clinical Pharmacologist, Oxford University Hospitals NHS Trust

Dr Raman Uberoi
President of the British Society for Interventional Radiology
Honorary Senior Lecturer and Consultant Interventional Radiologist, John Radcliffe Hospital, Oxford

Professor Helen M Ward MSc BSc (Hons) RGN RCN Nurse Practitioner PGCEA PG Cert NMP
Associate Professor, Non-Medical Prescribing, London South Bank University

Dr Martin Wilson MB ChB, MPhil (Glasgow) FRCP(Edin)
Consultant Physician in Care of the Elderly, Raigmore Hospital, Inverness

MEMBERSHIP OF THE SODIUM VALPROATE EXPERT WORKING GROUP

Chair

Professor Sir Munir Pirmohamed MB ChB (Hons) PhD FRCP FRCP (Edin) FBPhS FMedSci
David Weatherall Chair of Medicine, University of Liverpool, NHS Chair of Pharmacogenetics, Associate Executive Pro Vice Chancellor, Director of the Wolfson Centre for Personalised Medicine, Director of the MRC Centre for Drug Safety Science

Members

Professor J Helen Cross 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 Martin Duerden B Med Sci, MB BS, DRCOG, Dip Ther, DPH, FRCGP
Member of National Stakeholder Platform, Honorary Senior Research Fellow, Centre for Health Economics and Medicines Evaluation, Bangor University

Professor Jayne Lawrence
Professor of Biophysical Pharmaceutics, Division of Pharmacy and Optometry, School of Health Sciences, Faculty of Biology, Medicine and Health, Manchester University and Visiting Professor of Biophysical Pharmaceutics, Institute of Pharmaceutical Science, King's College London

Dr John Paul Leach
Honorary Associate Clinical Professor, School of Medicine, Dentistry and Nursing, University of Glasgow, Elected Member of the Association of British Neurologists (ABN)

Dr Janine Lynch BHSCT
Psychiatrist, Belfast Health & Social Care Trust

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

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

Professor Catherine Nelson-Piercy MBBSMA, FRCP, FRCOG
Professor of Obstetric Medicine and Consultant Obstetric Physician, Guy's & St Thomas' Foundation Trust

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

Ms Clare Pelham
Chief Executive of the Epilepsy Society

Dr Fergus Rugg-Gunn MB BS MRCP PhD
Consultant Neurologist, National Hospital for Neurology and Neurosurgery, Queen Square, London

Ms Laura Russell
Senior Policy and Public Affairs Officer
Family Planning Association

Professor Philip Smith
Consultant Neurologist, Cardiff School of Medicine and former President of the Association of British Neurologists (ABN)

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

Invited experts

Professor Thomas R. E. Barnes MD FRCPsych DSc
Emeritus Professor of Clinical Psychiatry, Imperial College London

MEMBERSHIP OF THE TAMOXIFEN AD HOC GROUP

The objective of the Ad Hoc Group was to discuss proposals for a chemopreventative indication for women at moderate to high risk of developing breast cancer. Patient representatives' names have not been included in the Report to protect their anonymity.

Chair

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

Members

Mr Ramsey Cutress BM BCh MA PhD FRCS
Associate Professor in Breast Surgery, University of Southampton

Dr Martin Duerden
Senior Clinical Lecturer, Centre for Health Economics and Medicines Evaluation, Bangor University

Professor Diana Eccles MB ChB MD FRCP
Professor of Cancer Genetics, University of Southampton

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

Dr Chris Gallagher
Retired Consultant Medical Oncologist

Professor Philip Hannaford
Professor of Primary Care, University of Aberdeen

Miss Fiona MacNeill
President of the Association of Breast Surgery; Consultant Breast Surgeon, Royal Marsden Hospital

Professor Sarah Meredith
Deputy Director, MRC Clinical Trials Unit, London

Professor David Miles MBBS BSc PhD FRCP
Consultant Medical Oncologist, Mount Vernon Cancer Centre, Mount Vernon Hospital

Dr Karen Miller
GP Partner, Adelaide Medical Centre, London

Dr Rupert Payne MB ChB PhD MRCGP FRCP
Consultant Senior Lecturer in Primary Care,
University of Bristol

Dr Martin Wilson
Consultant Physician in Care of the Elderly, Raigmore Hospital, Inverness

Visiting Experts

Professor Jack Cuzick PhD FRS FMedSci FRCP (Hon)
Director, Wolfson Institute of Preventive Medicine; Head, Centre for Cancer Prevention, Queen Mary University of London

Dr John Graham
Consultant Oncologist, National Institute for Health and Care Excellence (NICE)

Mr Andy Hutchinson
Medicines Adviser, National Institute for Health and Care Excellence (NICE)

MEMBERSHIP OF THE EXTERNAL COMMISSION EXPERT ADVISORY PANEL

Anaesthesia

Dr Thomas Clutton-Brock FRCP FRCA FFICM
Director, ERDF Medical Devices Testing and Evaluation Centre, Clinical Director NIHR Trauma Management Health Technology Cooperative, Deputy Director Institute of Translational Medicine, Chair, NICE Interventional Procedures Advisory Committee, Reader in Anaesthesia & Intensive Care Medicine, Edgbaston, Birmingham

Dr Lindsey Rylah MBA FRCA
Consultant Anaesthetist, Basildon Hospital, Essex

Dermatology

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

Diabetology/Endocrinology

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

Geriatric Medicine

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

Gynaecology/Family Planning/Well Woman/Obstetrics

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

Liver/Lipidology

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

Medicine (general)

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

Neurology

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

Nurse

Professor Karen Luker CBE BNurs PhD FMedSci
QNI Professor of Community Nursing, Division of Nursing, Midwifery and Social Work, University of Manchester

Palliative Medicine/Pain Management

Professor Karen Forbes MB ChB FRCP Dip Pall Med Cert Med Ed MILT
Consultant and Macmillan Professorial Teaching Fellow in Palliative Medicine, Bristol Haematology and Oncology Centre

Paediatricians

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

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

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

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

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

Professor Alan Smyth MA MBBS MRCP MD FRCPCH
Professor of Child Health, School of Medicine, University of Nottingham

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

Pathologists/Histopathology/Biology/Immunobiology

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Professor of Gynaecological Pathology, University of Edinburgh

Professor Sir Nicholas Wright MA MD PhD DSc FRCPath
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Professor Amin Rostami PharmD PhD FCP FAAPS FJSSX
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Radiology/Nuclear Medicine

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Dr Nigel Hoggard MBBChir MD MRCP FRCR
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Dr Andrew Scarsbrook BM BS B Med Sci FRCR
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Rheumatology

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Urology

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

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

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

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Mr Philip G Hykin FRCS FRCOphth
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Mr Teifion Emlyn James MBBS DO FRCP FRCS FBCLA FRCOphth
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Mr David P.S. O'Brart MD FRCS FRCOphth
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Professor of Ophthalmology & Consultant Ophthalmic Surgeon, England Foundation Trust, Birmingham and Midland Eye Centre and the Midlands Eye Institute

COMMISSION ON HUMAN MEDICINES/EXPERT ADVISORY GROUPS SECRETARIAT

Commission on Human Medicines (CHM)

Dr K Prasad
Principle Assessor, Licensing

Ms S Morgan
Principal Assessor, Pharmacovigilance

Ms S Singh (Until 11th September 2017)
Secretary

Ms F Norris (From 11th September 2017)
Secretary

Ms F Norris (Until 11th September 2017)
Assistant Secretary

Chemistry, Pharmacy and Standards Expert Advisory Group (CPSEAG)

Dr L A Anderson
Principal Assessor

Ms E Agca
Secretary

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

Dr J Bonnerjea
Principal Assessor, Licensing (Biologicals)

Dr Martin O'Kane
Principal Assessor, Licensing (Clinical Trials)

Dr P Bryan
Principal Assessor, VRMM

Ms F Norris
Secretary

Pharmacovigilance Expert Advisory Group

Ms C Davies
Principal Assessor

Ms N Nolen
Secretary

Appendix V

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 nonconfidential
information on all medicinal products authorised in the UK, together with the ability to track their own applications as they progress through the assessment process.

RCGP: Royal College of General Practitioners

RCHM: Register of Chinese Herbal Medicines

RCR: Royal College of Radiologists

RCT: Randomised (controlled) Clinical Trial

RFI: Request for Further Information

rINN: Recommended International Non-proprietary Name

RMP: Risk Management Plan

RMS: Reference Member State

ROR: Reporting Odds Ratio

RPPS: Regulatory Pharmacovigilance Prioritisation System

RP: Responsible Person

RPSGB: Royal Pharmaceutical Society of Great Britain

RMS: Records Management System

RSC: Royal Society of Chemistry

RSI: Request for Supplementary Information

RSM: Royal Society of Medicine

Rx: Abbreviation for a medical prescription

SABS: Safety Alert Broadcast System

SAE: Serious Adverse Effect

SAG: Scientific Advisory Group [of the EMA]

SAMM: Safety Assessment of Marketed Medicines - guidelines that apply to the conduct of all company sponsored studies designed to evaluate drug safety

SCOP: Pharmacovigilance Sub-Committee of the Committee on Safety of Medicines [Replaced by PEAG of the CHM]

SD: Standard Deviation

SEAC: Spongiform Encephalopathy Advisory Committee

Section 4 Committees: Committees established under the Medicines Act to promote advice on the safety, quality or efficacy of medicines and the collection and investigation of information concerning adverse drug reactions.

Section 44 Letters: Letters issued under the 1968 Medicines Act to seek additional information. For instance, S 21(1) or S 28(3) letters allow the provisional conclusions of the Committee on Safety of Medicines to be conveyed to a company.

SI: Statutory Instrument

SLA: Service Level Agreement

SMF: Site Master File

SMQ: Standardised MedDRA query - part of the Medical Dictionary for Drug Regulatory Affairs (MedDRA) terminology

SmPC: Summary of Product Characteristics - *see SPC*

SOC: System Organ Class - part of the Medical Dictionary for Drug Regulatory Affairs (MedDRA) terminology

SOL: Department of Health Solicitor's Branch.

SOP: Standard Operating Procedure

SPC: (see also SmPC) Summary of Product Characteristics

SPC: Special Precautions and Contra-indications

SPECT: Single Photon Emission Computed Tomography

SSRI: Selective Serotonin Reuptake Inhibitor

SUSAR: Suspected Unexpected Serious Adverse Reaction

SWP: Safety Working Party

Syn (Synonym): A botanical name that is commonly used but is not botanically accepted as the correct term for a species

TAG: Technical Advisory Group

TCM: Traditional Chinese Medicine

TGA: Therapeutic Goods Administration (Australia)

THM: Traditional herbal medicine

THMPD: Traditional Herbal Medicinal Products Directive

THMRS: Traditional Herbal Medicines Registration Scheme

THR: Traditional Herbal Registration

TO: Treat Officially - description used for all letters sent to the Secretary of State or ministers to be answered by officials.

TOPRA: The Organisation for Professionals in Regulatory Affairs

TOTO: Top Of The Office

TS: Tuberous Sclerosis

TSE: Transmissible Spongiform Encephalopathy

UKPAR: United Kingdom Public Assessment Report for Medicines

UKRC: United Kingdom Radiological Conference

USAN: United States Adopted Names - a list of drug names officially recognised in the US.

USP: United States Pharmacopoeia

UTI: Urinary Tract Infection

vAIC: Virtual Adverse Incident Centre

vCJD Variant Creutzfeldt-Jakob Disease

VMD: Veterinary Medicines Directorate

VRMM: Vigilance and Risk Management of Medicines division of the MHRA

VTE: Venous Thromboembolism

WHMP: Western Herbal Medicine Practitioner

WL: Wholesale dealer’s Licence

YCC: Yellow Card Centre

BRITISH PHARMACOPOEIA COMMISSION ANNUAL REPORT FOR 2017

INTRODUCTION

1. The British Pharmacopoeia Commission, appointed under Regulation 11 of the Human Medicines Regulations 2012, is responsible under regulation 317 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 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 2017 is shown in **Appendix I**. Professor Kevin Taylor was appointed for a second four-year term as Chair, with effect from 1st October 2017.

3. A list of members of the supporting Expert Advisory Groups, Panels of Experts and Working Parties for 2017 is given in **Appendix II**. During the year an *ad-hoc* group on New Analytical Technologies was established. The remit of this group is to develop a framework for introducing new methods of analysis into the British Pharmacopoeia.

CODE OF PRACTICE

4. Members of the British Pharmacopoeia Commission are required to comply with a Code of Practice on Declaration of Interests in the Pharmaceutical Industry. This Code of Practice differs from that applicable to the Commission on Human Medicines in that, with the exception of the Chair, members may continue to hold personal interests in the pharmaceutical industry. Members of the Expert Advisory Groups, Panels of Experts and Working Parties are also required to comply with the Code of Practice. Explanatory Notes clarifying how interests are recorded are included in the British Pharmacopoeia and British Pharmacopoeia (Veterinary).

MEETINGS

5. The British Pharmacopoeia Commission met three times during 2017. Sixteen meetings of the Expert Advisory Groups, Panels of Experts and Working Parties were also held during the year. In addition a preliminary meeting of the *ad-hoc* group on New Analytical Technologies was held to discuss ways of working and how best to identify and introduce new technologies. These meetings were held at the Medicines and Healthcare products Regulatory Agency (MHRA), 151, Buckingham Palace Road, London SW1W 9SZ.

6. Summary Minutes of the meetings of the British Pharmacopoeia Commission and its Expert Advisory Groups and Panels of Experts can be found on the British Pharmacopoeia website (https://www.pharmacopoeia.com/meeting-minutes).

BRITISH PHARMACOPOEIA BUSINESS REVIEW

7. The British Pharmacopoeia (BP) business review, conducted in 2015/2016, made a number of recommendations to explore opportunities to deliver better value to customers, allow flexibility and innovation and manage costs whilst maintaining and enhancing the BP's role in protecting public health. Key activities undertaken over the course of 2016/2017 included an organisational restructure to re-orientate the skills and knowledge base of our people to support the aims of the business review, the implementation of phase 1 of the BP transformation programme and the development of strategic plans for a number of key areas of our work, including the future scientific content of the BP.

SECRETARIAT

8. The British Pharmacopoeia Secretariat is based at the headquarters of the Medicines and Healthcare products Regulatory Agency (London). A list of members of the Secretariat is shown in **Appendix III**.

LABORATORY

9. The Laboratory is based at the Laboratory of the Government Chemist (LGC) (Teddington) and is managed under a collaboration agreement with LGC. The Laboratory Management Board is shown in **Appendix III**.

COSTS

10. For each meeting that they attend, members of the British Pharmacopoeia Commission are entitled to claim a taxable attendance fee of £325 (Chair's fee, £500). Members of the Expert Advisory Groups,

Panels of Experts and Working Parties are entitled to claim a taxable attendance fee of £200 per meeting attended (Chair's fee, £325). Travel and subsistence is also payable within MHRA guidelines.

PROGRESS AND PUBLICATIONS

British Pharmacopoeia 2017

11. Following publication of the British Pharmacopoeia 2017, three online updates were issued providing users with the text of the 9th Edition of the European Pharmacopoeia and that of Supplements 9.1 and 9.2.

