# Human Medicines Regulations 2012 Advisory Bodies

Annual Report 2018

**Medicines & Healthcare products Regulatory Agency**

# HUMAN MEDICINES REGULATIONS 2012

# ADVISORY BODIES ANNUAL REPORT 2018

**Laid before Parliament pursuant to Part 2,**

**Section 12 (4) of**

**the Human Medicines Regulations 2012**

Commission on Human Medicines

British Pharmacopoeia Commission

**Contact for information about these reports:**

**Zhirui Huang**

**Expert Committee Support**

**10 South Colonnade, Canary Wharf**

**London E14 4PU**

**020 3080 6060**



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Any enquiries regarding this publication should be sent to us at
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf
London
E14 4PU

Telephone (weekdays: 9:00 – 17:00): 020 3080 6000
Email: info@mhra.gov.uk

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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 2018 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.

Baroness Blackwood

# COMMISSION ON HUMAN MEDICINES ANNUAL REPORT 2018

## TERMS OF REFERENCE

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

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

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

## MEMBERSHIP

3. Commissioners' details are listed at **Appendix I**. There are currently 10 Expert Advisory Groups (EAGs) that report to the Commission, their remits and membership are listed at **Appendix II**.

4. The Commission paid tribute this year to **Professor Martin Gore CBE**, who sadly passed away on 10th January 2019 and **Mr Phil Willan**, who sadly passed away on 4th March 2019

5. The Commission wishes to record its gratitude and appreciation of the valuable work of its EAGs and other Working Groups listed below that met in 2018. Members' details are listed at **Appendix II**.

**Expert Advisory Group 2018**

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

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

Clinical Trials, Biologicals & Vaccines Expert Advisory Group (CTBVEAG)
Chaired by **Professor Angela E Thomas**

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

Infection Expert Advisory Group (IEAG)
Chaired by **Professor Jonathan S Friedland**

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

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

Oncology & Haematology Expert Advisory Group (OHEAG)
Chaired by **Professor Martin Gore**

Pharmacovigilance Expert Advisory Group (PEAG)
Chaired by **Professor Sir Munir Pirmohamed**

The Paediatric Medicines Expert Advisory Group (PMEAG)
Chaired by **Dr Rebecca Mann**

**Working Groups 2018**

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

Emollient Expert Group
Chaired by **Professor Michael Ardern-Jones**

Laxatives Ad Hoc Expert Group
Chaired by **Professor Angela E Thomas**

Raxone Patient Group
Chaired by **Dr J Colin Forfar**

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

Zebrafish Toxicology Ad Hoc Expert Group
Chaired by **Professor Alan Boobis**

## MEETINGS

6. The Committee for Medicinal Products for Human Use (CHMP) is the European Medicines Agency's (EMA) committee responsible for preparing the EMA'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).

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

    - Dr Richard Gilson (HIV/Viral Diseases SAG)
    - Professor Martin Gore (Served on Oncology SAG)
    - Professor Nigel Klein (HIV/Viral Diseases SAG)
    - Professor Malcom Macleod (Neurology SAG)
    - Professor David G C Owens (Psychiatry 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 2018. Two-day meetings were held in March, April and December. One day meetings normally lasted six hours. Meetings were held at the Medicines and Healthcare Products Regulatory Agency (MHRA), 151 Buckingham Palace Road, London, SW1W 9SZ until June 2018 then at 10 South Colonnade, Canary Wharf, London E14 4PU on the 10th Floor.

### 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 are also payable within the Department of Health and Social Care guidelines.

## FIRST CONSIDERATION BY THE COMMISSION

12. The Commission considered and advised on a total of 166 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-initially** |
|---|---|---|
| **New Active Substances** | **3** | **18** |
| **Abridged Applications** | **1** | **114** |

13. The Commission was extensively involved in applications made through the European Centralised Procedure. The Commission considered 20 new active substances, or new combinations of active substances, via the Centralised Procedure, providing input into the CHMP deliberations and a UK position.

14. The Commission considered 10 papers under the Early Access to Medicines Scheme (EAMS).

15. The Commission considered an average of nine applications at each of its 11 meetings in 2018, in addition to clinical trial applications, appeals, reclassifications, pharmacovigilance issues and other matters.

## APPEALS

16. The Commission considered a total of four pre-hearings covering five applications. Of these, one application was approved at the pre-hearing stage, on condition that the product particulars were amended. One pre-hearing covering one application was withdrawn. Two applications were not approved. Both of these proceeded to an oral hearing individually, one took place in March 2018. One pre-hearing covering one application was not approved. This proceeded to an oral hearing, which took place in January 2019.

17. The Commission considered a total of 17 written representations covering 31 applications. Of these, for 15 written representations

covering 28 applications, the Commission advised that marketing authorisations could be granted, subject to the resolution of the outstanding minor concerns. For the remaining 2 written representations covering three applications, the Commission advised against the grant of marketing authorisations.

## EXTERNAL EXPERTS AND STAKEHOLDERS

18. The Commission received the following external experts contributing to the discussions. There were also four observers who each attended one meeting:

### External Experts

**Dr Michael Ardern-Jones** BSc MBBS DPhil FRCP
Associate Professor, University of Southampton & Consultant Dermatology, Southampton University Hospital

**Professor Alan Boobis** OBE PhD CBiol FSB FBTS
Centre for Pharmacology & Therapeutics, Toxicology Unit, Department of Medicine, Hammersmith Campus, Imperial College London

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

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

**Professor Ash Soni** OBE FFRPS FRPharmS LPN
Pharmacy Chair (London); Executive & Council Member, National Association of Primary Care; English Pharmacy Board Member, Royal Pharmaceutical Society; Pharmacy Clinical Network Lead, Lambeth CCG

**Ms Laura Steeples**
Consultant Ophthalmic Surgeon - sub-speciality Uveitis (adult and paediatric) at
Manchester Royal Eye Hospital

**Mrs Madeleine Wang** BA (Hons)
Lay Representative. Patient Advocate.
Member of the Clinical Trials, Biologicals and Vaccines Expert Advisory Group

**Professor Anthony G Wilson** MB BCH BAO DCH PhD FRCPFull Professor of Rheumatology, School of Medicine, Conway Institute, Dublin

**Of these two were international observers**

**Dr Elizabeth Adeyeye**
Clinical Research Physician, NIHR Clinical Research Facility, Guy's and St. Thomas NHS Foundation Trust

**Mr Tim Brier**
Final year NHS clinical pharmacology trainee

**Ms Hacer Coşkun Çetintaş** MSC Pharm
Head of Department of Marketing Authorization for Medicines, Turkish Medicines and Medical Devices Agency

**Dr Hala Fadda** PhD
Associate Professor of Pharmaceutics, College of Pharmacy & Health Sciences, Butler University, USA

## 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:

## SAFETY OF MARKETED MEDICINES

### Emollient topical products and risk of serious and fatal burns

20. Following cases of serious and fatal burns involving use of emollients containing levels of paraffin less than 21%, the Commission convened an Expert Working Group and discussed the Group's recommendations at its December meeting. The Commission considered the preventable and tragic nature of the reported burn fatalities and also noted the important role and widespread use of emollients in the treatment of dry skin conditions such as eczema and psoriasis. The Commission concluded that the benefit of these products continues to outweigh the risk, taking into account that the risk was very rare and the important therapeutic role of emollients, but that additional measures were needed to protect public health, such as addition of a warning not to smoke and a symbol on the product labels, to be applied to all emollients both paraffin-containing and paraffin-free. The Commission considered there should be wide communications and endorsed the recommendation for initial public communication of the new information about the known risk followed by a second phase of more targeted education and awareness-raising

aimed at healthcare professionals and patients. An article was published in the December issue of Drug Safety Update[1].

**Safety of medicines in pregnancy - proposal for a working group on observational healthcare data**

21. In response to the recommendations of the Report of the Expert Working Group on Hormone Pregnancy Tests published in November 2017[2], the Commission advised on the formation of an Expert Working Group to consider better ways to collect and monitor data on the safety of medicines during pregnancy. This will be convened in 2019.

**Monitoring Suspected Adverse Drug Reaction reports relating to medicines in pregnancy**

22. The Commission considered the monitoring of suspected adverse drug reaction (ADR) reports relating to medicines in pregnancy and endorsed the proposals for the Medicines for Women's Health Expert Advisory Group (MWHEAG) to review these reports on its behalf. The Commission advised that the MWHEAG should provide regular, independent review by experts of all suspected adverse drug reactions in pregnancy that are reported by healthcare professionals and women in the UK to the MHRA and that these will be reported on annually by the Commission. The Commission highlighted that consultation with the Expert Advisory Groups with expertise in pharmacovigilance, paediatric medicines and non-clinical data may be appropriate for the evaluation of some signals.

**Opioid analgesics and dependence and addiction**

23. The Commission considered the current evidence on trends in the usage of opioid analgesics in the UK in the context of worldwide concern about overuse of opioids and the risk of dependence and addiction. The Commission advised that overall opioid prescribing was increasing in the UK and there was a need for improvement in regulatory risk minimisation measures and overall education for health care professionals and patients. The Commission also acknowledged that opioids play an important role in pain management. The Commission advised that an ad hoc expert advisory group should be formed to review available evidence on dependence and addiction, to recommend ways to improve risk minimisation measures and to improve communication and healthcare professional and patient education.

[1] https://www.gov.uk/drug-safety-update/emollients-new-information-about-risk-of-severe-and-fatal-burns-with-paraffin-containing-and-paraffin-free-emollients
[2] https://www.gov.uk/government/publications/report-of-the-commission-on-human-medicines-expert-working-group-on-hormone-pregnancy-tests

## MEDICINES AVAILABLE WITHOUT PRESCRIPTION

24. The Commission considered 9 applications for change of legal classification during the year: two applications were for Pharmacy Only (P) availability and seven applications were for General Sales List (GSL) availability. Subject to the resolution of certain points CHM advised that three of the P to GSL applications could be approvable:
    - a medicine for the temporary relief of mild to moderate pain associated with migraine, headache, backache, period pain, dental pain, rheumatic and muscular pain, cold and flu symptoms, sore throat and fever, for pain which requires stronger analgesia than ibuprofen and paracetamol alone;
    - a medicine for the treatment of mild to moderate acne affecting the face in patents aged 12 years and older;
    - a screening test for potential allergic contact dermatitis in people aged 16 years of age and over.

### Review of antibiotic-containing throat lozenges

25. On the basis of the current information the CHM advised that the use of antibiotic containing lozenges to treat sore throats was not clinically appropriate.

### Over the counter (OTC) stimulant laxatives

26. The Commission considered a review of the risks and benefits of stimulant laxatives, (senna, bisacodyl and sodium picosulfate, both oral and rectally administered formulations) and the appropriateness of their continued over-the-counter (OTC) availability under the current terms of their Marketing Authorisations. The Commission also considered the views of an ad hoc Expert Group. The Commission advised on a package of measures to manage the risk of abuse and misuse of these products in the OTC setting.

## THE COMMISSION'S EXPERT ADVISORY GROUPS (EAGs)

27. 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)

28. In 2018, the CDRRAEAG met once and convened three times via teleconference and provided advice by written correspondence on eight occasions.

29. In January, the EAG convened via teleconference and made recommendations on a medicine proposed through an extension of

indication for the treatment of respiratory decline in patients with Duchenne muscular dystrophy. This is a genetic disorder resulting in severe generalised weakening of muscles, including muscles of the chest wall which results in breathing problems.

30. In February, the EAG provided the following three papers for written comments:
    - a variation application to extend the use of a medicine to include use in hypercholesterolaemia associated with Human Immunodeficiency Virus (HIV) infection or its treatment;
    - a medicine indicated for the risk of stroke, haemorrhage, and mortality in older patients with chronic kidney disease newly started on anticoagulation for atrial fibrillation: assessment of a population-based study from UK primary care;
    - a medicine indicated for the treatment of asthma.

31. In May, the EAG met face to face and made recommendations on the following three applications:
    - a medicine used for diagnostic purposes to assess the severity of narrowing of the arteries to the heart;
    - an oral medicine licensed for the treatment of Type II diabetes for use as an adjunct to insulin for the treatment of type I diabetes;
    - a variation application for an antithrombotic medicine to extend the currently licensed indications to include prevention of cardiovascular events (when taken with aspirin) in patients with history of coronary artery disease or peripheral artery disease. The EAG considered the available evidence and discussed the expected benefits against the potential risks for patients taking this medicine with aspirin. The EAG made recommendations on the proposed indications and suggested changes to the product information.

32. In July, the EAG convened via teleconference and made recommendations on the following three applications:
    - a new medicine proposed to be used as an adjunct to insulin therapy to improve the control of blood sugar (glucose) in adults with Type I diabetes mellitus. The EAG considered the available evidence based on the results of clinical studies in patients with type I diabetes mellitus, and the expected benefits and possible risks of this new therapy. The EAG made recommendations on issues that need to be further reviewed and clarified and suggested changes to the proposed product information;
    - a medicine for the treatment of non-cystic fibrosis bronchiectasis (NCFEB) patients with chronic lung infection with the organism Pseudomonas aeruginosa;
    - a medicine that treats hereditary ATTR (hATTR) amyloidosis, a rare disease caused by the build-up of abnormal deposits of

a protein (amyloid) in the tissues of the body, especially in the nerves and in the heart, under the EAMS scheme. The EAG considered the benefits offered by the medicine for this rare condition with unmet need and the limitation of the available data in severe forms, concluding that the overall benefit risk was positive. Additional Risk Minimisation Measures are in place for the duration of the EAMS period.

33. In September, the EAG convened via teleconference and made recommendations on the following application:

- a medicine for treatment of asthma in children aged 5-11 years. The EAG was reassured by the evidence presented for this medicine from studies in children and from use of the medicine in children in other markets around the world over many years, and they considered that no additional risks are expected at the doses proposed in this age group compared with the adult population. They made recommendations on additional dosing information to be included in the product information.

34. Also, in September, the EAG provided written comments on a national application for a medicine indicated for the treatment of asthma.

35. In October, the EAG provided written comments on the following two papers

- a medicine for the treatment of chronic kidney disease;
- a medicine indicated for severe renal insufficiency where blood levels cannot be regularly monitored.

36. In November, the EAG provided written comments on the following two papers

- the recall of sartan products used for the treatment of high blood pressure or heart failure, contaminated with N-nitrosodimethylamine (NDMA) and N-nitrosodiethylamine (NDEA);
- a new active substance for the treatment of ANCA-associated vasculitis.