British Pharmacopoeia 2018

12. The British Pharmacopoeia 2018 was published in August 2017. This new edition is available as a package containing the five volumes of the British Pharmacopoeia 2018, the one volume of the British Pharmacopoeia (Veterinary) 2018 and access to the electronic versions of both publications (online BP and offline download format).

13. This new edition contains about 4000 monographs for substances and articles used in the practice of medicine and over 400 infrared reference spectra, together with the necessary appendices and supporting material. The effective date of the British Pharmacopoeia 2018 is 1st January 2018.

14. All monographs published within the 9th Edition of the European Pharmacopoeia, as amended by Supplements 9.1 and 9.2, 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.

15. The British Pharmacopoeia 2018 contains 35 new monographs of national origin which were not published in previous editions. These include four new monographs for Traditional Herbal Medicines and four new monographs for unlicensed formulations. Five new infrared reference spectra have been added to this edition.

16. Nineteen monographs were editorially amended to reflect changes introduced following a review of the content and format of monographs for Inhaled Products and changes to the European Pharmacopoeia General Monograph for Preparations for Inhalation. Further changes will be introduced in future publications. The updated policy was provided on

the BP website and was included in Supplementary Chapter I O: Inhaled Products.

17. Changes were made to 61 formulated preparation monographs containing Assays based on the average of the results obtained in the Uniformity of content / Uniformity of delivered dose tests so that the same approach can be followed regardless of the number of results obtained.

18. Four new Appendices were added to harmonise with the European Pharmacopoeia: Appendix XI W – High-Performance Thin-Layer Chromatography of Herbal Drugs and Herbal Drug Preparations; Appendix XIV O – Host-cell Protein Assays; Appendix XIV P – Determination of Bactericidal, Fungicidal or Yeasticidal Activity of Antiseptic Medicinal Products; Appendix XV L – Immunonephelometry for Vaccine Component Assay.

19. One new Supplementary Chapter was added to harmonise with the European Pharmacopoeia (IV S: Raw Materials of Biological Origin for the Production of Cell-based and Gene Therapy Medicinal Products).

20. The Supplementary Chapter on Unlicensed Medicines (V) was updated to clarify the medicines legislation relating to ‘Specials’ and that relating to formulations prepared under the supervision of a pharmacist and to reflect updated guidance from the Royal Pharmaceutical Society.

British Pharmacopoeia (Veterinary) 2018

21. The British Pharmacopoeia (Veterinary) 2018 was published as a companion volume to the British Pharmacopoeia 2018 in August 2017. 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) 2018 is 1st January 2018.

22. The British Pharmacopoeia (Veterinary) 2018 contains 6 new monographs of national origin which were not published in previous editions. These include a new monograph for Veterinary Vaccines for use in Emergency Situations. One new infrared reference spectrum has been added to this edition.

23. 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 2017

24. The first Supplement to British Approved Names 2017 (Supplement No. 1) was published in August 2017. The Supplement identifies and defines 46 new chemical and biological entities that are now used in medicines in the UK. The majority of the new names are for active

substances that have been licensed through the European Medicines Agency and have not previously been marketed in the UK.

BP Online

25. Access to the online version (www.pharmacopoeia.com) and the offline download edition of the publications is provided as a component of the British Pharmacopoeia 2018 package. The advantage 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.

26. Users can request access to a maximum of three individual BP monographs, together with the necessary supporting information including the Introduction, General Notices, Appendices and Supplementary Chapters.

Prices and Availability

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

Future Publications

28. By the end of 2017 work was progressing on the preparation of the next editions of the British Pharmacopoeia and British Pharmacopoeia (Veterinary). These will be published during 2018 and will have an effective date of 1st January 2019.

29. A digital update to the British Pharmacopoeia 2018 was issued in December 2017 providing users with the text of Supplement 9.3 to the 9th Edition of the European Pharmacopoeia which came into effect on 1st January 2018. Further updates will be issued to coincide with the implementation of Supplements 9.4 and 9.5 on 1st April and 1st July 2018 respectively. These updates will only be available via the online BP and the offline download. The texts will subsequently be included in the BP 2019 publications.

30. The Secretariat continued to liaise closely with The Stationery Office regarding improved ways of working and further improving the BP website.

OTHER PHARMACOPOEIAL MATTERS

BP Website

31. The BP website (www.pharmacopoeia.com) has continued to be positively received by users. The website incorporates a Document Review Tool (DRT) which is used by the BP Secretariat and members of

the BP Commission to ensure the quality of monographs and other texts for inclusion in the BP and BP (Vet) publications.

32. Following the regular public consultation schedule for new and revised monographs, four three-month consultation periods were held during 2017. In response to stakeholder feedback draft texts published in 2017 included additional details of the target publication date and, where appropriate, which tests had been revised. This innovation was welcomed by users.

Biological Medicines

33. The MHRA consultation on its strategy relating to pharmacopoeial quality standards for biological medicines, to which the BP Secretariat contributed heavily, ran from 9th January 2017 to 10th April 2017. Stakeholders were invited to provide feedback on the proposed strategy, on how pharmacopoeial standards were used and on how this could be improved. The BP Secretariat, along with cross-agency colleagues, ran a series of stakeholder meetings to maximise input and engagement.

34. The consultation was received extremely positively, with a large amount of stakeholder engagement. Responses confirmed the value of standards and focussed on the role that the MHRA can play, the need to explore alternative approaches and the importance of stakeholder collaboration and international engagement. The MHRA published an official response to the consultation in October. The document summarised the feedback received and the resultant changes to the strategy, which increased the emphasis placed on collaboration and knowledge building. A work programme was also included, demonstrating how the strategy would be implemented. The activities discussed focussed on development of standards, collaboration and knowledge building and international engagement.

35. The strategy continued to recognise the unique position of the MHRA with its incorporation of the regulator, the pharmacopoeia and the biological expertise of the National Institute for Biological Standards and Control (NIBSC). Collaborative work between the BP and NIBSC to establish reference materials to support new monographs was continued during the year and the first two materials were made available for users to purchase. Additionally, a further project was progressed to support a revision to a current BP monograph which will include a new British Pharmacopoeia Chemical Reference Substance (BPCRS) that will aid the analyst in carrying out the methods.

Unlicensed Medicines

36. Monographs that apply to specific 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 which may be widely used or required for certain patient populations.

38. In addition to developing monographs for unlicensed medicines, the BP is continuing to develop further guidance for prescribers, manufacturers and suppliers of these products which will be included in future publications.

Herbal and Complementary Medicines

39. The BP continues to focus on producing monographs for herbal substances widely used in Traditional Chinese Medicine and in Ayurvedic Medicine in the UK for which there are currently no European standards. The BP-NIBSC herbal team has strengthened collaborative links with leading national and international partners in the herbal industry.

40. The increased capabilities at the BP-NIBSC Herbal Laboratory has led to the production of more robust monographs with added value to the end user. The phytochemical analysis provided by the team has improved the quality of published standards by developing system suitability tests and intensity markers for HPTLC methods and introducing a robust and transferable second laboratory testing framework. The introduction of physical testing on site has provided robust analytical data and enabled validation of new technologies.

41. The innovative work of the BP-NIBSC herbal team on the use of DNA-based identification techniques was highlighted in a published article entitled “DNA Barcoding for Industrial Quality Assurance” (Sgamma *et al*., Planta Medica, 83 (14-15), 2017). Progress has been made in the development of a further innovative British Pharmacopoeia Nucleic Acid Reference Material (BPNARM) for identification purposes.

Nomenclature

42. The BP continued to provide advice and comments to the World Health Organization (WHO) Committee on International Nonproprietary Names (INN). Recommended INN (rINN) for products licensed in the UK are subsequently adopted as British Approved Names. UK Experts attended two meetings during the year and contributed to the evaluation of INN requests and the development of WHO policies on drug nomenclature. Two rINN Lists (77 and 78) were published by WHO during the year.

43. The BP Secretariat is also responsible for advising on 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 580 proposed invented names were assessed on behalf of the EMA. Following a successful training programme provided by BP staff on

the assessment of invented names, MHRA Licensing Division Assessors are now reviewing invented names in product licence applications. The BP continues to provide advice to manufacturers on the acceptability of invented names and remains the expert on the acceptability of invented names within the MHRA.

Analytical Quality by Design (AQbD)

44. The AQbD Working Party continued to investigate the application of the Quality by Design concept to analytical methods and the pharmacopoeia. Significant progress has been made in understanding the Analytical Target Profile (ATP) concept, with several theoretical ATPs being derived by statistical experts on the Working Party. The proposed ATPs have been investigated by the Laboratory, in collaboration with the Australian Therapeutic Goods Administration. It is anticipated that the outcomes of the work should be published during 2018.

45. The BP has maintained a strong global presence in AQbD, presenting at leading conferences in the USA and Europe. In addition to these activities the strong collaborative relationships with our peers in the USP and the Japanese Pharmacopoeia on this topic have been maintained through information and knowledge sharing.

Liaison with Other UK Organisations

46. The BP has built upon its strong existing links with academic institutions and has built new links with a number of universities. British Pharmacopoeia staff have given lectures to Pharmacy students and students of Herbal Medicine on topics relating to pharmaceutical analysis. The sponsored MSc project looking at the use of Raman Spectroscopy to test for the authenticity of medicines was successfully completed and the student received a distinction for their project.

47. The BP-NIBSC Herbal Laboratory staff were involved in the supervision of two PhD projects, which were completed during the year, and the publication of an article by a previous student and NIBSC staff entitled “The Use of Traditional Herbal Medicines Amongst South Asian Diasporic Communities in the UK” (Bhamra *et al*., Phytotherapy Research, 31 (11), 2017). The BP-NIBSC Herbal Laboratory staff are also members of a new EU Marie Curie Innovative Training Network (ITN), Plant.ID, which aims to develop innovative expertise relating to the identification and management of plant resources. The network comprises 27 international partners and will finance 15 PhD projects in the future. This project follows the successful completion of the MedPlant ITN, which came to a close in 2017.

48. The BP also supported the visiting postgraduate students on the European Pharmaceutical Education And Research with Regulatory Links (PEARRL) project, which was an innovative, international postgraduate training programme involving a collaboration between

academia, industry and regulators. During their time at the MHRA the students were provided with a full understanding of how medicines are regulated including licensing, inspection and pharmacovigilance.

49. The BP and Veterinary Medicines Directorate (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 medicine.

Laboratory

50. The Laboratory has continued to support the work of the British Pharmacopoeia Commission and also the wider MHRA remit relating to public health. In addition to supporting the development and revision of about 40 BP monographs, work performed by the Laboratory on behalf of the Agency's Defective Medicines Reporting Centre detected the presence of histamine in gentamicin-containing products for human and veterinary use. This work, as part of a cross-European network, was presented to the European Medicines Agency Quality Working Party and has triggered a revision of the European Pharmacopoeia monographs for Gentamicin Sulfate and Products of Fermentation. This will improve the quality standard of gentamicin-containing products and related products across the UK and Europe.

BP Reference Materials

51. Seventeen new BP Reference Materials were established to support the British Pharmacopoeia and British Pharmacopoeia (Veterinary) publications, 39 were replaced and 168 were re-tested to ascertain their continued stability.

52. The demand for these reference materials remained high throughout the year. 29966 vials were sold within the UK and to countries worldwide, representing a 16% increase in sales from the previous year.

European Pharmacopoeia

53. The third and fourth Supplements to the 9th Edition of the European Pharmacopoeia (Supplements 9.3 and 9.4) were published in July 2017 and October 2017 respectively. Supplement 9.3 came into effect on 1st January 2018 and Supplement 9.4 will come into effect on 1st April 2018. The fifth Supplement (9.5) was published in January 2018 and will come into effect on 1st July 2018. The text of these publications will be included in the next editions of the British Pharmacopoeia or British Pharmacopoeia (Veterinary), as appropriate.

54. 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 six Working Parties and experts to all of the principal Expert Groups and Working Parties. Members of the

UK delegation represented the British Pharmacopoeia Commission at meetings of the European Pharmacopoeia Commission, providing valuable input to the work of that Commission.

55. The Laboratory provides technical support for the work of the European Pharmacopoeia Commission, providing technical data to support the elaboration of new monographs and the revision of existing monographs.

56. 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.

57. 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 2017, is included in **Appendix V**.

International Liaison and Collaboration

58. 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.

59. Following the referendum on the UK's membership of the European Union the MHRA is working closely with the Government to ensure the continued safe and effective regulation of medicines and medical devices in the UK. The focus of the British Pharmacopoeia continues to be its public health role and staff are continuing to work with and support customers, partners and stakeholders. The BP continues to play a full and active role with all our international stakeholders including the European Pharmacopoeia, part of the European Directorate for the Quality of Medicines and Healthcare under the Council of Europe, and the contents of the European Pharmacopoeia will continue to be incorporated within the BP publications. The BP has ensured that all its international partners are regularly updated regarding the BP/MHRA position.

60. Representatives from the BP attended a number of technical meetings in order to support the work of the European Pharmacopoeia. A number of issues have been discussed including setting pharmacopoeial standards for biotherapeutic products, the control of elemental impurities, new analytical technologies and international harmonisation.

61. The Memoranda of Understanding between the BP and the State Pharmacopoeia of Kazakhstan and between the BP and the State Pharmacopoeia of the Ukraine were renewed during the year. These

agreements enabled the continued inclusion of a specified number of BP monographs in these national pharmacopoeias.

62. BP Staff attended the Eighth International Meeting of World Pharmacopoeias which was organised by the World Health Organization and was held in Brazil in July. The meeting focussed on the continuing development of the guidelines on “Good Pharmacopoeial Practices”, the main text of which was issued in 2016. The additional guidance relating to Compounded Preparations and Herbal Medicines was finalised during the meeting and was approved by the WHO Expert Committee on Specifications for Pharmaceutical Preparations later in the year. The BP has provided editorial assistance in the finalisation of these texts, which should be available in 2018.

63. The WHO meeting was followed by the 9th Annual Meeting of the Brazilian Pharmacopoeia. This provided an opportunity for BP staff to hold meetings with representatives from the Indian Pharmacopoeia, the Brazilian Pharmacopoeia and the Vietnamese Pharmacopoeia. The meetings focussed on current and potential future collaboration opportunities between the BP and these organisations.

64. 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.

65. The BP attended the annual meeting of the International Pharmacopoeia and the 52nd Meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations. These meetings covered a wide range of topics, including monographs and policies for the International Pharmacopoeia, future collaborations and harmonisation and the guidelines on Good Pharmacopoeial Practices.

66. BP staff attended the 64th and 65th WHO Consultations on International Nonproprietary Names (April and October). There has been a significant increase in the number of names requested for biological substances in recent years, with about half of new names now being for biologicals.

67. BP staff participated in discussions with representatives from the United States Pharmacopeia in January to expand the current successful joint working between the BP and the USP, in particular the ongoing project to revise monographs containing outdated technology. Several groups of monographs had been selected for revision in future publications.

68. The BP continues to work on informal prospective harmonisation projects, with monographs harmonised with the USP and the International Pharmacopoeia scheduled for publication in the BP 2019. Collaboration with both the US and International Pharmacopoeias to update a number of individual and family monographs is also on-going.

69. Representatives from the BP attended meetings with various US groups and manufacturers during a visit to Washington DC in March. The BP gave an overview of the MHRA/BP Analytical Quality by Design feasibility study and an update on the progress of the MHRA/BP consultation on biologicals.

70. The BP participated in the Joint Compendial meeting organised in association with the US Consumer Healthcare Products Association. Updates on current and future BP activities, including the consultations on Biologicals and Dissolution and the BP Customer Insight Survey, were provided. These meetings provide a useful means of sharing information and will be continued.

71. In a reciprocal arrangement, following the visit of two members of staff from the BP-NIBSC Herbal Laboratory to the Chinese Pharmacopoeia (CP) in 2015, a member of staff from the CP visited the MHRA and NIBSC for 4 weeks during the year.

72. BP staff attended the CPhI Annual Conference in Shanghai, China, in June which provided an opportunity to gain an understanding of the current and future pharmaceutical landscape of China. BP and MHRA staff members were able to participate in presentations at the conference and meet with the organising group from the China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCMHPIE).

73. The BP participated in an MHRA meeting with the CCCMHPIE and China industry in October. A number of issues had been discussed including the registration of traditional herbal medicines, control of medical devices, Licensing and Inspection requirements and the development of BP monographs.

74. Teleconferences were held with the Australian Therapeutic Goods Administration Office of Laboratories and Science Services in April and September to discuss knowledge sharing and organisational updates. In addition to the existing arrangement whereby the TGA assisted in the development and revision of BP monographs by acting as a second laboratory to assess the robustness of proposed methods, TGA had begun verification analysis for the MHRA/BP Analytical Quality by Design feasibility study.

ACKNOWLEDGEMENTS

75. The Commission wishes to place on record its heartfelt thanks to Dr Rodney Horder, who retired from the British Pharmacopoeia Commission at the end of the year after 16 years of service. Dr Horder had made a significant contribution to the work of the British and

European Pharmacopoeia Commissions and would be continuing with some of his pharmacopoeial activities.

76. 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.

77. 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.

78. The Commission wishes to acknowledge the advice of the publishing team at The Stationery Office in the production of the British Pharmacopoeia 2018, the British Pharmacopoeia (Veterinary) 2018 and Supplement No. 1 to British Approved Names 2017.

79. 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.

80. Dr Patience Holland and Dr Rosemary Pask-Hughes retired from the Secretariat during the year. The Commission wishes to place on record its gratitude to Dr Holland and to Dr Pask-Hughes for their long service to the BP, both of whom had been members of the Secretariat for over 25 years.

AWARDS

81. The Commission was pleased to note the following: Mr Robert Lowe, a member of the Commission, had been appointed as a Fellow of the Royal Pharmaceutical Society.

OBITUARY

82. It was with sadness and regret that the Commission learnt of the death of Professor Derek Calam. Professor Calam had been a member of the British Pharmacopoeia Commission for 23 years, and had served as its Chair for two terms. He had continued serving on the Expert Advisory Group on Biological and Biotechnological Products after retiring from the Commission and had made an exceptional contribution to the work of both the British and European Pharmacopoeias for many years.

APPENDIX I

MEMBERSHIP OF THE BRITISH PHARMACOPOEIA COMMISSION DURING 2017

Chair

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

Members

Professor Matthew Almond BSc DPhil DSc CChem FRSC PFHEA NTF
Professor of Chemistry Education, University of Reading

Dr Jon Beaman BSc PhD MBA CChem MRSC
Head of Development Analytical Group, Pfizer UK

Dr Anna-Maria Brady BSc PhD
Former Head of Biologicals and Administration, Veterinary Medicines Directorate

Dr Graham D Cook BPharm PhD MRPharmS
Senior Director, Process Knowledge/Quality by Design, Pfizer

Dr Andrew Coulson BVetMed MSc MRCVS MA
Member of the Royal College of Veterinary Surgeons; Non-Executive Director, Veterinary Medicines Directorate; former Superintending Inspector, Science & Research Group, The Home Office

Professor Alastair G Davidson BSc PhD FRPharmS **(Vice-Chair)**
Visiting Professor of Pharmaceutical Sciences, University of Strathclyde

Dr Alison Gleadle BSc PhD **(Lay representative)**
Former Group Product Risk Director, Tesco Stores Ltd.

Dr Rodney L Horder[1] 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

Mr Robert Lowe BPharm FRPharmS
Director of Pharmacy Quality Assurance Specialist Services, NHS East of England & Northamptonshire

[1] Retired, 31st December 2017.

Dr Brian R Matthews BPharm PhD FRPharmS FTOPRA
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

Ms Sharon Palser MSc **(Lay representative)**
Former Director of Development, NHS Plymouth

Professor Monique Simmonds OBE JP BSc PhD FLS FBS FRES FWIF
Deputy Director of Science, Royal Botanic Gardens, Kew

Dr Ronald Torano BSc PhD MRSC CChem
Pharmacopoeial Intelligence and Advisory Specialist; GlaxoSmithKline

Dr Paul Varley BSc PhD
Vice President of Biopharmaceutical Development, Medimmune Limited

Secretary and Scientific Director

Dr Samantha Atkinson[2] BSc MSc PhD MRSC
Group Manager, British Pharmacopoeia and Laboratory Services, MHRA; Visiting Fellow, University of Reading

Mr James Pound[3] BSc
Group Manager, British Pharmacopoeia and Laboratory Services, MHRA

[2] Seconded as Director of Business Transformation, MHRA, from 1st July 2017
[3] From 1st July 2017.

APPENDIX II

MEMBERSHIP OF EXPERT ADVISORY GROUPS, PANELS OF EXPERTS AND WORKING PARTIES OF THE BRITISH PHARMACOPOEIA COMMISSION DURING 2017

EXPERT ADVISORY GROUPS

ABS: Antibiotics	R L Horder (**Chair**), G D Cook (**Vice-Chair**), G Blake, P Ellis[1], E Flahive, V Jaitely, W Mann, J Miller, M Pires, I R Williams
BIO: Biological and Biotechnological Products	P Varley (**Chair**), A-M Brady (**Vice-Chair**), L Bissett*, A F Bristow[1]*, C Burns, D H Calam[2], K Chidwick*, A Cook*, J Cook*, S Gill, E Griffiths, C Jones*, A Kippen*, K Nordgren*, B Patel, A M Pickett*, T Pronce, L Randon, I Rees*, S Schepelmann*, D Sesardic, P Sheppard, P Stickings*, A H Thomas, R Thorpe, L Tsang, M Wadhwa*
HCM: Herbal and Complementary Medicines	M Simmonds (**Chair, *from June***), R Middleton (**Vice-Chair, *from July***), L A Anderson (*Vice-Chair, until July*), P Anderson, A Bligh[1], A Booker, S Gibbons[1], C Leon, B Moore, M Pires, E Reich, M Rowan, A Slater, K Strohfeldt-Venables, J Sumal*, E Williamson (*Chair, until June*), 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[1], J C Berridge, M Broughton[1], E Bush, A J Caws, D Deutsch, P Fleming, E Gray, A James[1], W J Lough, D J Malpas
MC2: Medicinal Chemicals	G Cook (**Chair**), C T Goddard (**Vice-Chair**), K Bracht, J Cowie, D Edwards, J Lim, J Miller, P Murray, A Ruggiero, M Turgoose, N Wynne (*Corresponding members* M Brits, W Sherwin)
MC3: Medicinal Chemicals	V Fenton-May[3] (**Chair, *until September***), M Almond (**Vice-Chair; Chair, *from October***), 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, A McFarlane, 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, J Lim*, R A Lowe, J MacDonald, A McFarlane, 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**), S Branch, D Caulfield, W Goddard, S Hartley, N Hussain[1], J Rickard, M Santillo, J Smith, A Sully, P Weir, M Westwood

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[1], R Cawthorne, D Deutsch, N Hussain[1]
DNA: Identification Techniques	A Slater (**Chair**), I Feavers, J Hawkins, E Mee, E Williamson
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
RAD: Radioactive Materials	J Brain, D Graham, G Inwards, R D Pickett, R Smith,
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, M Chatfield, S Ellison, M Hanna-Brown, C Gray, S Jones, P Nethercote, E Razzano (*Corresponding members* K Barnett, B Harrington, W Sherwin)

MCS: Microscopy	E Williamson (**Chair**), R Arroo, R Fleck, K Helliwell, K Maclellan Gibson

AD-HOC GROUP

New Analytical Technologies	M Almond, J Beaman, G Cook, J Miller, R Torano, M Simmonds

[1]*Resigned during the year*.
[2]*Deceased.*
[3]*Retired during the year.*
** Specialist member*.

APPENDIX III

MEMBERS OF THE BRITISH PHARMACOPOEIA COMMISSION STAFF DURING 2017

SECRETARY AND SCIENTIFIC DIRECTOR / EDITOR-IN-CHIEF

Mr J Pound (*from 1st July*)

SECRETARIAT

Mr S Young (*Head of Analytical Science*)
Ms H Corns
Mr P Crowley
Mr A Evans
Dr A Gardiner
Mr A Gibb
Ms S Gomersal
Dr P Holland (*until July*)
Dr G Kemp
Dr C Lenihan (*from March*)
Ms G Li-Ship
Mr S Maddocks (*from September*)
Mr H Makwana (*from August*)
Dr R A Pask-Hughes (*until February*)
Dr K Radi (from April)
Dr F J Swanson
Ms M-L Wall
Mr M Whaley

DH STAFF

Ms E Cotterill (*March to August*)
Mr J Parker (*from September*)
Mr J Ware (*until March*)

NIBSC BASED STAFF

Mr L Gibson
Ms C Gkouva
Dr C Howard
Ms M Kalantarzadeh
Ms C Lockie-Williams

LABORATORY MANAGEMENT BOARD

Dr S Atkinson (*Secretary and Scientific Director, BP, until July)*
Mr J Pound (*Editor-in-Chief and, from July, Secretary & Scientific Director, BP)*
Mr S Young (*Head of Analytical Science, BP)*
Mr M Whaley (*Laboratory Services Manager, BP*)
Dr R Adams (*Service Delivery Manager, LGC*)
Mr P Bedson (*Operations Director, LGC*)
Dr D Craston (*Chief Scientific Officer, LGC*)

ADMINISTRATIVE

Mr B Delahunty
Mr M Chaudhry (*January to October*)
Ms A Korzeniowska
Miss J Paine
Ms U Rothna (*from September*)

APPENDIX IV

BRITISH PHARMACOPOEIA COMMISSION PUBLICATIONS DURING 2017

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

British Pharmacopoeia 2018 package

Consisting of:-

British Pharmacopoeia 2018

British Pharmacopoeia (Veterinary) 2018

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APPENDIX V

EUROPEAN PHARMACOPOEIA COMMISSION

MEMBERS OF THE UNITED KINGDOM DELEGATION DURING 2017

Main: S Atkinson, A G Davidson, K M G Taylor

Alternates: R L Horder, J Pound

MEMBERS OF GROUPS OF EXPERTS FROM THE UNITED KINGDOM DURING 2017

Group 1	Biological Methods and Statistical Analysis	V Fenton-May (***Chair***), V Jaitely[1], I Venet
Group 6	Biological Substances	C Burns, B Cowper (*Specialist*)
Group 6B	Human Blood and Blood Products	A R Hubbard
Group 7	Antibiotics	V Jaitely[1] (*Specialist*), J Sumal
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)	E Bush
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 L Horder (***Chair***), S Wicks, G Nichols[1] (*Specialist*)
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 DURING 2017:

Alkyl Mesilates (*dormant group*)	J Midgley (***Chair***)
Allergens	A Cook
Bacterial Endotoxins Test	K Nordgren
Cell Therapy Products	G Stacey
Chromatographic Separation Techniques	S Young
Chairs of Chemical Groups	A G Davidson, M G Lee
Dialysis Solutions	M G Lee (***Chair***)
Extracts	K Helliwell (***Chair***), L Anderson, M Pires
Excipient Performance	C Mroz
General Methods	A G Davidson (***Chair***)
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 (*dormant group*)	A Kippen
Inhalanda	K M G Taylor
Live Biotherapeutic Products	A Stevenson
Monoclonal Antibodies	P Varley, S Prior, M Wadhwa
Paediatric Formulary	K Bracht, N Hussain[1], A Nunn
Pharmaceutical Preparations (*dormant group*)	V Fenton-May (***Chair***), M G Lee
Procedure 4 for Biologicals	M Wadhwa

Process Analytical Technology	I Lynch
Raw Materials for the Preparation of Cellular and Gene Therapy Products (*dormant group*)	L Bisset
Rules of Procedure (*dormant group*)	J Pound
Special Revision Programme (*dormant group*)	A Evans
Standard Terms	M Ahmed
Statistics (*dormant group*)	R Gaines Das
Sutures	L Ferris
Traditional Chinese Medicines	M Whaley[1]
Vibrational Spectroscopy and Analytical Data Modelling	I Lynch[1] (*Specialist*)
Water for Pharmaceutical Use	M G Lee (***Chair***)

[1]*Resigned during the year*.

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

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.

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.

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.

INTERESTS WHICH NEED TO BE DECLARED

Summary of interests that need to be declared

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

- Their own financial interests in the pharmaceutical industry; (financial interests are either personal or non-personal, and either specific to the product being discussed, or non-specific);
- Financial interests in the pharmaceutical industry held by members of their immediate family;
- Any other matter that could affect their impartiality, or that could reasonably be perceived as affecting their impartiality. Some examples of interests that are relevant in the context of this Code of Practice, not all associated with the pharmaceutical industry, are set out in section 4.7 below.

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

Personal interests

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

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

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

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

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

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

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

Personal interests - special rules applicable to the CHM and the Committees

4.4 The chairman and members of the CHM, HMAC and ABRHP serve on the committees that provide advice direct to the Licensing Authority. For this reason, they are not permitted to hold any current personal interests in the pharmaceutical industry. This policy also applies to the chairmen of the Pharmacy and Standards EAG, the Pharmacovigilance EAG and the Biologicals and Vaccines EAG by virtue of their membership of the CHM. The chairmen and members of the CHM and the chairmen and members of the HMAC and ABRHP, and the chairmen of the three EAGs specified are required to make a declaration on appointment that they are disposing /have disposed of any such current personal interests.