**Chemistry, Pharmacy and Standards Expert Advisory Group (CPSEAG)**

37. In 2018, the CPSEAG met 11 times and considered and advised on applications for new drugs, abridged applications, variations, written representations, pre-hearings, reclassification applications as well as position papers, defective medicines and draft guidelines. The EAG also provided advice by written correspondence on eleven Marketing Authorisation applications.

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

- a medicine indicated for the treatment of complicated intra-abdominal infection (cIAI), inflammation of the gastrointestinal tract in adults;
- a medicine indicated for the treatment of adult patients with acute myeloid leukaemia (AML), cancer of blood forming cells in the bone marrow;
- a medicine indicated for the treatment of indigestion and metabolic acidosis, a condition where the body fluids and tissues are unusually acidic;
- a medicine indicated for the treatment of the symptoms of overactive bladder;
- a radio-pharmaceutical medicine for diagnostic use only. It is given before a scan and helps a special camera to see inside a part of the body to help identify an illness;
- a medicine indicated for the treatment of acute myeloid leukaemia (AML) under the Early Access to Medicines Scheme (EAMS);
- The EAG were updated on the current situation and developments regarding histamine contamination in gentamicin preparations.

39. In February, the EAG considered and made recommendations on the following:
    - a medicine indicated for the prevention of breathing problems associated with lung conditions such as asthma and chronic obstructive pulmonary disease;
    - a medicine indicated for the treatment of various viral infections, such as chickenpox, shingles, cold sores, genital herpes and other herpes simplex infections;
    - a medicine indicated for the treatment of urinary incontinence in various forms;
    - a medicine indicated for the treatment of skin damage caused by long-term sun exposure.

40. The EAG also provided written comments on the following:
    - issues with residual solvent testing of a drug substance;
    - a medicine indicated for the treatment of a wide range of bacterial infections.

41. In March, the EAG considered and made recommendations on the following:
    - a medicine indicated for the treatment of narcotic dependence in adults and adolescents over 15 years who have agreed to be treated for addiction and who are also receiving medical, social and psychological support;
    - a medicine indicated for the treatment of severe influenza in patients who are in hospital, when other influenza treatments are not suitable;

- a medicine indicated for the short-term treatment of a range of severe infections, such as bacterial septicaemia;
- a medicine indicated for the topical treatment of scalp psoriasis in adults;
- two medicines indicated for the treatment of certain bacterial infections, including: chest, throat or nasal infections; ear infections; skin and soft tissue infections and certain sexually transmitted diseases;
- a medicine indicated for the symptomatic treatment of painful muscle tension, especially in the lower back;
- a medicine indicated for the treatment of a wide range of conditions, such as asthma, arthritis, allergies and suppression of the immune system;
- a medicine indicated for the treatment of adult patients with hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis), a slowly progressive condition characterised by the build-up of abnormal deposits of a protein called amyloid in the body's organs and tissues;
- a medicine indicated for the relief of pain and inflammation in patients with arthritis and ankylosing spondylitis.

42. The EAG reviewed the published advice and advised updates to be made to the published MHRA advice for prescribers and patients for the use of medicines/devices in the emergency treatment of anaphylaxis.

43. The EAG was updated on a Q&A document developed by the Quality Working Party (QWP) to assist applicants when preparing Marketing Authorisation (MA) submissions for multidose, preservative-free eye drops.

44. The EAG also provided written comments on:
    - a medicine indicated for use in birth control;
    - a medicine indicated for use for the treatment of a genetic disease that causes loss of sensation in the extremities.

45. In April, the EAG considered and made recommendations on the following:
    - a medicine indicated for the treatment of ovarian cancer;
    - a medicine indicated for the treatment of 1st and 2nd stage African Trypanosomiasis (sleeping sickness);
    - two medicines indicated for the treatment of HIV-1;
    - a medicine indicated for the treatment of traveller’s diarrhoea;
    - a medicine indicated for relief of neuropathic pain associated with herpes infections such as shingles;
    - a medicine indicated for the relief of spasticity of voluntary muscle resulting from disorders such as: multiple sclerosis, other spinal lesions;

- a medicine indicated for the relief and/or prevention of craving and nicotine withdrawal symptoms associated with tobacco dependence and to aid smokers wishing to quit or reduce prior to quitting;
- a medicine indicated for the emergency treatment of severe acute allergic reactions (anaphylaxis) to insect stings or bites, foods, drugs and other allergens;
- two medicines indicated for the treatment of an overactive thyroid gland.

46. In May, the EAG considered and made recommendations on the following:
    - a medicine indicated for use in combination with other antiepileptic medicines to treat seizures associated with two rare forms of epilepsy, viz. Dravet syndrome and Lennox-Gastaut syndrome, in adults and children aged from 2 years of age;
    - a medicine indicated for the treatment of sickle cell disease, an inherited condition affecting the red blood cells;
    - a medicine indicated for the treatment of epilepsy, schizophrenia and short-term relief of anxiety;
    - a medicine indicated for the treatment of anxiety and depression;
    - a medicine indicated for the treatment of various infections caused by bacteria;
    - a medicine indicated for the treatment of various infections caused by bacteria and/or parasites;
    - a medicine indicated for the treatment of increased amounts of parathyroid hormone (PTH). PTH is made by the 4 parathyroid glands which lie close to the thyroid gland in the neck, and regulates calcium levels in the blood.

47. The EAG was updated and made comments on a draft Guideline developed by the QWP on the sterilisation of the medicinal product, active substance, excipient and primary container to assist applicants when preparing MA submissions for sterile medicinal products.

48. The EAG was updated and made comments on a draft Guideline on quality and equivalence of topical products developed by the QWP to assist applicants when preparing MA submissions for topical products.

49. In May, the EAG also provided written comments on two medicines indicated for the treatment of cancer.

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

- a medicine indicated for the treatment of adult patients with moderate to severe active rheumatoid arthritis and psoriatic arthritis (a long-term disease that mainly causes pain and swelling of the joints);
- a medicine indicated for the treatment of non-cystic fibrosis bronchiectasis (patients with chronic lung infection);
- a medicine indicated for the treatment of rheumatoid arthritis inflammation in people with autoimmune diseases; juvenile idiopathic arthritis (most common rheumatoid arthritis in children) and discoid and systemic lupus erythematosus (a disease of the skin or the internal organs) and skin problems which are sensitive to sunlight;
- a medicine indicated for preventative treatment for asthma;
- two medicines indicated for the control of hypothyroidism (thyroid hormone deficiency, produced by a small gland at the base of the neck;
- a medicine indicated for the treatment of glaucoma (raised pressure within the eye and for epilepsy (fits and convulsions);
- a medicine indicated for use in pre-operative skin disinfection prior to minor and major surgical procedures;
- a medicine indicated for the treatment of advanced Buerger's disease (inflammation in blood vessels) and Raynaud's phenomenon (reduced blood circulation of the fingers and toes);
- a medicine indicated for the treatment of epilepsy in adults, adolescents and children aged six and above. Also indicated for the treatment of peripheral neuropathic pain such as painful diabetic neuropathy (nerve damage) and post-herpetic neuralgia (complication of shingles) in adults;
- a medicine indicated for the treatment of HIV -1 (Human immunodeficiency Virus) infection;
- a medicine indicated for the treatment of respiratory tract disorders (problems with the breathing passages) characterised by excessive, viscous (thick sticky) mucus including chronic obstructive airways disease (lung damage with restricted airways).

51. The EAG considered and made recommendations on a medicine indicated for the treatment of cancer, including gastric cancer under EAMS.

52. In June, the EAG also provided written comments on a medicine used to numb (anaesthetise) parts of the body to reduce pain and reflex gagging.

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

- a medicine indicated for the treatment of Type 1 diabetes by slowing the absorption of glucose in the intestine and increasing glucose excretion in urine;
- a medicine indicated for the treatment of heartburn and reduction of gastric secretion and acid output;
- a medicine indicated for relief of pain and inflammation
- a medicine indicated for the treatment of stage III colon cancer (anti-cancer drug);
- a medicine indicated for the treatment of leprosy, treatment of dermatitis herpetiformis, and prevention of pneumonia;
- a medicine indicated for the prevention and treatment of blood clots in the legs, lungs, brain and heart;
- a medicine indicated to produce a temporary loss of feeling in the eye before and during certain types of procedures;
- a medicine indicated for the reduction of swelling of nasal mucous membrane and relieving symptoms of nasal congestion associated with colds, sinusitis or other respiratory tract allergies, promote healing of mucous membrane lesions and treat worsened breathing after nose surgery;
- a medicine indicated for the treatment of fungal skin infections.

54. The EAG considered and made recommendations on the following:
    - a variation to a medicine indicated for use before an X-ray to make the image clearer;
    - a medicine indicated for the treatment of bacterial infections;
    - a medicine indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and children above 6 years of age.

55. The EAG was informed of the ongoing work concerning potential nitrosamine contamination in ‘Sartan’ medicinal products.

56. In September, the EAG considered and advised on the following:
    - a medicine indicated for the treatment of fungal infections;
    - a medicine indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD);
    - a medicine indicated for helping keep airways open and aid breathlessness and wheezing;
    - a medicine indicated for the treatment of gastro-esophageal reflux disorder (GERD), ulcers in intestine, ulcers caused by use of non-steroidal anti-inflammatory drugs and ulcers infected with bacteria called Helicobacter pylori;
    - a medicine indicated for the treatment of an over-active thyroid (Hypothyroidism);
    - a medicine indicated for the treatment of infections in the bladder, kidney and urinary tract;

- a medicine indicated for treatment of problems with the breathing passages (respiratory tract);
- a medicine indicated for use as a X Ray contrast;
- a medicine indicated for the treatment of problems with the breathing passages (respiratory tract).

57. In September, the EAG also provided written comments on a medicine indicated for the treatment of anaphylaxis.

58. In October, the EAG considered and advised on the following:
    - a medicine indicated for use in an emergency setting to increase blood pressure to normal levels in adult patients with seriously low blood pressure who do not respond to fluids or other medicines that raise blood pressure;
    - a medicine indicated to reduce the risk of bleeding during surgery and other procedures (including tooth extractions and endoscopy), given to adults who have low numbers of platelets because of chronic liver disease;
    - a medicine indicated to inhibit the growth of cancer cells in ovarian, breast and advanced non-small-cell lung cancers;
    - a medicine indicated for the prevention of asthma attacks, by reducing swelling and irritation in the lungs;
    - a medicine for the treatment of infections caused by bacteria;
    - a medicine indicated for hormone replacement therapy for the relief of symptoms occurring after menopause and the prevention of osteoporosis;
    - a medicine indicated for use in combination for the treatment of cancer;
    - a medicine indicated for the treatment of eye 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;
    - a medicine indicated for the treatment of the symptoms of overactive bladder.

59. In November, the EAG considered and advised on:
    - a medicine indicated for the treatment of osteoporosis, when bones become thin and fragile, in postmenopausal women;
    - a medicine indicated for the treatment and prevention of tuberculosis an infectious disease;
    - a medicine indicated for the treatment of several types of infections caused by bacteria;
    - a medicine indicated for the treatment of various infections caused by bacteria and/or parasites;
    - a medicine indicated for the treatment of viruses such as chickenpox, shingles and herpes. Also used to stop these problems returning in people with low immune systems;

- a medicine indicated for the control the release of urine and for treatment of incontinence;
- a medicine indicated for the treatment of bacterial infections of skin, ear, chest, throat and sexually transmitted diseases;
- a medicine indicated for the treatment of indigestion and when the body produces excess acid;
- a medicine indicated for the emergency treatment of severe acute allergic reactions (anaphylactic shock) to insect stings or bites, foods, drugs and other allergens;
- the EAG was updated on and made comments on a draft ICH guideline concerning the technical and regulatory considerations for pharmaceutical product lifecycle management;
- the EAG was updated on the new regulations which came into force on 1st November 2018 allowing certain cannabis-based products to be available for medicinal use in the UK. In addition, the EAG was informed of discussions at the Pharmacovigilance EAG concerning the arrangements for monitoring of potential adverse reactions to cannabis-based medicinal products;
- the EAG was updated on the ongoing issue of nitrosamine contamination, NDMA (N-nitrosodimethylamine) and NDEA (N-nitrosodiethylamine), in 'Sartan' medicinal products including details of recalls as well as control measures.

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

- a medicine indicated for the treatment of hyperthyroidism (overactive thyroid gland);
- a medicine indicated for the treatment of respiratory tract disorders characterised by excessive mucus including chronic obstructive airways disease;
- a medicine indicated for the treatment and prevention of Vitamin D deficiency and rickets (a condition that affects bone development in children and softening of bones in adults);
- a medicine indicated for use as a diluent for other medicines;
- a medicine indicated for the treatment various forms of epilepsy (seizures that are initially limited to certain parts of the brain), and for the treatment of peripheral neuropathic pain (long lasting pain caused by damage to nerves) due to diabetes or shingles;
- a medicine indicated for the treatment of glaucoma (a condition of the eye), for epilepsy (fits and convulsions);
- a medicine indicated for healing or stopping stomach ulcers, aiding with excess acid in stomach both in children and adults;
- a medicine indicated for numbing the inside of nose or throat before surgery or for other procedures involving the nose or throat;

- update on recall of sartan products contaminated with N-nitrosodimethylamine (NDMA) and N-nitrosodiethylamine (NDEA);
- an update to the ongoing Article 31 referral into potential nitrosamine contamination of the angiotensin II receptor blocker (sartan) class of medicines was presented to the committee for information and advice.

61. The CPS EAG was updated on the new regulations which came into force on 1st November 2018 to allow certain cannabis-based products to be available for medicinal use in the UK. The EAG were informed of discussions at the Pharmacovigilance EAG concerning the arrangements for monitoring of potential adverse reactions.

62. In December, the EAG provided written comments on:
    - a medicine used to treat bacterial infections;
    - a medicine used to treat ovarian cancer.

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

63. In 2018, the CTVBEAG met seven times and convened three times via teleconference and provided advice by written correspondence on four occasions.

64. In January, the EAG convened and made recommendations on the trial of a new drug substance in patients with transfusion-dependent β-thalassemia, a blood disorder that reduces the production of iron-containing protein in red blood cells.

65. In February, the EAG convened and made recommendations on:
    - a therapy for the treatment of white blood cell and lymphatic system cancers;
    - a workshop to discuss the benefits and risks associated with trials allowing patients who had previously received an Advanced Therapy Medicinal Product (ATMP). The aim of this and future workshops is to produce a guidance document to assist Sponsors when preparing a submission of clinical trials in patients who received Chimeric Antigen Receptor T cells, gene therapy or tumour vaccines.

66. Also, in February, the EAG provided written comments on a second paper of the ATMP workshop.

67. In April, the EAG convened and made recommendations on:
    - the benefits and risks associated with trials enrolling patients who had previously received an Advanced Therapy Medicinal Product (ATMP). The additional comments provided by the experts will be incorporated in a guidance document aimed at

assisting Sponsors when preparing a submission of clinical trials in patients who received Chimeric Antigen Receptor T cells (CAR-T cells), gene therapy or tumour vaccines;
- an update to company questions from a rejected clinical trial for which advice had been sought at a previous meeting.

68. In May, the EAG convened and made recommendations on:
    - a medicine used in combination with multi-agent chemotherapeutic regimens, for the treatment of children and adult patients with a cancer of the white blood cells called Philadelphia chromosome negative acute lymphoblastic leukaemia, who have either relapsed or failed first line treatment;
    - two clinical trial applications to evaluate and compare the efficacy and safety of an Advanced Therapy investigational Medicinal Product (ATMP) to be used in adult patients with aggressive cancer, B-cell Non-Hodgkin Lymphomas (B-NHL) and patients with high-risk, transplant-eligible relapsed or refractory aggressive B-cell non-Hodgkin lymphomas cancer;
    - a clinical trial application to evaluate and compare the efficacy and safety of an Advanced Therapy investigational Medicinal Product (ATMP) to be used as a first in man trial in patients with sickle cell anaemia;
    - a clinical trial application to evaluate and compare the efficacy and safety of an Advanced Therapy investigational Medicinal Product (ATMP) to be used as a first in man trial in patients with sickle cell anaemia to discuss the benefits and risks associated with trials enrolling patients who had previously received ATMP. It was agreed that the additional comments provided by the experts will be incorporated in a short paper to be published in a suitable peer review journal (i.e. Letter to the Editor on the New England Journal of Medicine).

69. In June, the EAG convened via teleconference and considered and advised on a clinical trial application for the treatment of patients with acute myeloid leukaemia, a cancer of the white blood cells.

70. Also, in June, the EAG provided written comments on:
    - a medicine with regards to an application concerning hATTR, cardiovascular specifications;
    - a Phase II, single arm, multicenter open label trial to determine the efficacy and safety of a medicine in adult patients with refractory or relapsed follicular lymphoma.

71. In July, the EAG convened via teleconference and considered and advised on a clinical trial application for the treatment of a study to evaluate the efficacy and safety of using a chimeric antigen receptor (CAR) T-cell therapy in children and young adult patients with acute

lymphoblastic leukaemia (ALL), who have failed prior therapies. ALL is a cancer in the bone marrow of the white blood cells.

72. Also, in July, the EAG considered and advised on

- a medicine used for the treatment of patients of all ages with haemophilia A, an inherited bleeding disorder, where the blood takes longer to clot due to a missing or reduced level of clotting protein.

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

- the responses received from the Sponsor of two trials for tisagenlecleucel. Data were presented and the EAG agreed that the responses were not acceptable without further changes to the protocol;
- a clinical trial application to evaluate the efficacy and safety of an allogeneic i.e. from a donor CAR-T cell therapy in patients with unresectable metastatic colorectal cancer;
- a clinical trial application to evaluate the efficacy and safety of an autologous i.e. from the patient CAR-T cell therapy in patients with relapsed and refractory multiple myeloma (RRMM) a blood cancer arising from plasma cells;
- a Phase I/IIa study to evaluate the safety, preliminary efficacy and impact of a stem cell product which is implanted into the brains of patients with early Alzheimer's disease;
- a phase II/III clinical trial application of a study to evaluate the efficacy of the delivery of gene therapy into the brain used in improving or stabilising the neurodevelopmental (e.g., intellectual functioning, reading ability, social skills, memory, attention or focus skills) status of patients after 24 months (main cohort), compared to the expected evolution based on natural history data. Mucopolysaccharidosis IIIA (MPS IIIA), also known as Sanfilippo Syndrome Type A, is a rare paediatric disease that is uniformly fatal;
- a detailed review of all CAR T-cell trials reviewed by MHRA since 2009. It was agreed that where a product has no novel aspects that MHRA CTU discretion can be used to determine if EAG review is required. Any novel aspect, for example a new target, vector or patient population, will require that product to need EAG review.

74. In October, the EAG convened via teleconference and considered and advised on a clinical trial application for a first in human treatment to kill prostate cancer cells in patients with advanced prostate cancer.

75. Also, in October, the EAG provided written comments on a medicine indicated in combination with other immunosuppressive medicinal products for the suppression of immune competent cells which are the cause for graft versus host disease after stem cell transplantation.

76. In November, the EAG convened and made recommendations on the following two clinical trial applications:
    - a new advanced therapy medicine in patients with non-small cell lung cancer;
    - a new advanced therapy medicine in patients with the more severe types of Osteogenesis Imperfecta (brittle bone disease).

77. In December, the EAG convened and made recommendations on the following four applications:
    - a medicine used to treat babies, children and adolescents aged up to 18 years old; for the treatment of haemophagocytic lymphohistiocytosis (HLH), a condition that causes some cells of the immune system to become overactive, which results in too much inflammation and can stop vital organs of the body from working properly;
    - a vaccine to help protect persons of 65 years of age and older against influenza (flu);
    - a clinical trial application to evaluate the grounds for a non-acceptance response and advised that the responses are acceptable, and the trial can be approved;
    - a clinical trial application regarding a GNA response and it's for the treatment of mucopolysaccharidosis type IIIA.

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

78. In 2018, The GRIDEAG convened three times and provided advice by written correspondence on five occasions:

79. In April, the EAG provided written comments on two medicines:
    - a medicine indicated as a diagnostic agent used as an adjunct in the detection of altered cerebral perfusion in stroke patients and is also indicated for white blood cell labelling as an adjunct in the localization of abdominal infections and inflammatory bowel disease;
    - a medicine indicated as a contraceptive.

80. In May, the EAG provided written comments on a medicine indicated for the treatment of mild skin abnormalities on the head or face called solar keratosis. These are small, rough, spots which develop on the skin. They are caused by a lot of exposure to the sun over many years. They are also called actinic keratosis.

81. In June, the EAG considered and advised on a medicine indicated for the treatment of moderate to severe active rheumatoid arthritis (RA), a condition that causes pain and inflammation in a joint.

82. In July, the EAG considered and advised on a product indicated for screening test for potential allergic reaction to PPD (Paraphenylenediamine) and its reclassification of a product from POM to GSL.

83. In September, the EAG considered and advised on a product indicated for mild acne on face for children aged 12 years and over, and its reclassification of a product from P to GSL.

84. In November, the EAG provided written comments on two medicines:
- a medicine indicated for the treatment of Hodgkin lymphoma (cancer that develops in lymph nodes);
- a medicine indicated for the treatment of actinic keratosis, also called solar keratosis, in adults. Actinic keratoses are rough areas of skin found in people who have been exposed to too much sunshine over the course of their lifetime.

**Infection Expert Advisory Group (IEAG)**

85. In 2018, the IEAG met twice and convened once via teleconference and provided written comments on seven occasions.

86. In January, the EAG discussed and made a recommendation on a medicine indicated for the treatment of complicated intra-abdominal infection (cIAI), inflammation of the gastrointestinal tract in adults.

87. In March, the EAG convened via teleconference and made a recommendation on a medicine used to treat severe flu (influenza virus infection) in patients who are in hospital. It is used when other flu treatments are not suitable. A doctor or nurse will administer the medicine as an infusion into a vein (a drip) or by using a syringe pump. This is used in adults and children 6 months or more.

88. In April, the EAG discussed and made recommendations on the following four applications:
- a medicine used in adults and children of at least 6 years of age and 20 kg in weight, to treat human African trypanosomiasis (also known as “sleeping sickness”) caused by the parasite *Trypanosoma brucei gambiense*;
- two medicines used to treat HIV in people 18 years of age and older. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome);
- a medicine used to treat travellers’ diarrhoea in adults caused by (enteropathogenic) disease in the intestinal tract when the diarrhoea is not accompanied by fever or blood in the stools.

89. In May, the EAG provided written comments on a paper on the protocol for a Registry to collect data on use of a medicine for Pre-Exposure Prophylaxis (PrEP) in the EU.

90. In June, the HIV Experts provided written comments on a paper on the potential clinical impact and communication strategy for the issue of an increased risk of treatment failure and an increased risk of mother to child transmission of HIV infection due to low exposure values of a medicine during the second and third trimesters of pregnancy.

91. In July, the EAG provided written comments on an Article 31 Referral to review evidence around an issue of serious, disabling, multiple adverse effects occurring together in patients exposed to systemic Fluoroquinolones products.

92. In August, the EAG provided written comments on an SPC wording in renal insufficiency.

93. In September, the EAG provided written comments on:
- a medicine indicated for the treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI) in adults;
- the need for regulatory action to minimise the risk of medication errors related to amphotericin product confusion.

94. In December, the EAG provided written comments on a medicine indicated for the treatment of the following infections: peritonitis and other intraabdominal and intra-pelvic infections, female genital tract infections, septicaemia, endocarditis, urinary tract infections, respiratory tract infections, bone and joint infections and skin and skin structure infections. It is also indicated for the prevention of postoperative infections associated with certain surgical procedures of the gastrointestinal, biliary and genital tracts.

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

95. In 2018, the MWHEAG met on six occasions during the year and provided comments by written communication on seven further occasions.

96. The EAG considered the latest evidence and made recommendations on the following issues with marketed medicines:
- risk of breast cancer associated with use of hormonal contraception;
- hormonal contraceptives and the risk of depression and suicidality;
- the effects of high BMI on efficacy of levonorgestrel-containing emergency contraception;
- aggravation of hypermobility symptoms associated with use of progesterone-only contraceptives;

- the risk of pregnancy with Nexplanon implants; proposals to reduce migration of Nexplanon implants away from their site of insertion.

97. The EAG considered the evidence and made recommendations on an application related to a new medicinal product for ovarian protection during chemotherapy.

98. Safety of Medicines during Pregnancy
    - the CHM Expert Working Group on Hormonal Pregnancy Tests (HPT EWG) made a number of recommendations aimed to improve knowledge on the safety of medicines during pregnancy. During the year the MWHEAG considered and made recommendations on several topics arising from these recommendations, including the need to avoid inadvertent exposure in pregnancy to medicines which may harm an unborn child.

99. The EAG provided comments and/or guidance on policy and regulatory guidance for:
    - regulatory guidance on investigating medicines in pregnancy, inclusion of pregnant women in clinical trials, and risk management for medicines in pregnant and breastfeeding women;
    - guidance on contraception and pregnancy testing during use of medicines with teratogenic potential;
    - changes to the information requested on the Yellow Card App related to possible exposures during pregnancy.

100. One of the specific recommendations from the HPT EWG was that there should be 'regular, independent review by experts of all suspected adverse drug reactions in pregnancy that are reported by healthcare professionals and women in the UK to the MHRA'. To address this, the MWHEAG reviewed all reports of suspected ADRs associated with use of medicines in pregnancy received by MHRA since May 2018.

101. The EAG initially considered and made recommendations on the proposed format and content of the ADR monitoring reports at its meeting in April 2018. To enable independent expert review of all suspected ADR reports, the expertise of the EAG was expanded to include clinicians with expertise on birth / genetic defects and, following EAG recommendations to CHM, a clinical geneticist has been appointed as a full member of the EAG.

102. At subsequent meetings the MWHEAG reviewed details of all Yellow Card reports related to exposures during pregnancy, particularly those reports associated with adverse outcomes in pregnancy (including pregnancy loss, birth defects and other effects on the fetus or

neonate). The MWHEAG considered highlighted reports or signals of interest that had been reviewed by MHRA and were provided with access to anonymised line listings of all individual Yellow Card reports received in the relevant time frame. The EAG was also informed of relevant ongoing EU reviews of medicines used during pregnancy.

103. The EAG reviewed 304 new reports of suspected ADRs associated with use of medicines in pregnancy received from May 2018 to September 2018. The majority of reports received from May 2018 to September 2018 did not raise any new concerns. The EAG was consulted on potential safety signals following use of the following medicines during pregnancy and recommended that no regulatory action was warranted in each case: gabapentin, quetiapine, Nexplanon, and infliximab. The EAG recommended that a potential signal of fetal growth restriction associated with sodium valproate should be kept under review.

104. The EAG considered further review and/or regulatory action should be taken for use of the following medicines during pregnancy:

- Sildenafil: an EU review had been undertaken of persistent pulmonary hypertension of the new born (PPHN) following in utero exposure within the Dutch STRIDER 1 Trial. The trial was stopped early due to an excess of PPHN following maternal administration of sildenafil. The MWHEAG considered that specialists were likely to be aware of this issue but supported the preliminary conclusions of the EU review and the distribution of a letter to health professionals advising against this off-label use of sildenafil for intrauterine growth restriction;
- Carbimazole: an EU review had been undertaken of the latest epidemiological data on carbimazole and its active metabolite thiamazole and congenital anomalies. Although the association between carbimazole and thiamazole exposure during pregnancy and congenital anomalies is already known, the EAG supported the provision of information on the frequency of anomalies in the Product Information and the recommendation to remind healthcare professionals of the need to avoid pregnancy during carbimazole treatment;
- Magnesium sulfate: US FDA issued a safety warning in 2013 concerning the risk of bone abnormalities in neonates following prolonged use (5-7 days) of magnesium sulphate for tocolysis. Magnesium sulfate is licensed for treatment of eclampsia but is not used for tocolysis in maternity units in the UK, so such prolonged use is unlikely to occur. However, use of magnesium sulfate off-label, for fetal neuroprotection for premature babies has increased and the maximum safe dose is not known. The EAG considered that the risk of fractures from the bone abnormalities described in the published literature is small, but that further review of the risks of

neonatal hypocalcaemia and hypermagnesemia was warranted and recommended seeking further specialist advice on the clinical implications of these reactions.