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

Non-personal interests

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

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

Support by the pharmaceutical industry or any other relevant industry: any payment, other support or sponsorship by the pharmaceutical or other industry that does not convey any pecuniary or

material benefit to the individual personally but that benefits his/her position or department;

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

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

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

Other relevant interests

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

- An individual, or his department, has done research work relating to a particular product, or class of products. Although the research has not been funded by any particular pharmaceutical company, the research has taken a particular line e.g. in relation to the safety of the products, or their efficacy;
- An individual has made public statements (either favourable or unfavourable) about a particular company, or product, or class of products or about a competitor's product or class of product;
- The relevant committee is considering whether a product should be reclassified e.g. from prescription only, to a pharmacy medicine, and the individual has a particular interest in the reclassification being made e.g. because he is a retail pharmacist and he will benefit financially;
- An individual participates in, or is connected with, a charity or pressure group that would have an interest in the outcome of the advice being given;
- An individual has a family member who suffers from an illness who would benefit from treatment if a product under discussion were to be authorised;
- An individual has a family member who has suffered a severe reaction or other problem as a result of treatment with a product under discussion;

- Matters relating to persons who are not immediately family members, but are closely connected with the committee expert e.g. adult child no longer living in the same household, or non-family member whose work or other interests are closely associated with the pharmaceutical industry and which could reasonably be perceived as affecting the individual's impartiality. An example might be where a committee is giving advice in relation to a product and a close family member or friend has had a major development responsibility for that product;
- Interests in a company manufacturing the delivery system (e.g. syringes or other medical equipment) for a particular medicinal product;

Attendance at conferences, scientific meetings and similar

4.8 Government recognises that it is usual for conferences, scientific meetings and other events associated with healthcare, medicines or related matters to receive some form of sponsorship either directly, or indirectly via a special fund, from the pharmaceutical industry. Government also recognises the importance of being able to receive advice from leading experts who are able to keep themselves up to date with developments at the cutting edge of science, and that this is mainly done through attendance at educational and scientific events and meetings. It is therefore essential to set out rules for attendance at these and similar events as questions may be legitimately raised as to whether participation in the event, or even mere attendance, will compromise their impartiality in any way. This is particularly important in respect of chairmen and members of the CHM, HMAC and ABRHP (including the chairmen of the Pharmacy and Standards EAG, the Pharmacovigilance EAG and the Biologicals and Vaccines EAG) who, as set out above, are not permitted to hold personal interests in the pharmaceutical industry.

4.9 The nature of the events that fall within the scope of this Code of Practice and the industry sponsorship received can vary widely from, at one extreme, a conference sponsored by a single company to launch a product to, at the other extreme, a scientific meeting organised by a learned society that has received some financial support from a number of companies paid into a dedicated meeting fund. Between these extremes there are many variations in events and funding that may occur.

4.10 In order that the chairmen and members of CHM, HMAC, ABRHP and the three EAG chairmen specified in paragraph 4.8 above should be able to attend appropriate scientific events to keep their knowledge up to date, the MHRA has established a discretionary fund to meet the reasonable expenses (e.g. travel and accommodation costs) incurred in their attendance. The relevant MHRA committee secretariat will administer the fund, and chairmen and members wishing to claim the costs of attendance at such events must make an application in good time to enable appropriate travel and other arrangements to be made. The fund will cover educational events that are relevant to maintaining the

expertise of individuals serving on the CHM, HMAC, ABRHP and the three specified EAGs, where acceptance of financial support from industry (for example a single pharmaceutical company) would not be appropriate. Separate guidance on the allocation of resources from the fund has been developed for use by the MHRA secretariat.

4.11 In some cases it will permissible for members of CHM, HMAC, ABRHP or the EAG chairmen to attend events sponsored by the pharmaceutical industry (and accept the payment of their expenses) without recourse to the MHRA discretionary fund. For example, where a learned society holds an international conference that is sponsored by a number of different pharmaceutical companies, it will generally be acceptable for the member to accept such an invitation and to receive payment of expenses, although in such instances declaration of attendance and receipt of funding must be declared in the normal way.

4.12 If funding and/or expenses are paid specifically for an individual's attendance but nevertheless paid to his department rather than the individual himself, it will not normally be acceptable for the individual to attend.

4.13 Benefits of this nature paid to an immediate family member that also benefit the committee chairman or member (e.g. a company pays his or her flight costs so that the he or she can attend a conference with a family member) must be declared as the individual's own interest. However, there is no requirement to declare educational conferences and similar events attended by immediate family members.

4.14 If an individual attends an educational conference or similar, he or she should avoid participation in, for example, "satellite" meetings sponsored and arranged by specific companies or focusing on specific products where involvement in discussions might reasonably be perceived as affecting his or her impartiality. If in doubt, this must be raised with the MHRA Secretariat at the earliest possible opportunity, who will be able to provide further guidance.

4.15 The rules for holding personal interest in the pharmaceutical industry do not apply to chairmen and members of EAGs, apart from chairmen of the 3 EAGS described at paragraph 4.8 above, and for the reasons set out in paragraph 4.4 above. Therefore, these experts may attend meetings sponsored by the pharmaceutical industry and accept funding of expenses, but these must be declared.

4.16 Attendance at conferences, scientific meetings and other events relevant to this Code must be declared at the first meeting of the committee after the event has taken place. This declaration may affect an individual's participation in discussions over the subsequent months. The declarations will be published annually in the report of the work of the committees.

4.17 The situations described are not exhaustive and individuals should always seek advice from the MHRA Secretariat if they are in any doubt about whether or not they should attend, or whether, having attended, they need to declare attendance as an interest.

SPECIAL POSITION OF EXPERTS ATTENDING FOR THE DAY AND EXPERTS CALLED TO ADVISE THE COMMITTEES ON SPECIFIC ISSUES

5.1 Experts who are invited to attend committees for the day, for example if a regular member cannot be available or cannot participate in discussions because of his or her interests, are known as “Experts for the Day”. They are co-opted as full members of the committee for that day, may participate fully in all discussions and may vote. They are therefore required to make a full declaration of interests in the same way as is required of a full member of that committee. Experts called to advise a committee on particular issues may not hold interests in the issue under discussion.

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.

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.

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.

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	Contsultancy with payment to Univeristy of Edinburgh	No	Three other commercial studies have been ongoing with the department during 2017 which are being run by other Consultants. These are supported by Novartis, GlaxoSmithKline, Abbvie and Roche. I have no involvement in these studies whatsoever and only mention them for completeness.
			Eli Lilly	Research grant to University of Edinburgh, and enrollment of patients into a clinical trial (Payment to NHS Lothian)		
			Ultragenyx	Enrollment of patients into a clinical trial. Lead investigator (Payment to NHS Lothian)		
			Abbvie	Enrollment of patients into a clinical trial. Lead investigator (Payment to NHS Lothian)		
			Gilead	Enrollment of patients into a clinical trial. Lead investigator (Payment to NHS Lothian)		
			Pfizer	Enrollment of patients into a clinical trial. Lead investigator (Payment to NHS Lothian)		
			Amgen/UCB Pharma	Enrollment of patients into a clinical trial. Lead investigator (Payment to NHS Lothian)		

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			UCB Pharma	Research grant to Edinburgh University		
Mrs Eileen Barrett	None	None	None	None	No	None
Dr J Colin Forfar	None	None	None	None	No	None
Dr Jamie Fraser	None	None	None	None	No	None
Professor Jonathan S Friedland	None	None	None	None	No	None
Dr Richard J C Gilson	None	None	ViiV	Antiretroviral therapies - My department is a collaborating site in clinical trials	Yes	None
			Pfizer	Maraviroc - UK Chief Investigator for one commercial trial, now complete. Chief investigator for one investigator-initiated study which is now compelte. My department is now conducting another clinical trial with this product.	Yes	
			Gilead Sciences	Antiretroviral therapies - My department is a collaborating site in clinical trials, and has funding for one investigator-initiated study. I am a site principal investigator for one clinical trial.	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Merck	Antiretroviral therapies - My department is a collaborating site in clnical trials	Yes	
			Janssen	Antiretroviral therapies - My department is a collaborating site in clnical trials	Yes	
			Mylan	I am a site principal investigator for one clinical study using a Mylan product, funded by NHS England.	Yes	
			GlaxoSmithKline	Antiretroviral therapies - My department is a collaborating site in clinical trials	Yes	
Professor Martin Gore	None	None	None	None	No	None
Professor Malcolm R Macleod	Charles River	Travel and subsistence expenses	Janssen Pharmaceutica NV	Co-supervise 2 PhD student,; Co-applicants on funded IMI consortium - see additional information	Yes	I am the coordinator of the EQIPD consortium, which receives funds from IMI 2 Call 9 Topic 3, Data Integrity. This is a stage 2 application. In stage 1 academic consortia submit proposals against the bid, form which one is selected to go forward to stage 2. In stage 2 the academic consortium joins with pharmaceutical companies to submit a revised bid. On 4th October we were informed that we were successful in stage 1, and so the expanded consortium came into being. Our stage 2 application was submitted on
			AbbVie Inc	Co-applicants on funded IMI consortium - see additional information	Yes	
			Boehringer Ingelheim International GmbH	Co-applicants on funded IMI consortium - see additional information	Yes	
			Novartis Pharma AG	Co-applicants on funded IMI consortium - see additional information	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Orion Corporation	Co-applicants on funded IMI consortium - see additional information	Yes	19th January, with a final positive funding decision made in April 2017. The funding mechanism for IMI is 50% funding from the EU, with 50% coming in cash or in kind from the EFPIA partners listed here, with total resource around €9m. 2 Junior researchers would be shared between my department and Janssen, with their salary paid by University of Edinburgh and 50% reimbursed to the University of Edinburgh from Janssen. This is described in the application and
			F. Hoffmann-La Roche Ltd	Co-applicants on funded IMI consortium - see additional information	Yes	
			Institut De Recherches Servier S.A.S	Co-applicants on funded IMI consortium - see additional information	Yes	
			UCB Biopharma SPRL	Co-applicants on funded IMI consortium - see additional information	Yes	
			Pfizer Limited	Co-applicants on funded IMI consortium - see additional information	Yes	
			PsychoGenics Inc.	Co-applicants on funded IMI consortium - see additional information	Yes	
			Sanofi-Aventis Research and Development	Co-applicants on funded IMI consortium - see additional information	Yes	
Dr Rebecca Mann	None	None	Ablynx	Medicinal product under investigation vs RSV infection - PI for ongoing study	Yes	None
Professor Sarah Meredith	None	None	Abbott	Lopinavir - Grant & product donated for trail. Ritonavir - Grant & product donated for a trial, financial support for a virology sub-study	No	None
			Astellas	Enzalutamide - Grant & product donated for a trial		

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			AstraZeneca	Cediranib - Grant & product donated for a trial. AZD 8931 - Product donated for a trial		
			Bayer	Sorafenib - Grant & product donated for a trial. Aspirin - Product donated for a trial		
			Boehringer Ingelhein, Bristol-Myers Squibb	Efavirenz, Atripla - Grant & product donated for a trial. Atazanavir - Product donated for a trial		
			Cipla	Albendazole, Azithromycin, Cotrimoxazole/Isonaiozid /Pyridoxine, Fluconazole, Efavirenz, Nevirapine, Lapimune Minitabs, Zidobudine/Iamvidune, Aabacavir/Iamividune, Stavudine/Iamivudine - Products donated for a trial		
			Gilead Sciences	Tenofovir, Emtricitabine, Atripla - Grant & product for a trial. Truvada - Product donated for 4 trials, grant for the Proud study. Efavirenz & Tenofovir (Viread) - Products donated for a trial.		
			GlaxoSmithKline	Lapatinib & Abacavir, Zidovudine, Lamivudine - Grant and Products		

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			GlaxoSmithKline	donated for a trial. Abacavir, Lamivudine - Product donated for a trial. Zidovine, Lamivudine & Abacavir & Lamivudine & Combivir & Kixeva & HIV Conserve Vaccine - Product donated for a trial.		
			Janssen	Bedaquiline - Grant & product donated for trial		
			Janssen-Cilag	Abiraterone - Grant & product donated for trial		
			Lilly	Gemcitabine - product donated for trial		
			Merck	Topotecan & Pegylated interferon & Doxoirubicin & Efavirenz - products donated for a trial. Temozolomide & Virinostat - Grant & product donated for a trial.		
			Pilatus	Amoxycvillin - product donated for a trial		
			Roche	Bevacizumab - Grant & product donated for a trial		
			Sanofi-Aventis	Docetaxel - Grant & product donated for a trial		
			Sanofi Pasteur	NYVAC C - Product donated for a trial		
			Tibotec	Darunavir - Product donated for a trial		

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Virco	Resistance-tests - Product donated for a trial		
			WHO/GDF	Clofazimine - Product donated for a trial		
			Emergent Biosolutions	Hyperimmune IVIG - Product donated for a trial		
Dr Siraj Misbah	None	None	No	None	No	I delivered an iunvited talk on PML at the Immunology Gotum (Royal Society June 2017) sponsored by Biotest foir which neither my department nor I received an honorarium or travel/accomodation expenses.
Professor David G C Owens	None	None	None	None	No	The Division of Psychiatry, University of Edinburgh, in which I am based, is part of the Centre for Clinical Brain Sciences, an administrative arrangement comprising a 'centre without walls', and including over 50 individuals actively involved in all aspects of CNS research, from basic sciences to clinical. I have no direct or indirect involvement with any indidivudals or projects in receipt of commercial funding.
Professor Sir Munir Pirmohamed	None	None	Astra Zeneca	Research grant to support PhD in Pharmacovigilance	No	None
			Eli Lilly	Research grant to support clinical training fellowships jointly with MRC	No	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Novartis	Research grant to support clinical training fellowships jointly with MRC	No	
			Roche	Research grant to support clinical training fellowships jointly with MRC	No	
			UCB Pharma	Research grant to support clinical training fellowships jointly with MRC	No	
			Bristol Myers Squibb	Unrestricted educational grant to support UK pharmacogenetics and stratified medicine network open meeting	No	
Professor Shirley Price	None	None	None	None	No	None
Professor Kevin M G Taylor	None	None	AstraZeneca	Contribution to EPSRC Doctoral Training Centre in my department	No	None
			Boots	Contribution to EPSRC Doctoral Training Centre in my department	No	
			Pfizer	Contribution to EPSRC Doctoral Training Centre in my department	No	
			GlaxoSmithKline	Contribution to EPSRC Doctoral Training Centre in my department	No	
			Quadrant	Contribution to EPSRC Doctoral Training Centre in my department	No	

	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	None	None	None	None	No	I am chair of the Trial Stering Group for the MATCH trial (Macrophage Therapy for Liver Cirrhosis). Co-sponsors: University of Edinburgh & NHS Lothian; Accord, The Queen's Medical Research Institute, 47 Little France Crescent, Edinburgh EH16 4TJ. Funded by Medical Research Council; Chief Investigator Professor Stuart Forbes. No remuneration or expenses.
Mrs Helen M Ward	None	None	None	None	No	None
Professor 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	
			Eli Lilly	Teriparatide - Research grant to institution, on which I am co-applicant	Yes	
Dr Martin Wilson	None	None	None	None	No	I am involved in four pieces of Research none of which have drug company sponsors. PD Med Trial - A large randomised assessment of the relative cost-effectiveness of different classes of drugs for Parkinson's disease. Funded by the NHS Health Technology Assessment programme and is supported by the European Parkinson's Disease

MEMBER	PERSONAL INTERESTS		NON-PERSONAL INTERESTS		WHETHER CURRENT	ADDITIONAL INFORMATION
	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS		
						the Parkinson's Disease Society and the Parkinson's Disease Nurse Specialists Association. Hosted by Birmingham Clinical Trials Unit. Running since 1999. I am the local principal investigator (taking over from my predecessor in 2005) this involves follow up of a single patient. Proband - Parkinson's Repository of Biosamples and Network Datasets: Prospective Observational Study of Parkinson's Disease with Repeat Clinical Assessment and Biobanking of Blood Samples Funding. Sponsored and based in NHS Greater Glasgow and Clyde. Funded by PD Society. I am local principal investigator with assessments carried out by PD nurse and Research nurse. Simpathy - Stimulating Innovation in Management of Polypharmacy and Adherence in the Elderly. Funded by European Union Health Programme. Research looking at the development of Polypharmacy programmes in different European regions. I am part of the Scottish Government team on this. Funding for travel and accomodation for meetings.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						Prescribing Outcomes for Implementing Enhanced Medication Summaries (POEMS) - Funded by CSO grant. I am on advisory board for this study. Other - I am a regular speaker at Royal Colleges, Regional Speciality meetings on a range of subjects including management of Polypharmacy. I receive travel and accomodation reimbursement. None of the meetings have been solely drug sponsored.
Mrs Madeleine Wang (Invited Expert)	None	None	None	None	No	None

N.B - Concerning Professor Malcolm Macleod's Personal Interest
The travel and expenses claims were repaid in full. Dr Macleod took no part in any relevant discussion between December 2017 (when MHRA was made aware of the interest) and March 2018.