## Neurology, Pain & Psychiatry Expert Advisory Group (NPPEAG)

105. The NPPEAG met two times during 2018 and provided advice by written correspondence on three occasions.

106. In February, the EAG convened and provided recommendations on:
- a substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment;
- a product that is indicated as a disease modifying therapy for relapsing multiple sclerosis.

107. In May, the EAG convened and provided recommendations on a medicine indicated for the additional therapy of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) in patients from 2 years of age and older.

108. In June, the EAG provided written comments on the safety review of a medicine indicated for the treatment Anxiety related to alcoholism and narcomania, sleep disorders in adults and premedication (in adults).

109. In July, the EAG provided written comments on a medicine indicated for the treatment of a medicine used to treat multiple sclerosis.

110. In October, the EAG provided written comments on a medicine indicated for the treatment of opioid drug addictions (as a narcotic abstinence syndrome suppressant).

## Oncology and Haematology Expert Advisory Group (OHEAG)

111. In 2018, the OHEAG convened seven times face-to-face and by teleconference and provided advice by written correspondence on twelve occasions.

112. In January, the EAG convened via teleconference and made recommendations on a medicine indicated for the treatment of adult patients with acute myeloid leukaemia (AML), cancer of blood forming cells in the bone marrow.

113. Also, in January, the EAG provided written comments on a medicine indicated for the treatment of mycosis fungoides (a skin condition) or Sézary syndrome (type of skin cancer) who have received at least one prior systemic therapy.

114. In February, the EAG convened via teleconference and made recommendations on a medicine indicated for the treatment of adults with castration-resistant prostate cancer, a cancer of a gland of the male reproductive system. This medicine reduces male hormones and is only used when the disease is causing pain, has not responded to treatment and has spread to the bone, but is not known to have spread to other internal organs.

115. Also, in February, the EAG provided written comments on a medicine indicated for the treatment of cancer effecting white blood cells.

116. In March, the EAG provided written comments on a medicine indicated for the treatment of ovarian cancer.

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

- a medicine to be used in combination with other medicines for the treatment of adults and children (over 1 year old) with acute lymphoblastic leukaemia (ALL), cancer of the white blood cells;
- a medicine for the treatment of advanced kidney and liver cancer in adults who have already had previous treatment.

118. Also, in May, the EAG provided written comments on a medicine indicated for the treatment of Sickle Cell (an inherited blood disorder).

119. In June, the EAG convened via teleconference and made recommendations on a medicine recommended to treat adult cancer patients with a single drug and for adult patients with gastric cancer who are recommended for combination treatment. This was an early access to medicines application.

120. In July, the EAG provided written comments twice on

- a medicine indicated for the treatment of patients of all ages with haemophilia A (a genetic disorder where blood does not clot) who have developed factor VIII inhibitors (an essential substance required to clot blood and stop bleeding);
- a medicine used to regulate hormone levels and treat prostate cancer.

121. In September, the EAG convened via teleconference and made recommendations on:

- an anti-cancer medicine recommended for treatment of cancer of lungs in adults;
- a medicine recommended to treat adult patients with ovarian cancer;
- a medicine recommended for use as a diagnostic agent used in radiological examinations.

122. October, no meeting but the EAG provided written comments twice on:
    - a medicine indicated for the treatment of anaemia (iron deficiency);
    - a medicine indicated for the treatment of lung cancer.

123. In November, the EAG convened via teleconference and made recommendations on two medicines for the treatment of breast cancer.

**Pharmacovigilance Expert Advisory Group (PEAG)**

124. The PEAGmembership includes expertise in pharmacovigilance, clinical pharmacology, toxicology, epidemiology, general practice, and pharmacy and includes lay representation. The PEAG met on nine occasions during 2018 and provided advice by written procedure on a further three occasions. Summary reports based on the minutes of each meeting are published on the GOV.UK website.

125. The EAG considered papers and advised on the following:
    - daclizumab and post-withdrawal autoimmune encephalitis;
    - review of benefit and risk of OTC availability of stimulant laxatives (senna, bisacodyl, sodium picosulfate);
    - risk of severe liver injury with ulipristal acetate for treatment of moderate to severe symptoms of uterine fibroids;
    - new information on breast cancer risk associated with hormonal contraceptives;
    - hormonal contraceptives and the risk of depression and suicidality;
    - the need for a comprehensive review of the evidence for the risk of dependence and addiction with opioid analgesics;
    - off-label use of hydrocortisone muco-adhesive buccal tablets to treat adrenal insufficiency in children and risk of adrenal crisis;
    - hydrochlorothiazide and the risk of skin cancer;
    - dolutegravir and neural tube defects in infants of women who become pregnant whilst taking dolutegravir;
    - paracetamol and new data on OTC availability in Europe and the frequency of paracetamol-related enquiries to Poisons Information Centres.

126. The EAG considered the proposed Risk Management Plan (RMP) for one new medicine and one RMP submitted as part of an application to extend the indication for an existing treatment for diabetes. The PEAG also provided advice on the need for and the appropriate design of post-authorisation safety studies for four medicines.

127. The EAG's advice on these issues was subsequently implemented nationally or 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.

128. The EAG also gave advice on pharmacovigilance considerations relevant to the rescheduling from Schedule 1 to Schedule 2 (of the Misuse of Drugs Regulations 2001) of unlicensed cannabis and cannabis-based products for medicinal use.

129. In addition to the monthly Yellow Card reporting statistics, the EAG reviewed proposals for improving signal detection of medication error-related safety issues through promotion of the Yellow Card Scheme and collaboration with the National Medication Safety Network.

## Paediatric Medicines Expert Advisory Group (PMEAG)

130. The PMEAG advises the Commission on the safety, quality and efficacy of medicines for paediatric use, including all matters relating to the implementation of the EU Paediatric Regulation. The PMEAG met seven times in 2018 and provided advice through written correspondence for four papers.

Paediatric Investigation Plans (PIPs)

131. The PMEAG advises on PIPs where UK is Rapporteur or Peer Reviewer. The PMEAG discussed 16 PIPs where the UK was Rapporteur for 13 and 3 where UK has acted as Peer Reviewer. The advice given covered a range of therapeutic areas, including neurology, bone diseases, cardiac arrhythmias, infectious diseases, rheumatology and immunology, psychiatry and rare metabolic diseases.

Work-sharing procedures

132. The PMEAG considered five products which were being assessed under work-sharing procedures, (coordinated at European level by Member States) for which the UK was Rapporteur. The therapeutic areas for these procedures included drugs used for treatment of muscle spasticity, antibiotics, treatment of arrhythmias and treatment of conjunctivitis and other ophthalmic diseases.

Marketing authorisation applications supported by paediatric data

133. The PMEAG advised on three applications for new products. The products covered a range of indications including the treatment of severe infections, paediatric asthma and a radiopharmaceutical product.

Safety of medicines in children

134. In 2018 the PMEAG reviewed monthly statistics on suspected adverse drug reactions in paediatric patients reported to MHRA, and an overview of all identified paediatric signals. The PMEAG advised on paediatric signals with regards to potential interactions between drugs used in oncology, the use of opioids during labour and the risk to the breastfeeding child when the mother is receiving treatment for opioid addiction. The PMEAG also advised on a safety review of hydrocortisone muco-adhesive buccal tablets used off-label for adrenal insufficiency. The PMEAG also considered the benefit: risk of OTC laxatives.

Other advice related to the use of medicines in the paediatric population
Regulatory guidance:

135. The PMEAG discussed and advised on a number of draft or revised guidances being developed at European or international level. The topics included the requirements for medicinal products for the treatment of venous thromboembolic disease, and of psychiatric diseases, and a concept paper on the need for revision of the guideline on the investigation of medicinal products in the term and preterm neonate.

136. Finally, the PMEAG heard an update on the departure of the UK from the EU, in particular on the consultation on amendments to the UK Human Medicines Regulations in relation to paediatric medicines in the event of no deal being negotiated.

Discontinuations of paediatric medicinal products:

137. In 2018, the PMEAG gave advice on the clinical implications of the proposed discontinuation of two medicinal products for children, an antihypertensive and an antibiotic.

138. The remit of the group is 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).

**Chronic Liver Disease Expert Working Group**

139. During the 2018, the group met twice – on 14 February and on 15 May.

140. On the 14 February, the deliberations by the Working Group (WG) broadly comprised two sessions: the first session was devoted to NASH. Consideration was given to the definition and classification including the severity and natural history of NASH. It was agreed to approach the study design by considering four areas: participants, intervention, outcomes and controls. The WG discussed the requirements for each study phase during the clinical development

program. It was also agreed that liver biopsy should only be a requirement for phase 2b and phase 3 studies; and that the most appropriate participants for such studies are patients with NASH F2-3.

141. On the 15 May, the discussions by WG were based on the recently issued EMA draft Reflection paper. The discussions focused on the classification and the design of clinical studies which would support the licensing of drugs for the treatment of Non-alcoholic steatohepatitis (NASH). The other two conditions: Primary Biliary Cholangitis (PBC) previously termed "Primary Biliary Cirrhosis") and Primary Sclerosing Cholangitis (PSC) were also briefly discussed. However, most of the input regarding PBC and PSC had already been provided as written comments which were inserted in the relevant sections of the EMA draft Reflection paper. The WG also discussed aspects for identifying adverse events given the potentially long-term use of drug therapy in these disease conditions.

142. The EMA draft Reflection paper was completed in December 2018 and planned to be released for public consultation during the first quarter of 2019.

**Hormone Pregnancy Tests Ad Hoc Working Group on new non-clinical data**

143. The Commission advised that an ad hoc meeting of experts be convened to consider a new publication[3] in a zebrafish dechorionated model in which the authors concluded that the components of the former hormone pregnancy test Primodos, norethisterone acetate (NETA) and ethinylestradiol (EE) were potentially teratogenic, since embryonic damage had been observed. The Commission considered the findings of the ad hoc group and endorsed their conclusions that, while well conducted, there are no implications from the reported findings in the zebrafish model for the safe use of medicines currently on the market which contain norethisterone and ethinylestradiol.

**Sodium Valproate Expert Working Group**

144. The Sodium Valproate Expert Working Group, convened in March 2017, met on three occasions in 2018 in March, May and November. The Group discussed the outcome of the European referral which completed in May 2018, and the updates agreed for the product information. The Group provided advice regarding the content, presentation and distribution of the additional materials to be circulated to healthcare professionals and patients to support the introduction of the new Pregnancy Prevention Programme for valproate. The Group discussed the ongoing communications and stakeholder engagement to support the implementation of the

[3] https://www.nature.com/articles/s41598-018-21318-9

valproate Pregnancy Prevention Programme. Practical issues considered to be a barrier to implementation were addressed as well as concerns raised by healthcare professionals regarding the use of the materials.

145. The Group noted the results of studies to monitor the effectiveness of the risk minimisation measures following the regulatory action, which showed a slow, continued decline in prescribing of valproate in women of childbearing potential. However, data from patient surveys continued to show a low level of awareness of the risks associated with the use of valproate in pregnancy and poor compliance by healthcare professionals with the provision of the additional risk minimisation materials. It was recommended that the MHRA should actively promote the new regulatory framework for valproate. This was achieved through a variety of means including communications via the Drug Safety Update Bulletin and presentations and participating stands at relevant national conferences for healthcare professionals involved in the care of patients receiving valproate.

146. The Group discussed the ongoing studies within Europe required following the referral as well as proposals to develop a UK valproate registry which would include patients and their offspring which should support continued close monitoring of the effectiveness of risk minimisation measures for valproate in women of childbearing potential.

**Ad hoc Expert Group on emollient products and risk of severe burns**

147. The ad hoc Expert Group on the risk of severe burns associated with paraffin-containing topical products met on 7 September and 30 November 2018, to consider the balance of risks and benefits of paraffin-containing topical products and measures necessary to minimise the risk. The Group considered more recent evidence of a risk of severe burns associated with emollient products containing lower levels (<50%) of paraffin and new evidence of a similar risk with paraffin-free emollients. The Expert Group concluded that the overall balance of risks and benefits of these products continues to be positive taking into account the very rare risk, the modifiable risk factors and their important therapeutic role. The Group recommended that the product information and labelling for all emollients (paraffin and paraffin-free) and for non-emollient topical products, should be updated to include information about the risk and advice not to smoke, and that the outer packaging and product containers should include a warning symbol.

148. The Expert Group considered that raising awareness of the risk amongst users of these products, their carers and health and social care professionals would be critical to effective risk minimisation. The Expert Group recommended that there should be an initial public

communication to alert the wider public of the new information about the risk and secondly, that a stakeholder group should be convened to design and deliver awareness raising, training and educational resources for healthcare professionals and the public that is impactful and sustainable in the long-term. The CHM considered and fully endorsed the conclusions and recommendations of the Expert Group at its meeting in December 2018 (see above).

### Ad Hoc Expert Group on Stimulant Laxatives

149. The Commission's Stimulant Laxative Ad Hoc Expert Group met on 31 July 2018. Membership included expertise in gastroenterology, psychiatry, psychology, eating disorders, geriatrics, palliative care and paediatrics; and community pharmacy and lay representatives. The Ad Hoc Expert Group considered four papers reviewing the benefit: risk balance of the stimulant laxatives, including the possible regulatory options to strengthen risk minimisation. The Expert Group noted that the concerns regarding abuse/misuse and overuse of stimulant laxatives were mainly associated with two groups: those with eating disorders and the elderly. They also noted that there are concerns regarding whether OTC use in children was appropriate considering current clinical guidance. The Group's recommendations, together with the recommendations of the GRID EAG, PMEAG and PEAG on this topic were considered by the CHM at their September meeting in formulating the CHM's advice.

## REPORTING OF SUSPECTED ADVERSE DRUG REACTIONS 2018

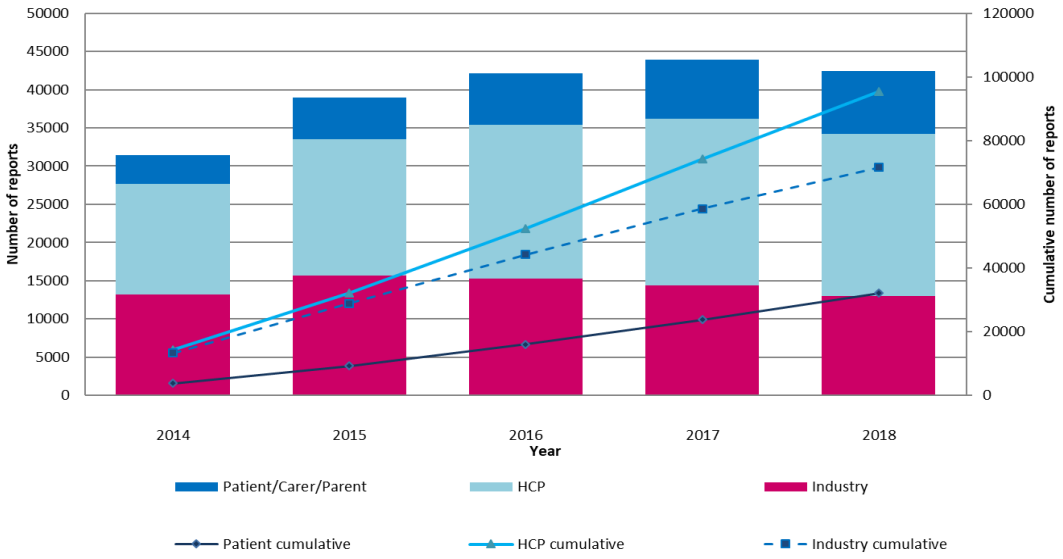
150. Suspected adverse drug reactions (ADRs) to medicinal products and vaccines are reported to the CHM and MHRA on a voluntary basis by healthcare professionals and members of the public through the Yellow Card Scheme. Reports are also submitted as a legal requirement by pharmaceutical companies holding Marketing Authorisations via the European Medicines Agency (EMA). 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 clinical knowledge about known ADRs.

151. The total number of UK spontaneous suspected ADR reports received from all sources over the last five years shows an increasing trend of 35% (11,039 additional reports) as shown in Figure 1 below. In 2017 suspected ADR reporting was the highest since the Scheme was established over 50 years ago. Overall, reporting levels remain robust with 2018 seeing the second highest reporting levels to date, with a small decrease of 3% (1,505 reports) compared to the previous year.

152. In 2018 direct Yellow Card reporting from healthcare professionals accounted for 50% (21,154 reports) of all suspected ADR reports received and 19% (8,272 reports) of all reports were received from members of the public (including patients, parents and carers). Reports received directly from members of the public increased by 7% compared with 2017 and are now the highest specific reporter group.

153. Yellow Card reports received directly by the MHRA from healthcare professionals and members of the public remained roughly consistent, with a 0.5% decrease in 2018, whilst suspected ADR reports from pharmaceutical industry reports saw the largest decline of 9% (1,312 reports).

**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 | 31,431 | 38,912 | 42,101 | 43,975 | 42,470 |

154. In 2018, suspected ADR reporting from the pharmaceutical industry accounted for 31% (13,045 reports) of all reports received by the MHRA. On further investigation, approximately 47% (612 reports) of the decrease could be attributed to a single company which has changed its reporting conventions in line with the European Medicines Agency (EMA) Important Medical Event list. Further discussions are ongoing with other companies where a decrease in reporting has been noted.

## Patient ADR Reporting

155. The year 2018 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 8,272 reports received. These reports accounted for 19% of all reports received and 28% of reports sent directly to the MHRA. There has been a 117% (4,461 reports) increase in patient, parent and carer reports compared to 2014. Over recent years, the MHRA and its 5 Yellow Card Centres have continued to make significant efforts to proactively encourage the reporting of suspected ADRs by this important reporter group via an engagement strategy to reach patients through their associations and organisations, and through MHRA's Patient and Public Stakeholder Engagement outreach work.

156. In 2018, MHRA also attended several large national conferences such as Patient First and Patient Safety Congress, presenting to organisations such as EURORDIS, a European Rare Diseases Organisation, which is a unique, non-profit alliance of 826 rare disease patient organisations from 70 countries. The MHRA also formed a partnership with the National Association for Patient Participation (NAPP), a UK umbrella organisation for patient-led groups in general practice. The MHRA and the West Midlands Yellow Card regional centre promoted and presented to the Patient Participation Groups in England at their annual conference on the importance of reporting to the Yellow Card Scheme.

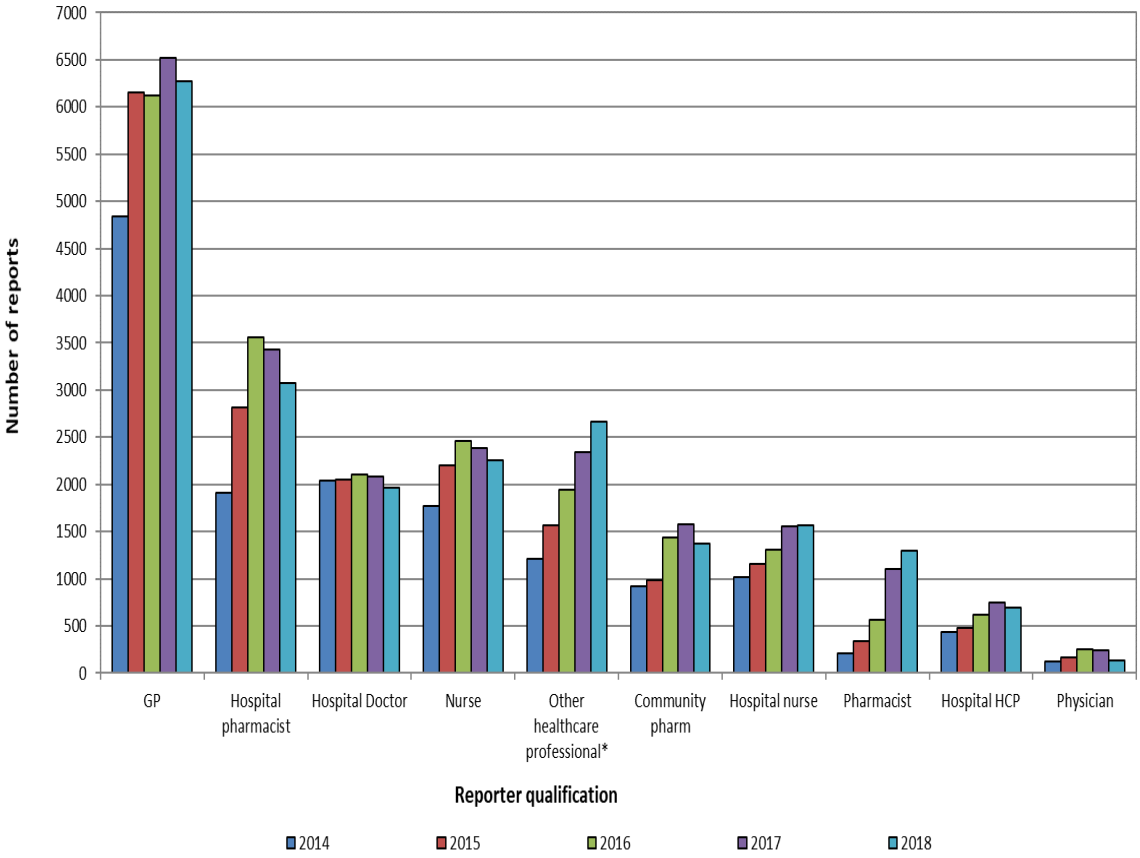
157. In November 2018, the MHRA together with the Uppsala Monitoring Centre, a collaborating centre of the World Health Organisation, led in its third EU wide social media campaign to raise general awareness of the Yellow Card Scheme with the public. The campaign in 2018 focused on the reporting of suspected ADRs that occur in babies, children, pregnant women and breastfeeding mothers. The campaign was supported by the release of new infographics including supporting messages to promote reporting of suspected ADRs in these patient populations. The key message was that the reporting of suspected side effects helps the safe use of medicines and protects public health. This was supported by a press release, contacting over 300 UK stakeholders and networks, and disseminating a Drug Safety Update bulletin article to raise awareness with healthcare professionals. The use of the #medsafetyweek worked well, resulting in 3,791 tweets reaching 8 million people and with 20 million impressions across the world. In the UK, our campaign reached 587,566 people in total, with 161,713 views of the animation and 5,515 engagements e.g. likes, clicks, retweets and shares on social media alone. The campaign week of the 16-25 November 2018 saw an overall increase of 24% in direct Yellow Card reports, with an 11% increase in reports from patients, parents and carers compared to the

ADR campaign week in November 2017. This was followed by a 7% (139) increase in direct Yellow Card reporting in December 2018 compared to December 2017.

## Healthcare professional Yellow Card reporting

158. In line with the overall slight downward trend in reporting, Yellow Card reports directly from healthcare professionals saw a decrease of 3% (667 reports). A breakdown of direct healthcare professional reports by reporter qualification between 2014 and 2018 is shown in Figure 2.

**Figure 2 – Graph showing the number of direct suspected 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, pre-reg pharmacists, pharmacy technicians and other non-specified health professionals.*

159. As in previous years, in 2018 GPs reported the most suspected ADR reports (6,271 reports) compared to all other healthcare professionals to the Yellow Card Scheme and accounted for 30% of all direct healthcare professional reports. However, reports from GPs declined by 4% (254 reports) in 2018 compared to the previous year. Along

with GPs, Figure 2 shows a decline in the number of reports received from healthcare professionals from a secondary care setting, most notably hospital pharmacists whose reporting decreased by 10% compared with the previous year.

160. In 2018, there was a decreasing trend in reports from pharmacists in both a community and hospital based setting. However, there was an increase in the number of Yellow Cards reports received from pharmacists, who did not specify their speciality or setting, compared to the previous year of 17% (191 reports). Based on the address of the reporter, approximately 64% of the pharmacist (unspecified specialty) reports were from clinical pharmacists practicing within General Practice. This trend reflects the increasing role of clinical pharmacists in primary care and can be attributed to direct strategic engagement through talks given at the Primary Care Pharmacy Association (PCPA) conferences and work with the Practice Pharmacy Group (PPG) on the importance of reporting to the Yellow Card Scheme. The PCPA is the largest and longest established independent organisation dedicated to supporting pharmacists working in primary care. The PPG is the specialist group set up by the PCPA to promote sharing best practice and to enable networking and support medical education. Other initiatives included articles for pharmacy trade journals such as the Chemist and Druggist and the Pharmaceutial Journal to encourage pharmacists to report suspected adverse drug reactions.

161. Reports from other healthcare professionals'increased by 13% (323 reports) in 2018. The most frequently reporting professions within this group were Pharmacy assistants (16%), Radiographers (12%) and Pre-registration pharmacists (11%).

162. The trends within these reporter qualifications highlight some positives in certain reporter groups that reflect a change in healthcare delivery but also highlight a need to re-engage with some professional groups, particularly in the acute/secondary care setting as part of Yellow Card strategic efforts.

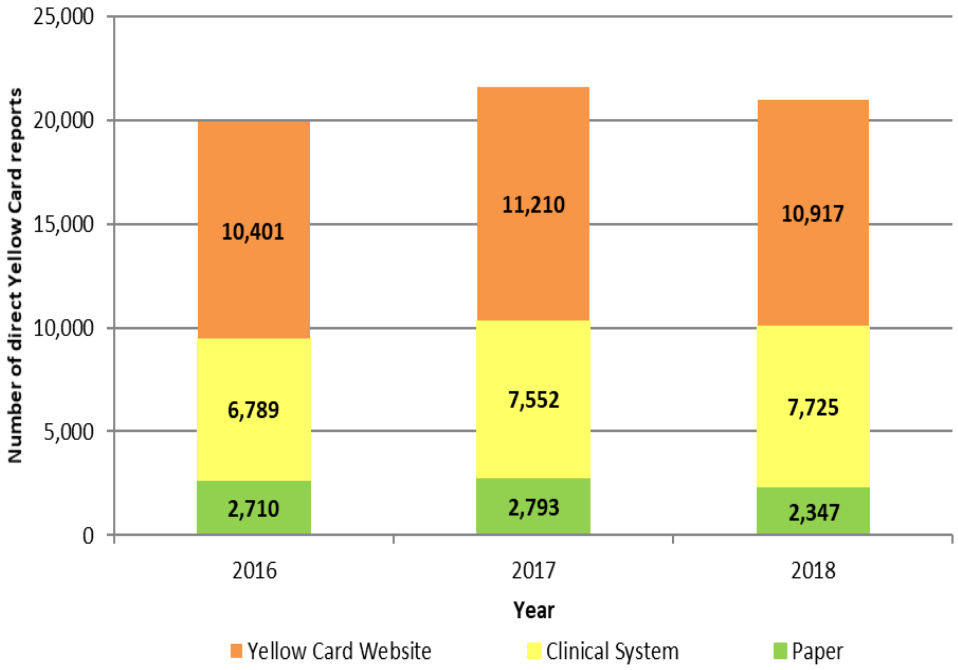
**Electronic Yellow Card Reporting**

163. In 2018 the majority of Yellow Card reports received by the MHRA were submitted electronically. Electronic reporting is the most popular method of reporting for both healthcare professionals and members of the public.

164. Specifically, 91% (7,600 reports) of all ADR reports from patients, parents and carers were reported electronically, with a 9% (623 reports) increase in reports via the Yellow Card website compared to 2017 and a 25% (35 reports) increase in reports via the Yellow Card app compared to 2017.

165. In 2018, 89% (18,766 reports) of all direct healthcare professional reports were received electronically, with 52% (10,917 reports) through the Yellow Card website and 37% (7,725) via clinical systems. Paper reports formed the majority of the remaining 11% (2,347 reports) of direct healthcare professional reports. A breakdown of the methods of reporting from healthcare professionals can be found in Figure 3.

**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.**




166. The number of ADR reports received directly from the Yellow Card integrated into Clinical IT systems increased by 2% (173 reports) compared to 2017. A key part of the MHRA's Yellow Card strategy is a focus on making Yellow Card reporting easier and more accessible to healthcare professionals. Integration of the Yellow Card form directly into clinical IT systems is a key approach to make reaching this goal feasible. To date, the MHRA has successfully integrated the Yellow Card in the primary care GP systems SystmOne (2010) and Vision (2016), as well as the secondary care medicines information system for pharmacy MiDatabank (2011).