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 J Forfar (Chair)	None	None	None	None	No	None
Dr Amanda Adler						
Dr Iolo J Doull	Astra Zeneca	Non-promotional lecture on childhood asthma for which I received a fee	None	None	No	None
Dr John Firth	None	None	Amgen	Aranesp, Mimpara - Support of renal acadaemia service/research and renal mineral and bone disease studies and of renal education meetings	No	None
			Astellas	Advagraf. Prograf - Support of renal transplantation service/research and of renal educational meetings	No	
			Genzyme	MabCampath, Renagel, Renvela, Thymoglobuline - Support of renal mineral and bone disease studies and of renal educational meetings	No	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Novartis	Sandimmun, Simluect - Support of renal transplantation service/research and of renal educational meetings	No	
			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.	No	
			Shire	Calcichew, Fosrenal - Support of renal mineral and bone disease studies and of renal educational meetings	No	
			Wyeth	Rapamune - Support of renal transplantation service/research and of renal educational meetings	No	
Dr Andrew Grace	None	None	None	None	No	None
Professor Wasim Hanif	Novo Nordisk	Grants, Consultancy - Degludec & Liraglutide	None	None	No	None
	Astra Zeneca	Grants, Consultancy - Dapagliflozin & Bydueron				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Boehringer Ingelheim	Grants, Consultancy - Empagloflozin & Linagliptin				
	Janssen	Grants, Consultancy - Cannagliflozin				
	Sanofi	Grants, Consultancy - Lixesenatide				
Dr Philip W Ind	Astra Zeneca	Ticagrelor - Attended departmental breakfast meeting	None	None	No	None
	Chiesi	Trimbow - Attended staff round meeting sandwich lunch				
Dr Patrick Mark	Astra Zeneca	Consultancy - ZS-9	Astra Zeneca	Dapagliflozin - research funding to institute	No	None
	Janssen	Non product specific lecture at national professional meeting	Boehringer Ingelheim	Empagliflozin - research funding into institute	No	
	Vifor	Consultancy - Patiromir, Ferriject				
Professor Theresa McDonagh						
Professor Ann Millar	None	None	Boehringer Ingelheim	Part time funding of MSc student	Yes	None
Professor Hilary Pinnock	Circle Partnerships	Private Healthcare - 1500 'Restricted' Shares in Circle in recognition of the contribution the practice has made to developing care pathways	None	None		Primary Care Respiratory Society-UK. (A registered charity that receives financial support from a number of pharmaceutical and respiratory device companies). I am a member of the research sub-committee - some of the projects are supported by unrestricted grants from respiratory

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Teva	Guidelines in Practice' Webinar - Honorarium for delivering a non-promotional presentation on asthma guidelines				interested Pharmacetical companies. International Primary Care Respiratory Group. (A registered charity that receives financial support from a number of pharmaceutical and respiratory device companies). I am education lead - some of the projects are supported by unrestricted educational grants from respiratory interested Pharmaceutical companies. 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 coordinator for this initiative which is supported by unrestricted educational grants from respiratory interested Pharmaceutical companies
Professor Pallav Shah	Olympus	Consultancy	ERBE	Sponsor Impreial College for Bronchoscopy course	No	None
	PneumRX/BTG	Lecture/workshop/ consultancy - RePneu lung volume reduction coils	Cook Medical	Sponsor Impreial 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	Consultancy/lecture - Endobronchial valves for emphysema (Zephyr)	Immotech	Sponsor Impreial College for Bronchoscopy course	No	
	Nuvaira	Consultancy/lecture - Trageted vagal nerve ablation	Coveidien	Sponsor Impreial College for Bronchoscopy course	No	
	CSA Medical	Consultancy/lecture - RejuvenAlr	Olympus	Sponsor Impreial College for Bronchoscopy course	No	
			PneumRX	Sponsor Impreial College for Bronchoscopy course	No	
			Pulmonx	Sponsor Impreial College for Bronchoscopy course	No	
			Pulmonx	RCT with endobroncial coils Royal Brompton Hospital and Chelsea & Westminster Hospital reimbursed for clinical trial expenses	Yes	
			PneumRX/BTG	RCT with endobroncial coils Royal Brompton Hospital and Chelsea & Westminster Hospital reimbursed for clinical trial expenses	Yes	
			Nuvaira	RCT with endobroncial coils Royal Brompton Hospital and Chelsea & Westminster Hospital reimbursed for clinical trial expenses	Yes	
			CSA	RCT with RejuvenAir Chelsea & Westminster Hospital reimbursed for clinical trial expenses	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Caroline Vaughan	None	None	None	None	No	None
Mr Phil Willan	None	None	None	None	No	None
Professor Sarah Wild	Novo Nordisk	Accomodation for Scottish study group for Diabetes in the Young meetings	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 H Taylor (Chair)	None	None	AstraZeneca	Contribution to EPSRC Doctoral Training Centre in my department	No	None
			Boots	Contribution to EPSRC Doctoral Training Centre in my department	No	
			Pfizer	Contribution to EPSRC Doctoral Training Centre in my department	No	
			GlaxoSmithKline	Contribution to EPSRC Doctoral Training Centre in my department	No	
			Quadrant	Contribution to EPSRC Doctoral Training Centre in my department	No	
Professor Michael E Aulton	Actelion	Fees and patent advice	None	None	No	None
Professor Graham Buckton	Teva	Consultancy Work	None	None	No	None
	Lupin	Consultancy - Meloxicam				
	GlaxoSmithKline	Consultancy Work				
	Silvergate	Consultancy - Enalapril				
	Impax	Consultancy - Formulation				
	Par	Consultancy Work				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Plant Impact	Consultancy - Agrochemical Formulation				
	Mylan	Consultancy - Nalaxone				
Professor Derek Calam						
Professor Brian J Clark	None	None	None	None	No	None
Professor Ruth Duncan	None	None	None	None	No	None
Mr V'Iain G Fenton-May	None	None	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 E Knott	Windcliff Management	Owner and Managing Director - Healthcare Consultancy business undergoing project work across the NHS, private hospitals and pharma industry.	None	None	Yes	Currently a Lay Member and Chair of Finance and Procurement committee for Nottingham west CCG. Locum pharmacist at the BMI Park Hospital Nottingham
	Baxter Healthcare	Shareholder			Yes	
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 and Europe.
Mr Robert Lowe	None	None	None	None	No	None
Professor Christopher Marriott	Halation Ltd	Directorship, fees, shares	None	None	No	My wife, Mrs Ann Marriott, has shares in Vectura Ltd, Medpharm Ltd and Halation Ltd.
	Medpharm Ltd	Shares				
	Remedica Ltd	Directorship, fees				
	Vectura Ltd	Shares				
Professor Yvonne Perrie	None	None	Colorcon	Grant to Aston University	No	None
			GlaxoSmithKline	EU Grant to University of Strathclyde	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			AMRI	Knowledge exchange contract (grant) from company to University of Strathclyde	Yes	
			Encap/Capsugel/ Lonza	KTP grant to University of Strathclyde	Yes	
			Pfizer Inc, Astra Zeneca, Precision Nanosystems, Centre for process Innovation Ltd, Malvern Instruments, Croda	Contract for grant signed in December 2017 (starts March 2018) which includes contributions from listed companies to University of Strathclyde.	Yes	
			Diagenode	Grant to Aston University	Yes	
			Microfluidics	Loan of free equipment to University of Strathclyde	Yes	
			Academy of Pharmaceutical Sciences (APSGB)	Executive board member (non-salary)	Yes	
			Precision Nanosystems	Advisory board member (non-salary)	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	Shares	Aquinox	Funded project at Crystecpharma	No	None
	Crystecpharma	Director, Shares	Biogen	Funded project at Crystecpharma	No	
	Lena Nanoceutics	Director				

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	None	None	No	I am chair of the Trial Stering Group for the MATCH trial (Macrophage Therapy for Liver Cirrhosis). Co-sponsors: University of Edinburgh & NHS Lothian; Accord, The Queen's Medical Research Institute, 47 Little France Crescent, Edinburgh EH16 4TJ. Funded by Medical Research Council; Chief Investigator Professor Stuart Forbes. No remuneration or expenses.
Professor Farzin Farzaneh	Cellectis, France	Chimeric Antigen Receptor T cells - Consultancy	None	None	No	None
	Autolus, UK	Chimeric Antigen Receptor T cells - Consultancy payments and shares in the company				
Professor Andrew George	Smart Targeting	Shares	Imperial College Health Partners	Director (Unpaid) - ICHP works to encourage adoption of innovation in the NHS	Yes	The Univeristy that I am employed by (Brunel University London) will collaborate with a variety of healthcare related companies. I am not directly

	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 (Unpaid) - Ethical review of clinical research		involved in any such collaboration. My wift is employed as a Divisional Director and consultant at Imperial College Healthcare NHS Trust. I have served on joint Committees of the MHRA and the Health research Authority (HRA) to facilitate the review of clinical research.
			West London Business	Director (Unpaid) - None direct through some of the company members of WLB may have interests in healthcare	No	
Dr Elwyn Griffiths	None	None	None	None	No	Member of a Special Advisory Board of the Korean Ministry of Food and Drug Safety (MFDS). Member of the Board of the International Alliance for Biologicals (IABS) which has membership drawn from regulatory agencies, academia and industry (unpaid). Member, WHO Expert Committee on Biological Standardization (Chairman: 2010-2015, Rapporteur: 2016, Temporary Adviser and Rapporteur: 2017). Keynote presentation on Biotherapeutics and Global Health - Future Perspective, International Symposium on Procedures, Data Requirements for Changes to Approved Biologicals, organised by MFDS, Seoul, Republic of Korea and the WHO, April 2017.

MEMBER	PERSONAL INTERESTS		NON-PERSONAL INTERESTS		WHETHER CURRENT	ADDITIONAL INFORMATION
	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS		
						Travel and expenses covered by MFDS. Invited presentation on *History, Current Status and Future of Recombinant Protein Products*, in Recombinany Protein Products Forum, Global Bio Conferences, June 2017, Seoul, Republic of Korea. Travel and expenses covered by the organisers, MFDS and KoBIA Republic of Korea. Participation and presentation at the First ASEAN Educational Workshop on Regulation and Approval of Biosimilars/Similar Biotherapeutic Products, Bangkok, Thailand, July 2017. Travel and expenses covered by Generics and Biosimilars Initiative (GaBI) and the ASEAN Consultative Committee for Standards and Quality Pharmaceutical Products Working Group. Also an honorarium of £1352.83 Participation and presentation in a Workshop of Biological Standards and Assays organised by the Coalition on Epidemic Preparedness Innovations (CEPI) at the Wellcome Trust, London, UK, 12th December 2017.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						My daughter, Nia Wyn Voase, was Manager, Respiratory Clinical Research Facility, Imperial College and Royal Brompton Hospital, London until July 2017. She has no personal interests in the pharmaceutical industry.
Dr Helen J Lachmann						
Professor Elizabeth Millar	None	None	None	None	No	None
Dr Siraj Misbah	None	None	None	None	No	I delivered an iunvited talk on PML at the Immunology Gotum (Royal Society June 2017) sponsored by Biotest foir which neither my department nor I received an honorarium or travel/accomodation expenses.
Professor B Kevin Park	None	None	Amgen Ltd (UK)	Generation and Validation of Models to Probe Keap1 Adduction as a Marker of the Hepatoxic Liability of Drug Candidates (Co-I grant)	No	None
			Astra Zeneca	North West England MRC Fellowships in Clinical Pharmacology and Therapeutics (Co-I grant)		

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			GlaxoSmithKline Research & Development Limited (UK)	North West England MRC Fellowships in Clinical Pharmacology and Therapeutics (Co-I grant)		
			GlaxoSmithKline Research & Development Limited (UK)	Quantitative assessment of drug-protein adduct formation and function (PI grant)		
			Icon Clinical Research LTD (UK)	North West England MRC Fellowships in Clinical Pharmacology and Therapeutics (Co-I grant)		
			Janssen Pharmaceuticals (Belgium)	Mechanism-based integrated systems for the prediction of drug-induced liver injury (MIP-DILI) (PI-grant)		
			Janssen Pharmaceuticals (Belgium)	Mitochondrial toxicity research		
			Medicines Evaluation Unit LTD (UK)	North West England MRC Fellowships in Clinical Pharmacology and Therapeutics (Co-I grant)		
			Merck & Co. Inc (USA)	To examine the potential preclinical value of mechanism-based biomarkers of DILI over more established and widely accepted clinical		

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
				diagnostics related to liver histopathology. Development and qualification of the use of a combination of established and mechanism-based biomarkers (HMGB1(+Ac/-AC); cytokeratin 18 or ccK18: Mir122) for DILI assay in preclinical studies (CDSS DILI Project) (PI grant)		
			Wellcome Trust (UK)	YEAR 1 Wellcome Trust ISSF Non-Clinical Fellowships (PI grant)		
			Wellcome Trust (UK)	Mutli-modal high resolution preclinical PET+SPECT+CT scanner (Co-I grant)		
Professor Andrew Pollard	None	None	Astra Zeneca	Grant to Oxford University - Unrestricted edicational funding for a three day course	No	Non-commercial research: Grants from the Bill & Melinda Gates Foundation to study typhoid vaccines (Tybar-CV) produced by Bharat Biotech, (2013-2021); Grant from the National Institute for Health Research (2015-2020) to study IVIG in encephalitis (supply & distribution funding agreement, CSL Behring); Grant from the Gavi on pneumococcal vaccines in Nepal (2013-2017). European