167. Through collaborative work, the MHRA has continued to integrate Yellow Card reporting functionality into additional clinical systems to encourage reporting by healthcare professionals. In October 2018, a pilot of integrated Yellow Card reporting in Ulysses began in Nottinghamshire Healthcare NHS Foundation Trust, announced via a

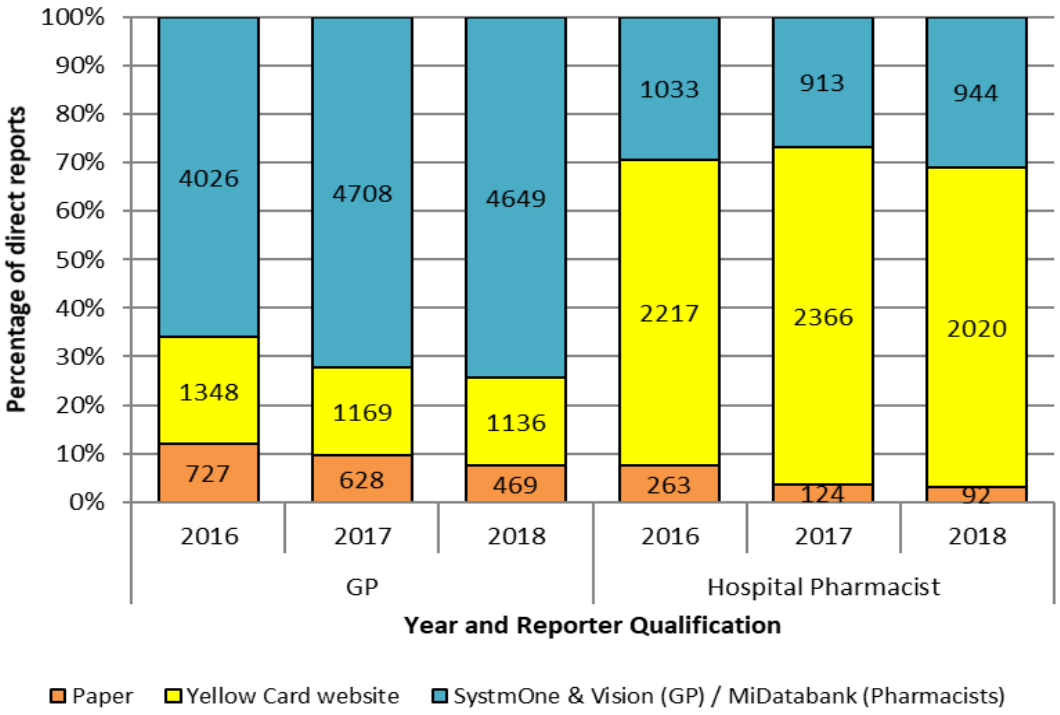
press release. Initial feedback has been positive, with reporting of Yellow Cards via Ulysses found to require 50% less time than via the Yellow Card website. Manchester University NHS Foundation Trust also integrated the Yellow Card reporting form in December 2018 and will be a second pilot Trust in early 2019. A number of further Trusts have expressed interest in adopting the reporting form, with full roll-out in all Ulysses' Trusts anticipated during quarter two of 2019.

168. The MHRA has also worked closely with Cerner on the redesign of the Yellow Card reporting functionality in this system, which previously had limited uptake. In November 2018, Cerner made the redesigned form available for adoption in the latest version of Cerner Millennium. The redesigned reporting form was demonstrated at a Cerner group meeting to keen interest. Oxford University Hospitals NHS Foundation Trust have agreed to be the first pilot Trust of the redesigned form, with the pilot expected to go live in early 2019.

169. Reports from all clinical systems formed 37% of all direct reports from healthcare professionals. Further work continues to engage other clinical system providers to integrate Yellow Card reporting functionality and further extend this proven method of increasing reporting. However, despite being a mandatory requirement as part of the GP Systems of Choice Framework, some primary care system suppliers, such as EMIS, continue to be slow to respond to the request for integration of Yellow Card reporting.

170. 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.

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




171. In 2018, 93% of all GP reports were received electronically, with GP reports via clinical systems accounting for 74% (4,649 reports) of all reports from GPs. Of this, SystmOne accounted for 62% (3,890 reports) of suspected ADR reports from GPs. GP reporting saw an overall decrease in reporting of 4% and reports received from GPs via SystmOne decreased by 5% (204 reports). Reports from Vision accounted for 12% (759 reports) of all GP reports in 2018, an increase in reports of 23% (146 reports) compared to the previous year.

172. Similarly, reports received from hospital pharmacists via clinical systems (MI Databank) increased by 3% (28 reports) although there was a decline of 15% (346 reports) by hospital pharmacists using the Yellow Card website. This trend highlights the need to work further with secondary care clinical system providers, particularly within a pharmacy setting.

**The Yellow Card App**

173. In 2018 the Yellow Card App underwent a major revamp based on user feedback. The updated App was released in July 2018 and provides a more stable user experience and easier navigation. A range of new features were also introduced, such as improved security, quick log in using Touch ID or Face ID, and improved news and data visualisations. The App can also be used while offline to create and save reports to send later, while a guest feature allows users to submit ADR reports and view newsfeed without creating an account.

174. In November 2018, to support the monitoring of the safety of medicines used during pregnancy, the Yellow Card App began a pilot of additional ‘smart’ questions focused on drug exposure during pregnancy. The update includes further questions about the timing of exposure, including details of the trimester in which exposure occurred, scans, previous pregnancies, use of supplements, and whether the suspected adverse effect was experienced during the pregnancy by the mother or child. The pregnancy-related changes to the App were implemented in time for the 2018 annual social media campaign which focused particularly on the safety of medicines in pregnancy and in children. The awareness week created increased exposure and publicity for the updated App and its new features. Feedback from the public will be considered to further improve the questions, before being added to the Yellow Card website reporting form.

175. The success of various App related promotional strategies and improved user experience was mirrored by an increase in the number of suspected ADR reports received via the App since the relaunch in July 2018. When comparing reporting numbers in the first six months of 2018 to the latter six months, the number of ADR reports received through the App increased from 108 to 194 reports respectively.

176. Following the success of the first Innovative Medicines Initiative WEB-RADR project, which delivered the Yellow Card App, further funding was granted to exploit the initial deliverables. The second WEB-RADR project began in September 2018. A key deliverable of the project will be to build on the App functionality to expand access to the platform. This includes making the reporting and newsfeed functionality of the App available through Application Programming Interfaces (APIs). This will help facilitate third party organisations and software (including external Apps, websites and electronic health record systems) to easily embed the Yellow Card reporting form and MHRA newsfeed into their own systems. Development of the API began in late 2018 and is anticipated to be completed in May 2019. The APIs will present significant opportunity to expand the reach of the Yellow Card Scheme to increase volumes of reporting and delivery of safety messages, including the potential to integrate into the NHS App.

**The General Data Protection Regulation**

177. The General Data Protection Regulation (GDPR) came into force on the 25 May 2018 and all Yellow Card reporting processes were reviewed prior to this date to ensure compliance. Yellow Card data are collected in the interest of protecting public health and do not rely on patient consent as dictated in the GDPR. The MHRA already has a number of procedures in place to protect confidential patient and

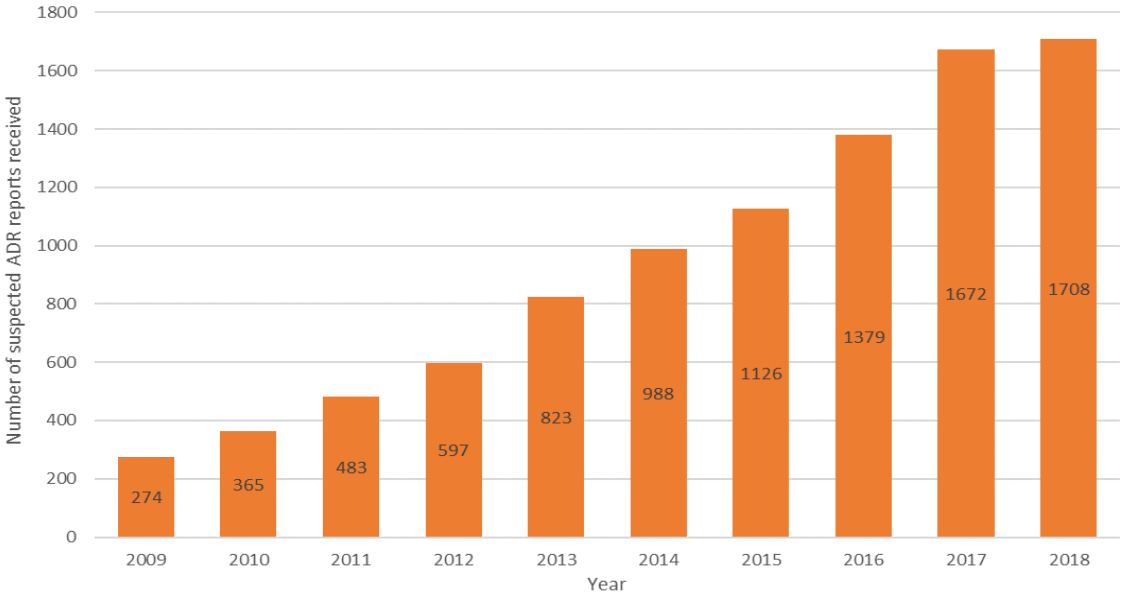
reporter data. Therefore, Yellow Card compliance with the GDPR is already robust and the changes which have been implemented have been to provide greater transparency to reporters and patients about how their data are handled. Changes included updating the Yellow Card privacy policy and introducing a mandatory requirement for all reporters to confirm they have understood our privacy policy on the Yellow Card website or Yellow Card App.

**Medication Safety Officers Network in England**

178. Since 2014 the National Medication Safety Network, operating in partnership with NHS Improvement (NHSI), 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. At the end of 2018, the National Medication Safety Network had 500 registered Medication Safety Officers (MSOs). In England, the majority of MSOs are hospital pharmacists, and they continue to report suspected ADRs 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 in relation to the use of medicines.

179. The main focus of the MSO network's activity is medication error. Figure 5 shows that over a ten-year period there has been an increase in the number of UK spontaneous suspected ADRs associated with medication errors and other product use errors. The dissemination of relevant research, information concerning new risks, and best medication safety practice, alongside the MHRA's signalling process, have supported improvements in the identification of and response to new harms.

**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.**




180. Data from the National Reporting and Learning System (NRLS) are shared with the MHRA for analysis on a weekly basis. Of the 11,557 reports received between December 2017 and November 2018, 32% (3,650) 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 of MSOs to focus on increasing reporting and improving coding and quality of medication error reports.

181. The NRLS is 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 continuing to work closely with NHSI to integrate and better capture Yellow Card fields within the new system.

182. 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. Representatives from MHRA have been invited to

[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 25/01/19).

and attended quarterly London MSO network meetings, a useful event for shared learning and discussion. A joint conference organised by the MHRA and NHSI took place in January 2019. The event explored key themes in 'Championing Patient Safety' and was attended by approximately 300 MSOs and Medical Device Safety Officers.

**UK Yellow Card Centres**

183. The MHRA works with its five UK Yellow Card Centres (YCCs) to increase awareness of the Yellow Card Scheme and increase ADR reporting rates within their regions. The YCCs operate in Wales, Scotland, Northern & Yorkshire, North West and the West Midlands. The YCCs are involved in various programmes which improve ADR reporting rates, including the establishment of nominated hospital pharmacists or pharmacy technicians as 'Yellow Card Champions'.

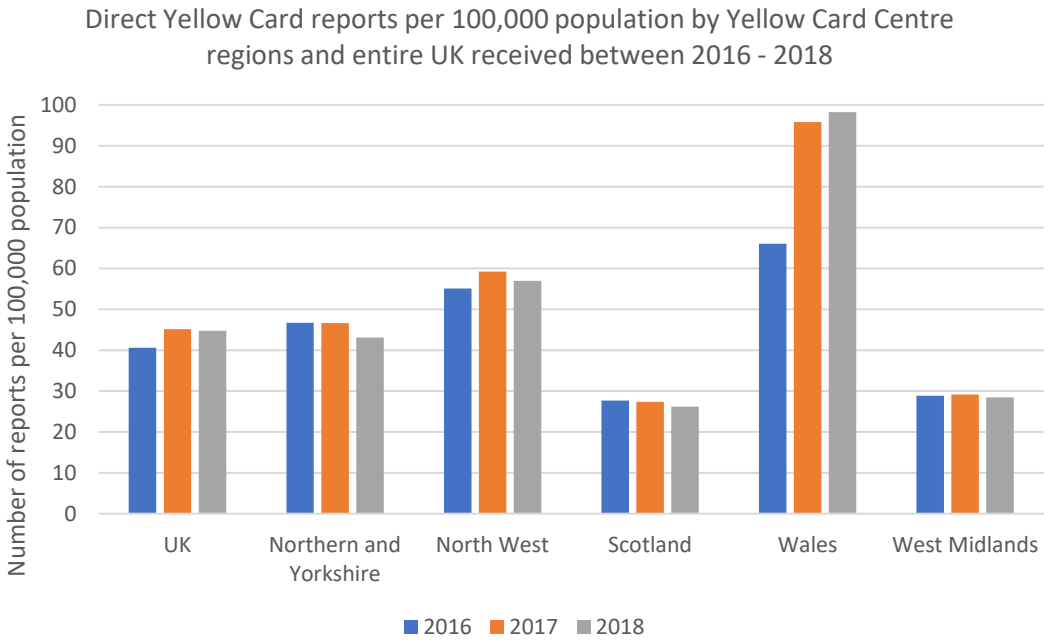
184. Three of the YCCs: Wales, West Midlands and North-West, have developed successful Yellow Card Champion Schemes, which have been set up to promote the Yellow Card Scheme. In 2017 YCC Wales invited practice-based pharmacists to join their Yellow Card Champion Training Day for the first time. Following a successful pilot of this expanded day, YCC Wales has gone on to hold their annual Yellow Card Champion Training Day in 2018 and are currently planning their 2019 event.

185. The YCCs continue to promote the Yellow Card Scheme and provide educational services to both undergraduate and postgraduate healthcare students, as well as qualified healthcare professionals, in the form of lectures, educational materials and other resources. The YCCs also work with local charities and support groups to provide useful insight into the Yellow Card Scheme. The YCCs played an important part in the social media campaign promoting the Yellow Card Scheme and this year's ADR Awareness Week by supporting the campaign on their YCC social media pages. The YCCs also attend relevant events and conferences where they are able to discuss the importance of ADR reporting with attendees. For example, YCC West Midlands attended the International Society of Pharmacovigilance conference in 2018, where they presented a number of posters.