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Gilead	Grant to Oxford University - Unrestricted edicational funding for a three day course	No	Commission (EC): FP7 grant (EUCLIDS; 2011-2017) to study the cause of fever with Bexsero (vaccine provided under a supply agreement with University by Novartis/GSK); (ADITEC, 2011-2016) to study influenza vaccines (FluAd, Novartis). EC IMI grants (EBOVAC), to study Ebola vaccine, from Janssen (2015-current); (PERISCOPE) to study pertussis vaccines (2016-current); (RESCEU) to study biomarkers for RSV (2016-Current). EC Horizon 2020 grant (PERFORM) to study pneumococcal carriage (2016-2020). Grants from Innovate UK to develop plague (2016-2020) and Q fever vaccines (2017-2018). Grant from the meningitis research foundation to study a booster dose of Bexsero in teenagers (2018-2019). Chair of UK Dept. Health's Joint Committee on Vaccination & Immunisation & the vaccines scientific advisory group, European Medicines Agency, and is a member of the WHO's SAGE.
			GlaxoSmithKline	Grant to Oxford University - Unrestricted edicational funding for a three day course	No	
			MSD	Grant to Oxford University - Unrestricted edicational funding for a three day course	No	
Dr Stephen Poole	Janssen Research & Development LLC	Consultancy - Validation of the monocyte	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**
		activation test to be applied to various products				
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. Until my retirement on 31/12/2017 I also advised the University Hospitals Birmingham NHSFT on matters relating to biological safety of genetically modified organisms, particularly gene therapy clinical trials. Since February 2010, my research group has held a License 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. For the last few years, Crucell has been owned by Janssen.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Robin Thorpe	None	None	None	None	No	None
Professor Marc Turner	None	None	None	None	No	Medical Director, Scottish National Blood Transfusion Service. Professor of Cellular Therapy, University of Edinburgh, Non-Executive Director, Cell and Gene Therapy Catapult.
Mrs Madeline Wang	None	None	None	None	No	None
Professor 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	
			Eli Lilly	Teriparatide - Research grant to institution, on which I am co-applicant	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	Amgen	Advisory Board	None	None	No	None
	Eli Lilly	Advisory Board				
	Novartis	Fee for lecture at academic meeting				
Dr Michael Ardern-Jones	GW Pharma	Consultancy	GlaxoSmithKline	Consultancy	Yes	None
	Enteromed	Consultancy	Unilever	Consultancy		
	Lilly	Consultancy	Novartis	Provide a nurse to assist with delivery of Chronic spontaneous urticaria service		
Dr Ian Barrison	GlaxoSmithKline	Shares	None	None	No	None
Mr David Chandler	None	None	None	None	No	I'm employed by a patient charity, but the charity has a policy not to receive any funding or financial support whether monetary, in kind or via 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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						accomodation. My wife also works for the same charity, and the above applies to her. My daughter works within the NHS as a diagnostic radiographer with nuclear medicine speciality, but has no personal or financial connections in the pharmaceutical industry. No other members of my immediate household have any financial interests in the pharmaceutical industry or associated organisations.
Dr Richard Groves	None	None	None	None	No	None
Professor Kevin Moore	Servieer	Agomelatine - Consultancy fees	None	None	No	None
	Gideon Richter	Esmya - Consultancy Fees				
	Mallinckrodt	Consultancy Fees				
Dr Frances MK 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 S Friedland (Chair)	None	None	None	None	No	None
Professor David Dockrell	None	None	GlaxoSmithKline	Grant investigating NRF2 agonists in macrophage innate responses in COPD - NRF2 Agonists	Yes	I have participated in advisory boards for: Lilly on consequences of anti-IL-17 therapy to host responses for
			GlaxoSmithKline	PhD Studentship	No	Viiv on the use or NRTI sparing integrase inhibitor antiretroviral regimens in 2017.
Dr Andrew Freedman	Gilead	Invited lecturer on postgraduate training course in HIV medicine in Saudi Arabia - programme organised by independent training company but sponsored by Gilead.	None	None	No	None
Dr Richard JC Gilson	None	None	ViiV	Antiretroviral therapies - My department is a collaborating site in clinical trials	Yes	None
			Pfizer	Maraviroc - UK Chief Investigator for one commercial trial, now complete. Chief investigator for one	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
				investigator-initiated study which is now compelte. My department is now conducting another clinical trial with this product.		
			Gilead Sciences	Antiretroviral therapies - My department is a collaborating site in clinical trials, and has funding for one investigator-initiated study. I am a site principal investigator for one clinical trial.	Yes	
			Merck	Antiretroviral therapies - My department is a collaborating site in clnical trials	Yes	
			Janssen	Antiretroviral therapies - My department is a collaborating site in clnical trials	Yes	
			Mylan	I am a site principal investigator for one clinical study using a Mylan product, funded by NHS England.	Yes	
			GlaxoSmithKline	Antiretroviral therapies - My department is a collaborating site in clinical trials	Yes	
Dr Richard Hobson	None	None	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Susan Hopkins	None	None	None	None	No	None
Dr Katie Jeffery	None	None	None	None	No	None
Professor Martin Lombard	None	None	None	None	No	None
Dr Hermione Lyall	None	None	None	None	No	None
Professor Kevin Moore	Servieer	Agomelatine - Consultancy fees	None	None	No	None
	Gideon Richter	Esmya - Consultancy Fees				
	Mallinckrodt	Consultancy Fees				
Professor Robert R Read	None	None	None	None	No	None
Dr Matthias Schmid	None	None	None	None	No	I am the Head of the Department of Infection & tropical Medicine. We run regular weekly educational meetings and have financial support from various companies including Gilead, Pfizer, Abbvie, ViiV and MSD to help with funding of those meets. There is no personal funding and no influence of the content of the meeting. None of my family members has any financial or other personal interest in any pharmaceutical company.
Ms Hilary A Shenton	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 Philip Hannaford	None	None	None	None	No	None
Professor Mary Ann Lumsden						
Ms Linda Pepper	None	None	None	None	No	None
Professor Siobhan Quenby	None	None	None	None	No	None
Dr Clare Spencer	None	None	None	None	No	None
Professor Jonathan H 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	The Division of Psychiatry, University of Edinburgh, in which I am based, is part of the Centre for Clinical Brain Sciences, an administrative arrangement comprising a 'centre without walls', and including over 50 individuals actively involved in all aspects of CNS research, from basic sciences to clinical. I have no direct or indirect involvement with any indidivudals or projects in receipt of commercial funding.
Professor Thomas R E Barnes	Janssen	Speaker fee	None	None	No	Contributor and co-editor for the next edition of the Maudsley Prescribing Guidelines
	Newron Pharmaceuticals	Evenamide - Advisory Board Member				
Professor Naomi Fineberg	Abbott	Speaker fees for delivering two webinars on OCD treatment	Wellcome Foundation	Research into translational mechanisms in OCD - research grant.		I work as a medical lead of an NHS England service providing pharmacological treatment for obsessive compulsive disorders. I act as an unpaid medical adviser and trustee to national consumer charities for OCD and related disorders. I chair the ECNP Research Network on OCD and related disorders.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	British Association for Psycho-pharmacology	Travel expenses for delivering educational masterclasses on treating anxiety disorders	EU Horizon 2020	Grant supporting research into problematic internet usage.		I have contributed to the British Association of Psychopharmacology (BAP) treatment guidelines for anxiety disorders (2014) and the NICE Treatment Guidelines including the most recent update (2013). No personal interests in the pharmaceutical industry are held by my partner or any adult members of my immediate household.
	European College of Neurophsycho-pharmacology (ECNP)	Research meetings and symposia touching upon medication related to OCD and related	NIHR	Research grant, touching upon drug treatment of OCD.		
	International Forum of Mood and Anxiety Disorders	Invited speaker on OCD Treatments. Travel and subsistence expenses to attend the meeting.				
	Royal College of Psychiatrists	Psychopharmacology special committee work and invited conference lecturer; travel expenses to attend meetings.				
	Wiley	Invited speaker - Latest advances in psychiatry symposium; Honorarium and travel expenses.				
	Oxford University	Pocketbook obsessive compulsive and related disorders - royalties				
	International Society of Affective Disorders	Invited speaker, honoriarium and travel expenses.				
Dr Anthony L Johnson	None	None	None	None	No	None
Professor Malcolm R Macleod	Charles River	Travel and subsistence expenses	Janssen Pharmaceutica NV	Co-supervise 2 PhD student,; Co-applicants on funded IMI consortium - see additional information	Yes	I am the coordinator of the EQIPD consortium, which receives funds from IMI 2 Call 9 Topic 3, Data Integrity. This is a stage 2 application. In stage 1 academic consortia submit

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			AbbVie Inc	Co-applicants on funded IMI consortium - see additional information	Yes	proposals against the bid, from which one is selected to go forward to stage 2. In stage 2 the academic consortium joins with pharmaceutical companies to submit a revised bid. On 4th October we were informed that we were successful in stage 1, and so the expanded consortium came into being. Our stage 2 application was submitted on 19th January, with a final positive funding decision made in April 2017. The funding mechanism for IMI is 50% funding from the EU, with 50% coming in cash or in kind from EFPIA partners listed here, with total resource around €9m. 2 Junior researchers would be shared between my department and Janssen, with their salary paid by University of Edinburgh and 50% reimbursed to the University of Edinburgh from Janssen. This is described in the application and will be further described in the consortium agreement.
			Boehringer Ingelheim International	Co-applicants on funded IMI consortium - see additional information	Yes	
			Novartis Pharma AG	Co-applicants on funded IMI consortium - see additional information	Yes	
			Orion Corporation	Co-applicants on funded IMI consortium - see additional information	Yes	
			F. Hoffmann-La Roche Ltd	Co-applicants on funded IMI consortium - see additional information	Yes	
			Institut De Recherches Servier S.A.S	Co-applicants on funded IMI consortium - see additional information	Yes	
			UCB Biopharma SPRL	Co-applicants on funded IMI consortium - see additional information	Yes	
			Pfizer Limited	Co-applicants on funded IMI consortium - see additional information	Yes	
			PsychoGenics Inc.	Co-applicants on funded IMI consortium - see additional information	Yes	
			Sanofi-Aventis Research and Development	Co-applicants on funded IMI consortium - see additional information	Yes	
Professor John T O'Brien	TauRx	Personal fees for consultancy	None	None	No	None
	Axon	Personal fees for consultancy				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Waqar Rashid						
Dr Fergus Rugg-Gunn	Livanova	Speaker fee for educational sessions sponsored by Livanova - Vagal Nerve Stimulator (medical device)	None	None	No	None
Dr Aditya Sharma	None	None	None	None	No	None
Dr Catherine F Stannard	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	
			Eli Lilly	Teriparatide - Research grant to institution, on which I am co-applicant	Yes	

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)	None	None	None	None	No	None
Professor David Bowen Professor Stephen Devereux	Novartis	Consultancy fee - Tisagelecleucel	None	None	No	None
	Bristol Myers Squibb	Consultancy fee - Nivolumab				
	Gilead	Travel and conference fee sponsorship, and Consultancy fee - Idelalisib				
Dr Hugo Ford	None	None	None	None	No	My wife is a Conservative MP (Vicky Ford MP)
Dr Chris Gallagher Dr Geoff Shenton	None	None	None	None	No	None
Professor Angela E Thomas	None	None	None	None	No	I am chair of the Trial Stering Group for the MATCH trial (Macrophage Therapy for Liver Cirrhosis). Co-sponsors: University of Edinburgh & NHS Lothian; Accord, The Queen's Medical Research Institute, 47 Little France Crescent, Edinburgh EH16 4TJ. Funded by Medical Research Council; Chief Investigator

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						Professor Stuart Forbes. No remuneration or expenses.

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	Ablynx	Medicinal product under investigation vs RSV infection - PI for ongoing study	Yes	None
Dr Eileen M Baildam	Pfizer	Consultancy	None	None	No	None
	Abbvie	Speaker's fee for BSPAR 2016				
	Sanofi	Speaker's fee for BSPAR 2016				
	Alexion	Speaker's fee for BSPAR 2016				
	Bayer	Study advisory meeting				
Dr Helen Burdett	None	None	None	None	No	None
Professor J Helen Cross						
Dr Steven Cunningham	Janssen Pharmaceuticals, Netherlands	RSV novel therapeutics (JNJ-53718678 and ALS8176) - Personal fees received for one day Advisory Board meeting.	Janssen Pharmaceuticals, Netherlands	RSV Paediatric (Adenovirus) Vaccine programme. Member of Data Safety monitoring board. Consultancy fees paid to University of Edinburgh.	Yes	
			Ablynx Pharmaceuticals, Belgium	ALX-0171 - International Coordinating Investigator for Phase I and II studies in children. Consultancy	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
				fees paid to University of Edinburgh		
			Ablynx Pharmaceuticals, Belgium	ALX-0171 - International Coordinating Investigator for Phase I and II studies in children. Consultancy fees paid to University of Edinburgh	Yes	
			Pulmocide Pharmaceuticals	Consultancy for development of paediatric programme. Consultancy fees paid to University of Edinburgh	Yes	
			Boehringer Ingelheim	Nintedanib - Consultancy for development of paediatric programme. Consutlancy fees paid to University of Edinburgh	Yes	
			Vertex Pharmaceuticals	Ivacaftor - Clinical lead for the UK CF Registry contribution to a post marketing safety and effectiveness study of Ivacaftor in children aged 2-5 years. Consultancy fees paid to University of Edinburgh by the UK Cycstic Fibrosis Trust.	Yes	
Professor Peter C Hindmarsh	Medtronic Diabetes	Medtronic Insulin pump - consultancy	None	None	No	None
	Diurnal	Chronocort - Safety advisor for the clinical trial				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Meriel Jenney	None	None	None	None	No	None
Dr Caroline Jones	None	None	Alexion	Eculizumab	Yes	Research - registry data on patients with aHUS
			Astellas	Advograf	Yes	Research (colleague is PI - trial now closed)
			Astellas	Modigraf	Yes	Research (colleague is PI - trial closing soon)
Professor Nigel Klein	ViiV Healthcare	Novel HIV medicines for Children - Recipient of an academic grant administered by PENTA Foundation	Ablynx	ALX-0171 - Member of the IDMC	No	None
Dr Rubin Minhas	None	None	None	None	No	None
Professor Marie-Louise Newell	Crucell BVm, a Janssen Pharmaceutical company of Johnson&Johnson	Ebola vaccine - Member of the DSMB for phase II 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 and the MEA excipients working group. I am a BPC nominee to 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 reformation

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						of a medicine in children with cancer. Nova Laboratories is an industry partner in the project and administers the grant. 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	PHG Foundation, Cambridge	Health Policy, Writer and Presenter	None	None	No	Work I do at PHG is general medical policy themed (eg. genomics, medical devices) and workshops. Commercial companies do sponsor such workshops but the themes are wide and not commercial.
Dr Beverley Tsai-Goodman	None	None	None	None	No	None
Dr Catherine L C Tuleu						
Professor Heather M Wallace	None	None	None	None	No	Owns less than 0.1% shares in Novabiotics, Precious Cells and Antoxis, and is a Director in CellProTx. The companies are all spin outs from the university and I receive no financial benefit.
Dr Mark Whiting	None	None	None	None	No	None
Dr Morris Zwi	None	None	None	None	No	None