186. The impact of the YCCs' dedication and continued support of the Yellow Card Scheme can be seen by the steady ADR reporting rates for four of the five YCCs in figure 6, in contrast with the slight decrease in average reporting rates for the UK as a whole. In 2018 two YCCs had a higher reporting rate per 100,000 people than the UK average (45): North West (57) and Wales (98). Following their successful year in 2017 when YCC Wales increased their reporting

rates by 46% on the previous year, they were able to continue to improve their reporting rates in 2018.

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




## Signal Detection

187. The MHRA signal management system is designed for the timely detection and management of signals 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 2018, there were a total of 105 validated signals – potential signals that have been identified by a statistical algorithm or from external sources such as the published literature which subsequently require additional detailed investigation and review. Once evaluated, these validated signals can result in regulatory action, such as updates to product information, or may 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 2018**

| | **Signal Priority** | | |
|---|---|---|---|
| | **Top** | **Increased** | **Standard** |

| | | | |
|---|---|---|---|
| **Number of signals** | 2 | 10 | 93 |

Top priority = 3 months; Increased priority = 6 months; Standard priority = 1 year

Of special note, there has been a significant increase in the number of validated signals in 2018 despite a decrease in the overall number of ADR reports received through the Yellow Card Scheme. A 33% increase in the number of validated signals has been observed when comparing with the number of validated signals in 2017 (79).

188. In 2018, ADR reports received from members of the public contributed towards 44 signals being detected, with 25 patient reports being the cases which initiated investigation of a signal (i.e. index case). Suspected ADR reports received from health care professionals contributed to 64 signals, of which 26 reports were the index case.

189. Some examples of signals which stimulated regulatory action in 2018 include pressurised metered dose inhalers and the risk of airway obstruction from aspiration of loose/foreign objects: advice on the safety issue was communicated via Medication Safety Officers and a Drug Safety Update bulletin article. Another example of a signal related to direct-acting antivirals and the risk of hypoglycaemia in patients with diabetes: warnings were added to strengthen the product information and a Drug Safety Update bulletin was published to communicate the risk.

190. A signal feedback pilot began in April 2018, in which signals raised in the previous two years were reviewed to determine whether feedback could be given to reporters regarding any regulatory action taken. The number of Yellow Card reports that qualified for inclusion in the pilot was limited given that many signals involve reports received over a number of years and the criteria for contacting reporters only included reports received since 2016 (i.e. the previous 2 years). A questionnaire was included with all feedback letters asking whether reporters wished to receive this feedback regardless of when they submitted their report. Responses received through the questionnaire have been very positive. The pilot is ongoing and feedback letters are now being sent for all signals. However, it is recognised that further work is required to improve and develop the process of feedback to reporters when they have contributed to the detection of a signal via the Yellow Card Scheme.

191. Following recommendations from the CHM Expert Working Group on Hormone Pregnancy Tests (HPT) in 2017, new signal processes relating to reports of drug exposures in pregnancy have been implemented. A pilot of a dedicated Pregnancy Signal Detection

meeting to support our routine signal detection activities began in August 2018. The aim of the meeting is to review all reports of drug exposures in pregnancy received each week as well as all reports of abnormal pregnancy outcomes, to develop a safety profile of the medicine's use during pregnancy. The reports are assessed and reviewed by a multidisciplinary team. The meetings have generated several validated signals that have been taken forward for discussion at Signal Management Review Meetings. All validated signals and reports of interest identified through the Pregnancy Signal Detection meetings are highlighted to the Medicines for Women's Health Expert Advisory Group (MWHEAG) for comment or advice. Further details of this process can be seen in the MWHEAG section of the CHM Annual report.

192. In May 2018, the MHRA joined the International Post-Market Surveillance (IPMS) group, comprised of the US Food and Drug Administration (FDA), Health Canada, Therapeutic Goods Administation (TGA), Medsafe, Health Sciences Authority (HSA) and Swissmedic. Every two months, each agency has the opportunity to propose topics to the other agencies for discussion, who subsequently provide written responses, followed up with a telephone conference if required. In general, the topics relate to potential drug safety issues, but may entail more general pharmacovigilance questions. The MHRA proposed six topics for discussion in 2018, through which further information and worldwide evidence has been obtained to aid the assessment of signals. For example, information on previous reviews and details of case reports were requested for a signal regarding omeprazole and rebound acid hypersecretion. The responses from other regulators provided insight into the strength of the evidence for the signal, which in this case enabled an informed decision that no regulatory action was currently required.

## MEMBERSHIP OF THE COMMISSION ON HUMAN MEDICINES

### Chair

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

### Members

**Ms Susan Bradford**[5]
Lay Representative

**Professor Jamie Coleman**[6] MD MA (Med Ed) FRCP FBPhS
Professor in Medical Education / Consultant Clinical Pharmacologist, University of Birmingham

**Dr J Colin Forfar**[7] BSc (Hons) MBChB PhD MD MA FRCP FRCP (Edin)
Consultant Physician and Cardiologist, John Radcliffe Hospital, Oxford

**Dr Jamie Fraser**[8] BSc MB ChB MRCGP
GP Partner, Southside Surgery, Inverness

**Professor Jonathan S Friedland**[9] MA PhD FRCP FRCPE FRCPI FMedSci
Hammersmith Campus Director & Head of Section of Infectious Diseases & Immunity, Imperial College London; Hon Consultant in Infectious Diseases ICHT

**Dr Richard JC Gilson**[10] 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

**Professor Martin Gore**[11] MBBS PhD FRCP
Consultant Medical Oncologist, The Royal Marsden NHS Foundation Trust and Professor of Cancer Medicine, Institute of Cancer Research

**Professor Malcolm R Macleod**[12] BSc MBChB MRCP PhD FRCP (Edin)
Professor of Neurology and Translational Neurosciences, University of Edinburgh and Honorary Consultant Neurologist, NHS Forth Valley

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[5] Appointed 01/09/2018
[6] Appointed 01/09/2018
[7] Retired 06/12/2018
[8] Reappointed 01/04/2018
[9] Reappointed 01/04/2018
[10] Reappointed 15/12/2018
[11] Passed away 03/01/2019
[12] Reappointed 01/04/2018

**Dr Rebecca Mann**[13] BMBS FRCPCH
Consultant Paediatrician, Taunton and Somerset NHS Foundation Trust

**Professor Sarah Meredith**[14]
Deputy Director, MRC Clinical Trials Unit at UCL, Institute of Clinical Trials and Methodology, University College London

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

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

**Professor Sir Munir Pirmohamed**[15] 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

**Professor Shirley Price**[16] MSc PhD FBTS FRSB ERT FHEA FRSC MBPharmacolSoc
Head of Academic Appeals and Academic Quality and Professor of Toxicology, University of Surrey

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

**Professor Angela E Thomas**[17] MB BS PhD FRCPE FRCPath FRCPCH **(Vice-Chair)**
Consultant Paediatric Haematologist, Royal Hospital for Sick Children, Edinburgh

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

**Professor Christopher Weir**[18] 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

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

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[13] Reappointed 01/04/2018
[14] Reappointed 11/12/2018
[15] Reappointed 11/12/2018
[16] Reappointed 01/04/2018
[17] Expired 31/12/2018
[18] Reappointed 07/12/2018

## Invited Experts to Commission Meetings

**Dr Michael Ardern-Jones** BSc MBBS DPhil FRCP
Associate Professor, University of Southampton & Consultant Dermatologist, Southampton University Hospital

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

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

**Professor Ash Soni** OBE FFRPS FRPharmS
LPN Pharmacy Chair (London); Executive & Council Member, National Association of Primary Care; English Pharmacy Board Member, Royal Pharmaceutical Society; Pharmacy Clinical Network Lead, Lambeth CCG

**Ms Laura Steeples**
Consultant Ophthalmic Surgeon - sub-speciality Uveitis (adult and paediatric) at Manchester Royal Eye Hospital

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

**Professor Anthony G Wilson** MB BCH BAO DCH PhD FRCP
Full Professor of Rheumatology, School of Medicine, Conway Institute, Dublin

## Observers of Commission Meetings

**Dr Elizabeth Adeyeye**
Clinical Research Physician, NIHR Clinical Research Facility, Guy's and St. Thomas' NHS Foundation Trust

**Mr Tim Brier**
Final year NHS clinical pharmacology trainee

**Ms Hacer Coşkun Çetintaş** MSC Pharm
Head of Licensing Department, Department of Marketing Authorization for Medicines

**Dr Hala Fadda** PhD
Associate Professor of Pharmaceutics, College of Pharmacy & Health Sciences, Butler University

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

### Remit

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

### Chair

**Dr J Colin Forfar**[19] BSc (Hons) MBChB PhD MD MA FRCP FRCP (Edin)
Consultant Physician and Cardiologist, John Radcliffe Hospital, Oxford

### Members

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

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

**Dr John Firth** BA BM ChB DM FRCP
Deputy Medical Director, Cambridge University Hospitals FT, Consultant Physician and Nephrologist, Addenbrooke's Hospital, Cambridge

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

**Dr Philip W Ind**[20] BA Cantab MB BChir MA Cantab FRCP
Consultant Respiratory and General Physician, Adjunct Reader NHLI, Imperial School of Medicine

**Dr Patrick Mark** MB CHB (Hons) PhD FRCP
Clinical Reader/Honorary Consultant Nephrologist University of Glasgow/Queen Elizabeth University Hospital, Glasgow

**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

[19] Retired 06/12/2018
[20] Reappointed 12/11/2018

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

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

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

**Dr Caroline Vaughan** PhD
Lay Representative of MHRA EAGS. Shadow Governor of the Surrey and Sussex Hospital

**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

**Mr Phil Willan**[21] MSc
Lay Representative. Member of MHRA Pharmacovigilance EAG, Cardiovascular, Diabetes, Renal, Respiratory and Allergy EAG, Patient and Public Engagement EAG (acting Chair), Lay Members Forum; Member of the Royal College of Physicians' (RCP) Patient and Carer Network; Member of the RCP Joint Speciality Committee (JSC) for Renal Medicine, Healthcare Associated Infections Working Group, Specialist Advisory Committee for Renal Medicine, JSC for Allergy and Immunology, Faculty of Forensic and Legal Medicine, Federation CPD Policy Committee, and Patient Safety Committee. Member of the NHS England Clinical Reference Group for Renal Transplantation

[21] Passed away 06/03/2019

## MEMBERSHIP OF THE CHEMISTRY, PHARMACY AND STANDARDS EXPERT ADVISORY GROUP

### Remit

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

### Chair

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

### Members

**Professor Michael E Aulton**[22] BPharm PhD FRPharmS FAAPS FSP
Emeritus Professor, De Montfort University, Leicester

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

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

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

**Mr V'lain G Fenton-May** 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

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

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

[22] Retired 19/09/2018

**Dr Majella Lane** BSc PhD
Senior Lecturer in Pharmaceutics, UCL School of Pharmacy

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

**Professor Christopher Marriott**[23] PhD DSc Hon DSc FRPharmS CChem FRSC FRSM **(Vice Chair)**
Emeritus Professor of Pharmaceutics, King's College, London

**Professor Yvonne Perrie** BSc Hons MRPharmS FAPS FSB PhD
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

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

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

[23] Reappointed 17/09/2018

## 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**[24] 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

[24] Retired 31/12/2018

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

**Dr Siraj Misbah**[25] MBBS (Hons) MSc FRCP FRCPath
Consultant Clinical Immunologist, Lead for Clinical Immunology, Oxford University Hospitals

**Professor B Kevin Park**[26] BSc PhD FMedSci FRCP (Hon) FBTS
Director of MRC Centre for Drug Safety Science, Professor of Pharmacology & Head of Institute of Translational Medicine, University of Liverpool

**Professor Andrew Pollard**[27] PhD FRCPCH FMedSci
Chair of the Joint Committee on Vaccination and Immunisation; Professor of Paediatric Infection and Immunity, University of Oxford

**Dr Robin Thorpe** 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** BA (Hons)
Lay Representative. Patient Advocate

**Professor Christopher Weir**[28] 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

[25] Appointed 07/12/2018
[26] Reappointed 19/05/2018
[27] Reappointed 17/07/2018
[28] Reappointed 09/12/2018

## 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**[29] MB BCH BAO DCH PhD FRCP
Professor of Rheumatology, Medical School, University of Sheffield

### Members

**Professor Michael Ardern-Jones** BSc MBBS DPhil FRCP
Associate Professor, University of Southampton and Consultant Dermatologist

**Dr Ian Barrison**[30] BSc MB FRCP FEBGH
President European Board of Gastroenterology and Hepatology; Associate Dean, Postgraduate Medicine, School of Life and Medical Sciences, University of Hertfordshire

**Dr Andrew Carmichael**[31] MB BS, MRCP, FRCP
Honorary Clinical Lecturer, University of Newcastle-upon-Tyne; Clinical Supervisor Dermatology & GP StRs FY2s; External Dermatology PYA assessor RCP Ireland

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

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

**Professor Celia Moss**[32] BA, MB BS, MA, MRCP, DM, FRCP, MRCPCH
Consultant Dermatologist, Birmingham Children's Hospital, Honorary Professor of Paediatric Dermatology, University of Birmingham

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

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[29] Reappointed 14/10/2018
[30] Step down 03/01/2019
[31] Resigned 21/06/2018
[32] Appointed 07/12/2018

## 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**[33] MA PhD FRCP FRCPE FRCPI FECCMID FMedSci
Deputy Prinicipal, St. George's University of London: Hon Consultant in Infectious Diseases St George's University Hospitals NHS Foundation Trust

### Members

**Professor David Dockrell** MB BCh MD FRCPI FRCP (Glas) FACP
Professor of Infection Medicine, University of Edinburgh

**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**[34] MD FRCP
Reader in Sexual Health and HIV and Honorary Consultant Physician Director, UCL Centre for Sexual Health and HIV Research Head, Research Department of Infection and Population Health University College London

**Dr Richard Hobson** 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
Deputy Director of Infection Prevention and Control, 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