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Sir Munir Pirmohamed (Chair)	None	None	Astra Zeneca	Research grant to support PhD in Pharmacovigilance	No	None
			Eli Lilly	Research grant to support clinical training fellowships jointly with MRC	No	
			Novartis	Research grant to support clinical training fellowships jointly with MRC	No	
			Roche	Research grant to support clinical training fellowships jointly with MRC	No	
			UCB Pharma	Research grant to support clinical training fellowships jointly with MRC	No	
			Bristol Myers Squibb	Unrestricted educational grant to support UK pharmacogenetics and stratified medicine network open meeting	No	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Darren Ashcroft		None	Abbvie, Celgene, MedImmune, Becton, Dickinson, Novartis, GlaxoSmithKline, Stiefel, Pfizer, Qiagen, Sanquin, Janssen, Eli Lilly	Biologic therapies for the management of psoriasis - MRC Stratified Medicine Research Grant: Psoriasis Stratification to Optimise Relevant Therapy (PSORT). Several industry partners making funding contributions	Yes	None
			Leo Foundation, Eli Lilly, Abbvie, Novartis	Research grant to support the development of the Global Psoraisis Atlas	Yes	
			Abbvie	Research grant to examine burden of comorbidities in patients with psoriasis	No	
			Mundipharma	Research grant to examine use of Targinact in the management of Restless Leg Syndrome	Yes	
Professor Jamie Coleman	None	None	None	None	No	None
Professor Ann Daly	None	None	Genentech	General consultancy advice on pharmacogenetics arranged via Newcastle University with fees paid to Newcastle University	Yes	None
Professor William Dixon	Bayer	Consultancy	None	None	No	None
Dr Ian J Douglas	GlaxoSmithKline	Shares	GlaxoSmithKline	Grant funding	Yes	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Association for the British Pharmaceutical Industry	Grant funding	Yes	
Dr Daniel Hawcutt	None	None	None	None	No	None
Ms Susan Hunneyball	None	None	None	None	No	None
Ms Amanda Lee	None	None	None	None	No	None
Professor Glyn Lewis	None	None	None	None	No	I have acted as an expert witness in a case that involves litigation against GSK in relation to withdrawl effects for paroxetine.
Professor Simon R J Maxwell	None	None	None	None	No	None
Dr Karen Miller	None	None	None	None	No	None
Dr Rupert Payne	None	None	None	None	No	None
Dr Nicholas J Plant						
Ms Christine Randall	None	None	None	None	No	None
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

CHRONIC LIVER DISEASE 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 Kevin Moore (Chair)	Servieer	Agomelatine - Consultancy fees	None	None	No	None
	Gideon Richter	Esmya - Consultancy Fees				
	Mallinckrodt	Consultancy Fees				
Professor Guru Aithal	Aglos	AG-519 - Consultancy	Kaneka	Potential research study	Yes	None
	Aegerion	Consultancy				
	Shire	Consultancy				
Professor Quentin Anstee	Allergan	Speaker fees	Antaros Medical, Allergan/Tobira, Boehringer Ingelheim International GMBH, Echosens, Ellegaard Gottingen Minipigs AS, Eli Lilly & Company, Exalenz Bioscience, Genfit SA, Intercept Pharma Europe Ltd, Nordic Bioscience,	Active research collaborations: funded through peer-reviewed EU Innovative Medicines Initiative (IMI2) funding stream grant to the LITMUS consortium that I coordinate. LITMUS is a consortium of >50 partners, half universities from across Europe, half industrial partners. The IMI2 funding stream uses a peer-reviewed matched funding model, with grant gunds being derived from the EU	Yes	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Novartis Pharma AG, Novo Nordisk A/S, One Way Liver Genomics SL, Perspectium Diagnostics, Pfizer Ltd, Sanofi-Aventis, Somalogic Inc, Takeda Pharmaceuticals International SA	H2020 budget and pharmaceutical companies.		
	Genfit	Speaker fees	Abbott Laboratories, Allergan/Tobira, Eli Lilly & Company Ltd, Galmed, Genfit SA, Gilead, Grunthal, Imperial Innovations, Intercept Pharma Europe Ltd, Inventive, Janssen, MedImmune, Novartis, Pfizer Ltd	Consultancy - On behalf of my university, I perform consultancy for these companies	Yes	
	Clinical Care Options	Speaker fees	Abbvie, Allergan/Tobira, Genfit, GlaxoSmithKline, Novartis Pharma AG	Research grant funding to my unversity/hospital	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Christopher D Byrne	Kenes International None	Speaker fees None	None	None	No	Christian Hansen plc provide at no cost a synbiotic and placebo for the INvestigation of SYmbiotic TreatmEnt in non alocholic fatty liver disease (INSYTE) study: A randomised placebo-controlled study to test the efficacy of a synbiotic on liver fat, disease biomarkers and intestinal microbiota in non-alcoholic fatty liver disease. Professor Byrne is the Principal Investigator for INSYTE. Christian Hansen have had no unput (financial or otherwise) into the study designed for INSYTE, conduct of the trial, and will have no input into the analyses nor publication of the trial results.
Dr Roger Chapman	Dr Falk Pharmaceuticals Perspectum Diagnostics	Consultancy (Advisory board) and Lectures (3 per year) Consltuancy (Advisory board)	None	None	No	None
Professor Mike Heneghan						
Dr Gideon Hirschfield	Intercept Cymabay Novartis	Ocaliva - Consultancy & Speaker Seladelpar - Consultancy Experimental agents - Trial steering committee	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**
	GlaxoSmithKline	ASTB Inhibition - Consultancy				
	Gilead	Experimental agents - Educational Support				
Professor David Jones						
Dr George Mells						
Professor Phil Newsome	Affimune	Co-ordinating investigator	None	None	No	None
	Boehringer Ingelheim	Co-ordinating investigator, consultancy				
	E3BIO	Consultancy				
	Gilead	Consultancy				
	Novo Nordisk	Co-ordinating investigator				
	Shire	Co-ordinating investigator				
Dr Emmanuel Tsochatzis	Promethera	Consultancy	None	None	No	None

DOVONEX AD HOC STAKEHOLDER 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 H Taylor	None	None	AstraZeneca	Contribution to EPSRC Doctoral Training Centre in my department	No	None
			Boots	Contribution to EPSRC Doctoral Training Centre in my department	No	
			Pfizer	Contribution to EPSRC Doctoral Training Centre in my department	No	
			GlaxoSmithKline	Contribution to EPSRC Doctoral Training Centre in my department	No	
			Quadrant	Contribution to EPSRC Doctoral Training Centre in my department	No	
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 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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						includes: registration fees, travel, subsistence and accomodation. My wife also works for the same charity, and the above applies to her. My daughter works within the NHS as a diagnostic radiographer with nuclear medicine speciality, but has no personal or financial connections in the pharmaceutical industry. No other members of my immediate household have any financial interests in the pharmaceutical industry or associated organisations.
Dr Martin Duerden	Astellas	I received payment for travel expenses and one day of consultancy work on advice for research programme for 'drug in pipeline'	None	None	No	None
	Reckitt Benkiser	I received payment for travel expenses and to speark at two educational meetings on the subject of Antimicrobial Resistance. These talks had no promotional content.				
Ms Carla Renton	None	None	LEO Pharma	Please see additional information	Yes	LEO Pharma is one of six corporate members of the Psoriasis Association and as such pays an annual Corporate

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						Membership fee to the organisation of £1500.
Ms Ruth Wakeman	None	None	None	None	No	None
Ms Nicola Broad (Invited Expert)	Leo Pharma	Payment for provision of education sessions regarding dermatology in primary care	None	None	No	None
	Dermal Pharma	Payment for provision of education sessions regarding dermatology in primary care				
Dr George Moncrieff (Invited Expert)						
Mr Ade Williams (Invited Expert)	None	None	None	None	No	None

HORMONE PREGNANCY TESTS 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 (Chair)	None	None	None	None	No	None
Professor Pat Doyle	None	None	None	None	No	None
Mrs Joyce Epstein	None	None	None	None	No	None
Professor Joyce Harper	None	None	Cook IVF	Paid for two conferences: a one-day meeting in Barcelona and a three-day meeting in South Africa	No	None
			MSD	Paid speaker	No	
Professor Axel Heep	None	None	None	None	No	None
Professor Stephen Hillier	None	None	None	None	No	None
Professor Alison MacFarlane	None	None	None	None	No	I have a portfolio of shares managed by my bank and I never know at any one time what shares I have. I have told them types of companies I don't want my money invested in and pharmaceuticals may or may not be on this list.
Ms Sara Payne	PHG Foundation, Cambridge	Health Policy, Writer and Presenter	None	None	No	Work I do at PHG is general medical policy themed (eg. genomics, medical devices) and workshops. Commercial companies do sponsor such workshops but the themes are wide and not commercial.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Mrs Farrah Pradhan	None	None	None	None	No	None
Professor Siobhan Quenby	None	None	None	None	No	None
Dr Richard Quinton	None	None	None	None	No	None
Dr Connie Smith	None	None	None	None	No	None
Professor Michael D Threadgill	None	None	None	None	No	None
Dr Diana Wellesley	None	None	None	None	No	None
Mr Nick Dobrik (Invited Expert)	None	None	None	None	No	None
Professor Helen Dolk (Invited Expert)	None	None	None	None	No	None
Professor Stephen Evans (Invited Expert)	None	None	None	None	No	LSHTM receives grants from a number of companies, but I have no knowledge or involvement in any of them; my salary and research are not funded by them.
Professor Kay Marshall (Invited Expert)	None	None	None	None	No	In the past (over ten years ago) I have collaborated with Bayer and GSK but the laboratory based projects were focused on compounds that may have had potential to prevent uterine hypercontractility and so had potential in the management of conditions such as pre-term labour.
Dr Irene Petersen (Invited Expert)	None	None	None	None	No	I have a part time appointment at Aarhus University, as a Professor in biostatistics. Academic members within that department receive funding from Pfizer in New York.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Shirley Price (Invited Expert)	None	None	None	None	No	None
Professor Faith Williams (Invited Expert)	None	None	None	None	No	I own some shares in GlaxoSmithKline plc which are held through a nominee company of HSBC bank plc. I do not have shares in any of the other companies listed or have had any other interests in the companies which originally marketed HPTs. I received non-personal research funding from Pfizer for a member of staff in my team at Newcastle between 2004-2007.
Dr Laura M Yates (Invited Expert)	None	None	None	None	No	None

INDEPENDENT PRESCRIBING AD HOC 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 J Colin Forfar (Chair)	None	None	None	None	No	None
Dr John Black	None	None	Kinapse Ltd	Brother is a Founder, previous CEO and a Shareholder	Yes	I am a consultant in Emergency Medicine Oxoford University Hospitals, Medical Director of South Central Ambulance Service Foundation Trust, a member of National Ambulance Medical Direcotrs Group (NASMeD), a reservist member of the Royal Army Medical Corps RAMC(V), and a member of the Intercollegiate Board for Training in Pre-Hospital Emergency Medicine. I relinquished my Share Holding in Kinapse Ltd in 2016 - a consulting business for the Life Sciences Sector.
			Medinnovate Ltd	Brother is a Director	Yes	
			Black Life Sciences Ltd	Brother is a Director/Shareholder	Yes	
Professor Jamie Coleman	None	None	None	None	No	None
Dr Gillian M Hawksworth	None	None	None	None	No	None
Dr Jamie Fraser	None	None	None	None	No	None
Dr Clifford Mann	None	None	None	None	No	None
Dr Rebecca Mann	None	None	Ablynx	Medicinal product under investigation vs RSV infection - PI for ongoing study	Yes	None
Dr Karen Miller	None	None	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr John Reynolds	None	None	None	None	No	None
Dr Raman Uberoi	Merit Medical	Consultancy	None	None	No	None
	Bolton	Grant for conderence attendance				
	Stellarex	PI for international study				
Professor Helen M Ward	None	None	None	None	No	None
Professor Anthony G Wilson	Amgen	Advisory Board	None	None	No	None
	Eli Lilly	Advisory Board				
	Novartis	Fee for lecture at academic meeting				

SODIUM VALPROATE EXPERT 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 Munir Pirmohamed (Chair)	None	None	Astra Zeneca	Research grant to support PhD in Pharmacovigilance	No	None
			Eli Lilly	Research grant to support clinical training fellowships jointly with MRC	No	
			Novartis	Research grant to support clinical training fellowships jointly with MRC	No	
			Roche	Research grant to support clinical training fellowships jointly with MRC	No	
			UCB Pharma	Research grant to support clinical training fellowships jointly with MRC	No	
			Bristol Myers Squibb	Unrestricted educational grant to support UK pharmacogenetics and stratified medicine network open meeting	No	
Professor J Helen Cross						

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Martin Duerden	Astellas	I received payment for travel expenses and one day of consultancy work on advice for research programme for 'drug in pipeline'	None	None	No	None
	Reckitt Benkiser	I received payment for travel expenses and to speark at two educational meetings on the subject of Antimicrobial Resistance. These talks had no promotional content				
Professor Jayne Lawrence						
Dr John Paul Leach	UCB	Speaker's fee - Levetiracetam, brivaracetam	None	None	No	Publication of review article on AED treatment in Pregnancy: Epilepsy and Pregnancy: For healthy pregnancies and happy outcomes. Suggestions for service improvements from the Multispeciality UK Epilepsy Mortality Group. Leach JP et al. Seizure. 2017; 50:67-72. doi: 10.1016/j.seizure.2017.05.004.. PMID: 28641176 Also joint grant holder from HTA. (SANAD2) looking at use of Valproate in newly diagnosed epilepsy - results awaiting, recruitment finished.
Dr Janine Lynch	Shares	AstraZeneca	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Rebecca Mann	None	None	Ablynx	Medicinal product under investigation vs RSV infection - PI for ongoing study	Yes	None
Dr Karen Miller	None	None	None	None	No	None
Professor Catherine Nelson-Piercy	UCB	Certulizumab - Consultancy, lecture fees and webcast	None	None	No	None
	Sanofi Aventis	Enoxaparin - Lecture fees				
	Leo-pharma	Tinzaparin - Support for London Obstetric Group meetings (provisional of refreshments)				
	Warner-Chilcott	Mesalazine - Lecture fees				
	Alliance Pharma	Diclectin - Consultancy				
Professor David G C Owens	None	None	None	None	No	The Division of Psychiatry, University of Edinburgh, in which I am based, is part of the Centre for Clinical Brain Sciences, an administrative arrangement comprising a 'centre without walls', and including over 50 individuals actively involved in all aspects of CNS research, from basic sciences to clinical. I have no direct or indirect involvement with any indidivudals or projects in receipt of commercial funding.
Ms Claire Pelham						
Dr Fergus Rugg-Gunn	Livanova	Speaker fee for educational sessions sponsored by Livanova - Vagal Nerve Stimulator (medical device)	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 Laura Russell						
Professor Philip Smith	None	None	None	None	No	None
Mrs Madeleine Wang	None	None	None	None	No	None
Professor Thomas R E Barnes (Invited Expert)	Janssen	Speaker fee	None	None	No	Contributor and co-editor for the next edition of the Maudsley Prescribing Guidelines
	Newron Pharmaceuticals	Evenamide - Advisory Board Member				

TAMOXIFEN AD HOC 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)	None	None	None	None	No	None
Mr Ramsey Cutress	None	None	None	None	No	A colleague of mine has made an application to AstraZeneca for funding for implementation of a decision aid for Genetic Testing in young patients with breast cancer. I have not been directly involved in this application but was a co-applicant in the original work (funded by the charity Breast Cancer Now) to develop the decision aid. I believe the outcome of the application is not yet known.
Dr Martin Duerden	Astellas Reckitt Benkiser	Travel expenses and consultancy Travel expenses and speaker fees	None	None	No	None
Professor Diana Eccles	AstraZeneca	I have received occasional honoraria fees for advisory board work around BRCA testing and PARPi use. I am lead author on a	AstraZeneca	I have made an application to AZ-medimmune for funding for a research project that explores the utility of an online decision aid	No	I was the Southampton PI for IBIS-1 recruting patients and returning data. I was a member of the IBIS-1 steering group. I was not involved in data analysis or the long term follow up

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
		paper about BRCA testing in ovarian cancer where a medical research company funded by AZ conducted a systematic review of the literature		(developed in Southampton with funding support from BCN) to improve the patient experience of BRCA testing through mainstream oncology. A funding decision has not been made.		studies and analyses. I have not been involved in the recent meta-analyses.
	Pierre Fabre	Lecture fee				
Dr Jamie Fraser	None	None	None	None	No	None
Dr Chris Gallagher	None	None	None	None	No	None
Professor Philip Hannaford	None	None	None	None	No	None
Ms Fiona MacNeill	None	None	None	None	No	None
Professor Sarah Meredith	None	None	Abbott	Lopinavir - Grant & product donated for trail. Ritonavir - Grant & product donated for a trial, financial support for a virology sub-study	No	None
			Astellas	Enzalutamide - Grant & product donated for a trial		
			AstraZeneca	Cediranib - Grant & product donated for a trial. AZD 8931 - Product donated for a trial		
			Bayer	Sorafenib - Grant & product donated for a trial. Aspirin - Product donated for a trial		
			Boehringer Ingelhein, Bristol-Myers Squibb	Efavirenz, Atripla - Grant & product donated for a trial.		

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
				Atazanavir - Product donated for a trial		
			Cipla	Albendazole, Azithromycin, Cotrimoxazole/Isonaiozid /Pyridoxine, Fluconazole, Efavirenz, Nevirapine, Lapimune Minitabs, Zidobudine/Iamvidune, Aabacavir/Iamividune, Stavudine/Iamivudine - Products donated for a trial		
			Gilead Sciences	Tenofovir, Emtricitabine, Atripla - Grant & product for a trial. Truvada - Product donated for 4 trials, grant for the Proud study. Efavirenz & Tenofovir (Viread) - Products donated for a trial.		
			GlaxoSmithKline	Lapatinib & Abacavir, Zidovudine, Lamivudine - Grant and Products donated for a trial. Abacavir, Lamivudine - Product donated for a trial. Zidovine, Lamivudine & Abacavir & Lamivudine & Combivir & Kixeva & HIV Conserve Vaccine - Product donated for a trial.		

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Janssen	Bedaquiline - Grant & product donated for trial		
			Janssen-Cilag	Abiraterone - Grant & product donated for trial		
			Lilly	Gemcitabine - product donated for trial		
			Merck	Topotecan & Pegylated interferon & Doxoirubicin & Efavirenz - products donated for a trial. Temozolomide & Virinostat - Grant & product donated for a trial.		
			Pilatus	Amoxycvillin - product donated for a trial		
			Roche	Bevacizumab - Grant & product donated for a trial		
			Sanofi-Aventis	Docetaxel - Grant & product donated for a trial		
			Sanofi Pasteur	NYVAC C - Product donated for a trial		
			Tibotec	Darunavir - Product donated for a trial		
			Virco	Resistance-tests - Product donated for a trial		
			WHO/GDF	Clofazimine - Product donated for a trial		
			Emergent Biosolutions	Hyperimmune IVIG - Product donated for a trial		

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor David Miles						
Dr Karen Miller	None	None	None	None	No	None
Dr Rupert Payne	None	None	None	None	No	None
Dr Martin Wilson	None	None	None	None	No	I am involved in four pieces of Research none of which have drug company sponsors. PD Med Trial - A large randomised assessment of the relative cost-effectiveness of different classes of drugs for Parkinson's disease. Funded by the NHS Health Technology Assessment programme and is supported by the European Parkinson's Disease Association, the Parkinson's Disease Society and the Parkinson's Disease Nurse Specialists Association. Hosted by Birmingham Clinical Trials Unit. Running since 1999. I am the local principal investigator (taking over from my predecessor in 2005) this involves follow up of a single patient. Proband - Parkinson's Repository of Biosamples and Network Datasets: Prospective Observational Study of Parkinson's Disease with Repeat Clinical Assessment and Biobanking of Blood Samples Funding. Sponsored and based

MEMBER	PERSONAL INTERESTS		NON-PERSONAL INTERESTS		WHETHER CURRENT	ADDITIONAL INFORMATION
	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS		
						in NHS Greater Glasgow and Clyde. Funded by PD Society. I am local principal investigator with assessments carried out by PD nurse and Research nurse. Simpathy - Stimulating Innovation in Management of Polypharmacy and Adherence in the Elderly. Funded by European Union Health Programme. Research looking at the development of Polypharmacy programmes in different European regions. I am part of the Scottish Government team on this. Funding for travel and accomodation for meetings. Prescribing Outcomes for Implementing Enhanced Medication Summaries (POEMS) - Funded by CSO grant. I am on advisory board for Other - I am a regular speaker at Royal Colleges, Regional Speciality meetings on a range of subjects including management of Polypharmacy. I receive travel and accomodation reimbursement. None of the meetings have been solely drug sponsored.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Jack Cuzick (Invited Expert)	None	None	AstraZeneca	Continued support for IBIS-2 and LATTE clinical trials	Yes	Involvement in one or more of the studies cited in the Tamoxifen Ad Hoc Group discussions.
Dr John Graham (Invited Expert)	None	None	None	None	No	None
Mr Andy Hutchinson (Invited Expert)	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	Astra Zeneca	Studentship	No	
			Astra Zeneca	Research Funding	No	
			Eli Lilly	Studentship	Yes	
			Roche	Studentship	Yes	
Prof Chris Chapple	Allergan	Botox - Meeting participant, lecturer, consultant, advisor	Astellas	Mirabegron - Grant, scientific study/trial (researcher/author)	Yes	None
	Astellas	Tamsulosin, solifenacin, mirabegron - Meeting participant, lecturer, consultant, advisor.				
	Pfizer	Fesoterodine - Meeting participant, lecturer, consultant, advisor.				
Dr Thomas Clutton-Brock	None	None	None	None	No	None
Professor Peter Crome	None	None	None	None	No	None
Professor Karen Forbes	None	None	None	None	No	None
Dr Clive Grattan	Novartis	Omalizumab - Fee for chairing a meeting	None	None	No	None
Professor Paul Griffiths	None	None	None	None	No	None
Professor Nedim Hadzic	Alexion	Ad hoc consultancy fees	None	None	No	None
Professor Freddie Hamdy	None	None	None	None	No	None
Dr Nigel Hoggard	None	None	None	None	No	None
Professor David Isenberg	None	None	Astra Zeneca	Consultancy - Honoraria passed onto a local arthiritis charity	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Baxalta	Consultancy - Honoraria passed onto a local arthiritis charity	No	
			Merck Serono	Consultancy - Honoraria passed onto a local arthiritis charity	No	
			Novartis	Consultancy - Honoraria passed onto a local arthiritis charity	No	
			Sanofi	Consultancy - Honoraria passed onto a local arthiritis charity	No	
Professor Colin Kennedy	None	None	None	None	No	None
Professor Karen Luker	None	None	None	None	No	None
Professor Robert Pickard	None	None	None	None	No	None
Professor Stephen Powis	None	None	None	None	No	None
Professor Shakeel Qureshi	Venus Medtech	Venus P-Valve - Consultancy and PI for CE study in Europ	None	None	No	None
	Numed Inc	Tyshak Balloons - Constulancy				
	Occlutech	Variety of Devices, eg PLD - Consultancy				
	Lifetech	Variety of devices - Proctor				
	Medtronic	Melody valve - Proctor				
Professor Amin Rostami	Certara	Shares via Certara's Holding Company, contribution to university salary	Daiichi-Sankyo	Consultancy fee	No	The following Pharmaceutical companies are part of the Simcyp Consortium and they are relied on to fund research in Simcyp: Abbvie, Actelion, Amgen, Astellas Pharma Inc,

MEMBER	PERSONAL INTERESTS		NON-PERSONAL INTERESTS		WHETHER CURRENT	ADDITIONAL INFORMATION
	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS		
						AstraZeneca, Biogen Idec, Bristol Myers Squibb, Celgene Corporation, Daiichi-Sankyo, Dainippon-Sumitomo, Eisai, Eli Lilly, F. Hoffmann-La, Roche Ltd, Gilead, GlaxoSmithKline, Gruenthal, H Lundbeck A/S, Idorsa, Incyte Corporation, Johnson & Johnson Pharmaceutical Research & Development, Kyowa HAkko Krini Pharma, Merck & Co, Merck KGaA, Mitsubishi Tanabe Pharma Corporation, Nektar Therapeutics, Novartis Pharma, Ono Pharmaceutical Co, Otsuka Pharmaceutical Group, Pfizer, Sanofi-Aventis, Servier, Shionogi & Co, Shire Pharmaceuticals, Taisho Pharmaceutical, Takeda, UCB Pharma, Vertex Pharmaceuticals. 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:

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						Certara, Janssen, Eli Lilly, Merck, Genentech and Takeda.
	Diurnal	Shares	Angelini	Consultancy fee	No	
	Zilico	Shares	AbbVie	Consultancy fee	No	
Dr Lindsey Rylah	None	None	None	None	No	None
Dr Andrew Scarsbrook	None	None	Blue Earth Diagnostics	Flourine-18 Fluciclovine - Investigator initiated Research Grant (£45k)	Yes	None
Professor Alan Smyth	PTC	Ataluren - Consultancy, Speaker Honorarium & Expenses	Teva	Sponsor a twice yearly multidisciplinary education meeting for our team	No	None
	Vertex	Orkambi (Ivacaftor/Lumcaftor) - Consultancy, Speaker Honorarium & Expenses				
	Teva	Colistin - Speaker Honorarium & Expenses				
	Novartis	Inhaled tombramycin - Speaker Honorarium & Expenses				
Professor Paul Stewart						
Professor Gilbert Thompson	Astra Zeneca	Shares	None	None	No	None
	Glaxo Smith Kline	Shares				
	Shire	Shares				
Dr David Tuthill	None	None	None	None	No	None
Dr David Wheeler	Amgen	Speaker fees	AstraZeneca	Fees paid to department for staff training	Yes	None
	AstraZeneca	Consultancy				
	Boehringer Ingelheim	Consultancy				
	Kyowa Hakko Kirin	Speaker fees				
	Vifor Fresenius	Consultancy				
Dr Alistair R W Williams	Bayer	Consultancy - Vilaprisan	None	None	No	None
	Gegeon Richter	Consultancy - Esmya (ulipristal acetate)				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	HRA Pharma	Consultancy - Ulipristal acetate				
	ASKA Pharmaceutical Co Ltd	Consultancy - Ulipristal acetate				
Professor Sir Nicholas Wright						

OPTHALMIC AD HOC 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	Santen	Ikervis - Advisory board meeting	Chiesi	Holoclar - clinical trial	Yes	None
	VISUfarma	VISUXL - Advisory board meeting				
	Dompe	Cenegermin - Advisory board meeting				
	Thea	Talk at meeting sponsored by Thea				
	Nanomerics	Advisory board meeting				
Mr Bruce Allan	None	None	None	None	No	I am an NHS consultant opthalmologist working at Moorfields Eye Hospital. I also work in private practice specialising in refractive surgery and cataract surgery at Moorfields Private. I receive part salary funding for research sessions from the NIHR BRC in opthalmology at Moorfields and the UCL Institute of Opthalmology. In the last year, I provided unpaid consultancy advice for Schwind Eye Tech Solutions GmbH (Kleinostheim, Germany) and Staar Surgical (Monrovia, CA)
Mr Ejaz Ansari	Thea	Fees	None	None	No	None
Professor Paul N Bishop	Acucela Inc	Optogenetic gene therapy treatment in preclinical development -	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**
		Consultancy, technology licensed to Acucela Inc through University of Manchester and as an inventor have financial interests				
	Astra Zeneca	AZD4547 - Consultancy				
Mr Charles Claoué						
Professor Baljean Dhillon						
Ms Cecilia H Fenerty	None	None	None	None	No	Please note that I delivered a talk at an educational meeting sponsored by Allergan 17th January 2018. This meeting was not product related and my talk did not include any mention of pharmaceuticals products (the theme of the meeting was talk was the design and delivery of glaucoma services.) I did not accept an honorarium and I funded my own travel to and from the meeting on the day.
Mr Philip G Hykin	Allergan	Ozurdex - Advisory board panel	None	None	No	None
	Bayer	Eylea - Advisory board panels, travel expenses and Investigator-initiated grants				
	Novartis	Lucentis - Advisory board panels and travel expenses				
Mr Teifion Emlyn James						

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Sir Peng T Khaw	Santen	Speaker fee, advisory board	None	None	No	None
	National Medical Research Council Singapore	Grant panel				
	Novartis	Advisory board & fees				
	Alcon	Scientific selection panel				
	Valid Insight Interview	Honorarium				
	Aerie Pharmaceuticals	Advisory Board				
	Radiance Therapeutics	Founder				
	Optceutics	Founder				
Mr Anthony J King						
Mr Martin McKibbin						
Mr David P S O'Brart	Alcon Inc	Cataract surgery - consultancy fee	Alcon Inc	Cataract surgery - non-commercial research grant	No	None
	Sooft Italia SPA	Corneal collagen cross linking surgery - consultancy fee	Alcon Inc	Cataract surgery intraocular lens study - non-commercial research grant	No	
Professor Sunil Shah	Presbyopia Treatments Ltd	Shares	None	None	No	None
	The Laser and Lens Network Ltd	Dormont				
	The Eye Doctors Ltd	Shares				
	SS Laser Consultancy Ltd	Shares				
	Visual Entrepreneurs Ltd	Dormont				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Eye-Docs Ltd	Shares				
	Allergan	Consultancy				
	Shire	Consultancy				

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 K 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	
Prof M Almond	GlaxoSmithKline	Salary, Shares (immediate family member)	None	None	No	None
Dr J Beaman	Pfizer	Salary, Shares	None	None	No	None
Dr A-M Brady	Bayer	Consultancy (specific product)	Biologicals journal	Associate Editor (veterinary section) (unpaid)	Yes	None
	AstraZeneca	Shares (immediate family member)	VAC2VAC Working Party	Member (unpaid)	Yes	
	GlaxoSmithKline	Shares (immediate family member)				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Vernalis	Shares (immediate family member)				
Dr G D Cook	Pfizer	Salary, Shares	None	None	No	None
Mr A Coulson	Pfizer (formerly Upjohn)	Pension	None	None	No	None
	LabCorp (formerly Covance Ltd)	Pension				
	Veterinary Medicines Directorate	Non-Executive Director; meeting fees				
Prof A G Davidson (Vice-Chair)	None	None	None	None	No	None
Dr A Gleadle	Tesco PLC	Shares	None	None	No	None
	Medimmune	Salary (other person)				
	AstraZeneca					
Dr R L Horder	Abbott Laboratories	Shares (until November)	None	None	No	None
	AbbVie	Shares (until December)				
Dr M G Lee	None	None	None	None	No	None
Mr R Lowe	None	None	None	None	No	None
Dr B R Matthews	None	None	None	None	No	None
Prof J Miller	None	None	None	None	No	None
Ms S Palser	None	None	None	None	No	None
Prof M Simmonds	None	None	College of Medicine	Member	Yes	None
			Hong Kong Department of Health - Pharmacopoeia International Advisory Committee	Member	Yes	
			Walgreen Boots Alliance	Research Grant	Yes	
Dr R Torano	GlaxoSmithKline	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**
Dr P Varley	MedImmune AstraZeneca	Salary, Shares	None	None	No	None

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