[33] Reappointed 01/04/2018
[34] Reappointed 15/12/2018

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

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

**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

## 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

**Mrs Claire Bellone**[35] RGN MSc NMP
Clinical Nurse Specialist, Chelsea & Westminster Hospital, London

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

**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

**Ms Julia Louise Tassano-Edgecombe**[36]
Nurse Consultant, Department of Sexual Health, Royal Berkshire NHS Foundation Trust

**Professor Jonathan H Tobias**[37] BA (Cantab) MBBS (London) MD (London) PhD (London) FRCP (London).
Professor of Rheumatology, University of Bristol; Honorary Consultant Rheumatologist, North Bristol Trust

[35] Appointed 24/05/2018
[36] Appointed 24/05/2018
[37] Reappointed 13/03/2018

**Dr Diana Wellesley**[38] FRCP
Head of Prenatal Genetics, Consultant and Honorary Senior Lecturer in Clinical Genetics, Wessex Clinical Genetics Service, Princess Anne Hospital, Southampton

[38] Reappointed 19/07/2018

## MEMBERSHIP OF THE NEUROLOGY, PAIN & PSYCHIATRY EXPERT ADVISORY GROUP

### Remit

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

### Chair

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

### Members

**Professor Thomas R. E. Barnes** MD FRCPsych DSc
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 David Hunt** MBMS MRCP PhD
Honorary Consultant Neurologist/ Wellcome Trust Clinician Scientist, Anne Rawling Regenerative Neurology Clinic, University of Edinburgh

**Professor Malcolm R Macleod**[39] 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

**Dr Catherine F Stannard** MB ChB FRCA FFPMRCA
Consultant in Complex Pain/Pain Transformation Programme Clinical Lead, NHS Gloucestershire CCG

[39] Reappointed 01/04/2019

**Professor Christopher Weir**[40] 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

[40] Reappointed 09/12/2018

## 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**[41] 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** 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 Robert Marcus**[42]
Consultant Haematologist, King's College Hospital London

**Dr Geoff Shenton** 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**[43] OBE MB BS PhD FRCPE FRCPath FRCPCH **(Vice Chair)**
Consultant Paediatric Haematologist, Royal Hospital for Sick Children, Edinburgh

[41] Passed away 11/01/2019
[42] Appointed 19/04/2018
[43] Retired 31/12/2018

## MEMBERSHIP OF THE PAEDIATRIC MEDICINES EXPERT ADVISORY GROUP

### Remit

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

### Chair

**Dr Rebecca Mann**[44] 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

**Mrs Catrin Barker**[45]
Chief Pharmacist, Pharmacy Department, Alder Hey Children's NHS FT, Eaton Road, 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

**Professor Steven Cunningham** MBChB PhD FRCPCH **(Vice Chair)**
Professor of Paediatric Respiratory Medicine, University of Edinburgh and Honorary Consultant, NHS Lothian

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

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

[44] Reappointed 01/04/2018
[45] Appointed 15/01/2018

**Professor Nigel Klein**[46] 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

**Dr Rubin Minhas** MB ChB MBA
GP Principal

**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 Guido Pieles**[47]
Consultant Congenital Cardiologist
Congenital Hear Unit, Bristol Heart Institute

**Professor Heather M Wallace**[48] 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**[49] 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, Child & Adolescent Mental Health Services

[46] Reappointed 19/07/2018
[47] Appointed 15/03/2018
[48] Reappointed 12/11/2018
[49] Resigned 24/01/2019

## 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**[50] MB ChB (Hons) PhD FRCP FRCP (Edin) FBPhS, FFPM (Hon) FMedSci
David Weatherall Chair of Medicine, University of Liverpool, NHS Chair of Pharmacogenetics, Director of the Wolfson Centre for Personalised Medicine, Director of the MRC Centre for Drug Safety Science

### Members

**Professor Darren Ashcroft** BPharm, MSc, PhD, FRPharmS
Professor of Pharmacoepidemiology, University of Manchester

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

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

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

**Ms Susan Hunneyball** BSc (Hons)
Lay Member

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

[50] Reappointed 01/01/2018

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

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

**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

**Mr Phil Willan**[51] 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

[51] Passed away 06/03/2019

## 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 EMOLLIENT EXPERT GROUP

### Members

**Professor Michael Ardern-Jones** BSc MBBS DPhil FRCP
Associate Professor, University of Southampton and Consultant Dermatologist

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

**Professor Michael J Cork** BSc MB PhD FRCP
Professor of Dermatology, University of Sheffield & Consultant Dermatologist, Sheffield Children's Hospital and Sheffield Teaching Hospitals

**Ms Sandra Gidley** BPharm FRPharmS
Community Pharmacist; Chair, English Pharmacy Board

**Professor Jonathan Hadgraft**
Professor of Biophysical Chemistry

**Dr Majella Lane** BSc PhD
Senior Lecturer in Pharmaceutics, UCL School of Pharmacy

**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 Celia Moss** BA, MB BS, MA, MRCP, DM, FRCP, MRCPCH
Consultant Dermatologist, Birmingham Children's Hospital, Honorary Professor of Paediatric Dermatology, University of Birmingham

**Dr Clare Spencer** MA MB BCHIR DM MRCOG MRCGP DFFPRHC
GP Partner

**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

### Invited Experts

**Mr Chris Bell**
Paraffin-based skin products Project, West Yorkshire Fire & Rescue Service

**Dr Sarah Hall** MRSC, SFHEA, MAFI(UK), MSWFS & AMCSFS
Senior Lecturer & Head of Forensic and Investigative Sciences Research Group, Anglia Ruskin University

**Mr Graeme Kirkpatrick**
Head of Patient Safety (Advice & Guidance), NHS Improvement

**Ms Kate Livesey**
Patient Safety Lead, Community Pharmacy Patient Safety Group

**Ms Pauline Lockey**
NHS Improvement

**Ms Victoria Lowry**
Community Safety Manager, London Fire Brigade

**Ms Joanne Morrissey**
Senior Lecturer & Course Leader for Crime and Investigative Studies, Anglia Ruskin University

**Ms Claire Tabert**
Paraffin-based skin products Project, West Yorkshire Fire & Rescue Service

## MEMBERSHIP OF THE GENTAMICIN AD HOC GROUP

### Members

**Dr John Firth** BA BM ChB DM FRCP
Deputy Medical Director, Cambridge University Hospitals FT, Consultant Physician and Nephrologist, Addenbrooke's Hospital, Cambridge

**Dr Andrew 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

**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

**Dr Patrick Mark** MB CHB (Hons) PhD FRCP
Clinical Reader/Honorary Consultant Nephrologist University of Glasgow/Queen Elizabeth University Hospital, Glasgow

### Invited Expert

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

## MEMBERSHIP OF LAXATIVES AD HOC EXPERT GROUP

### Chair

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

### Members

**Dr Qamar Abbas**
Deputy Medical Director & Consultant in Palliative Medicine, St Clare Hospice

**Dr Rachel Bryant-Waugh**
Consultant Clinical Psychologist, Great Ormond street

**Dr Matthew Cahill**
Consultant Psychiatrist in Eating Disorders, MRC Psychology Course Tutor

**Ms Anne Cawdron**
Community Pharmacist

**Dr Richard Cooper**
Academic in Community Pharmacy Practice

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

**Ms Zoe Girdis** BPharm, Clinical Diploma, MRPS
Pharmacist Independent Prescriber Medicines Implementation Consultant | South of England and Channel Islands

**Dr Pippa Hugo**
Lead Clinician for Eating Disorders, Priory Hospital, Roehampton

**Professor Raymond Playford**
Member British Society Gastroenterology
Member American Gastroenterology Association

**Dr Paul Robinson**
Psychiatrists in Eating Disorder, Principle Teaching Fellow

**Ms June Rogers** MBE
Paediatric Nurse, Bladder and Bowel UK Paediatric Continence Specialist

**Mrs Hilary Shenton** CPFA
Lay Representative, Retired Secretary to School of Medicine, University of Sheffield

**Dr Caroline Vaughan** PhD
Lay Representative of MHRA EAGS. Governor of the Surrey and Sussex Hospital

**Mr Hadar Zaman**
Community Pharmacist

**Dr Natalia Zarate-Lopez**
Gastroenterologist, UCLH NHS Foundation Trust

## MEMBERSHIP OF THE RAXONE PATIENT 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 Rebecca Mann** BMBS FRCPCH
Consultant Paediatrician, Taunton and Somerset NHS Foundation Trust

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

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

### Patient Group Representatives

**Janet Bloor and Phillip Carroll**
Mother and son; Action Duchenne

**Phillippa Farrant**
The Duchenne Family Support Group

**Jon Hastie**
Contacted via DMD Pathfinders

**Tyran Hawthorn**
Contacted via DMD Pathfinders

**Kaye Hemming**
On behalf of her son Dominic; contacted via Duchenne UK

**Alex Johnson**
Duchenne UK

**Caroline Tress**
On behalf of her son Josh; contacted via Duchenne UK

### Observers

**Gabriel Les**
Carer for Tyran Hawthorn

**Miguel Ramos**
Carer for Jon Hastie

**Jacqui Walker**
Carer for Tyran Hawthorn

## MEMBERSHIP OF THE SODIUM VALPROATE 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

**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 expert

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

### Visiting experts

**Ms Juliet Ashton**
Adult Epilepsy Specialist Nurse, Dereham Hospital

**Dr Ailsa McLellan**
Chair of the British Paediatric Epilepsy Group

**Ms Emma Murphy**
Independent Fetal Anti- Convulsant Trust (INFACT/FACSA)

**Ms Janet Williams**
Independent Fetal Anti- Convulsant Trust (INFACT/FACSA)

## MEMBERSHIP OF ZEBRAFISH TOXICOLOGY AD HOC EXPERT GROUP

### Chair

**Professor Alan Boobis** OBE PhD CBiol FSB FBTS, Centre for Pharmacology & Therapeutics, Toxicology Unit, Department of Medicine, Hammersmith Campus, Imperial College London

### Members

**Professor Len Levy**
Emeritus Professor of Environmental Health School of Water, Energy and Environment, Cranfield University, Cranfield

**Professor Aldert Piersma**
RIVM, National Institute for Public Health and the Environment Centre for Health Protection, The Netherlands

**Professor Marysia Placzek**
Professor in Developmental Neurobiology, Department of Biomedical Science, University of Sheffield, Sheffield

**Professor Andy Smith**
Director, Integrative Toxicology Training Partnership, MRC Toxicology Unit, Leicester

**Professor Stephen Wilson**
Professor of Developmental Genetics, University College London

### Visiting Expert

**Professor Neil Vargesson** BSc (Hons) Ph.D. FHEA
Senior Lecturer, Institute of Medical Sciences, University of Aberdeen

### Observers

**Mrs Marie Lyon**
Association for Children Damaged by Hormone Pregnancy Tests

**Mr Nick Dobrik,** MBE
Volunteer, The Thalidomide Trust

**Dr Sonia Macleod**
Independent Medicines and Medical Devices Safety Review Representative

### Providing written comments only

**Dr Leo T.M. van der Ven**
RIVM, Department of Pathology, Laboratory of Toxicology, National Institute of Public Health and the Environment, The Netherlands

## 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

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

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

### Pharmacokinetics

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

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

### Radiology/Nuclear Medicine

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

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

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

### Renal Medicine/Nephrology

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

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

### Respiratory Medicine

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

### Rheumatology

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

### Urology

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

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

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

## MEMBERSHIP OF THE OPHTHALMIC EXTERNAL EXPERT PANEL

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

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

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

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

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

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

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

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

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

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

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

**Mr David P.S. O'Brart** MD FRCS FRCOphth
Consultant Ophthalmic Surgeon, St Thomas' Hospital, London. President Elect for the UK and Ireland Society of Cataract & Refractive Surgeons (UKISCRS)

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

**Miss Laura Steeples** MBChB(Hons) FRCOphth
Consultant Ophthalmologist, Uveitis Manchester Royal Eye Hospital

## COMMISSION ON HUMAN MEDICINES/EXPERT ADVISORY GROUPS SECRETARIAT

### Commission on Human Medicines (CHM)

**Dr K Prasad**
Principal Assessor, Licensing

**Ms F Norris** (Until 7th November 2018)
Secretary

**Ms E Agcu** (From 7th November 2018)
Secretary

### Chemistry, Pharmacy and Standards Expert Advisory Group (CPSEAG)

**Dr L A Anderson**
Principal Assessor, Licensing (Pharmaceutical)

**Ms M Guler**
Secretary

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

**Dr J Bonnerjea**
Principal Assessor, Licensing (Biologicals)

**Dr C Niederlaender**
Principal Assessor, Licensing (Biologicals)

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

**Ms P Edwards**
Secretary

### Pharmacovigilance Expert Advisory Group (PEAG)

**Ms C Davies**
Principal Assessor, VRMM

**Ms P Edwards**
Secretary

### Paediatric Medicines Expert Advisory Group (PMEAG)

**Dr A Siapkara**
Principal Assessor, Paediatric Care

**Ms M Guler**
Secretary

## 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 2018

## INTRODUCTION

1. The British Pharmacopoeia Commission, appointed under Part 2 of the Human Medicines Regulations 2012, is responsible under regulation 317(4) of the 2012 Regulations for preparing new editions of the British Pharmacopoeia and the British Pharmacopoeia (Veterinary) and for keeping them up to date. It also provides advice to the United Kingdom delegation to the European Pharmacopoeia Commission, of which the United Kingdom is a member by virtue of its obligations under the Convention on the Elaboration of a European Pharmacopoeia (European Treaty Series No. 50; UK Treaty Series No. 32 (1974) CMND 5763) as amended by the Protocol to the Convention (European Treaty Series No. 134; UK Treaty Series No. MISC 16 (1990) CMND 1133). Under regulation 318(2) of the 2012 Regulations the Commission also selects and devises names to be used at the head of monographs, which are subsequently published as British Approved Names.

## MEMBERSHIP

2. A list of members of the British Pharmacopoeia Commission during 2018 is shown in **Appendix I**.

3. The term of office for several members of the BP Commission was due to end on 31st December 2018. Following a review carried out in collaboration with the Department of Health and Social Care Appointments and Honours Team, three members were successfully re-appointed for a period of three years with effect from 1st January 2019.

4. A list of members of the supporting Expert Advisory Groups, Panels of Experts and Working Parties for 2018 is given in **Appendix II**. In order to support the work arising from the MHRA strategy for pharmacopoeial standards for biological medicines, a new Working Party on Alternative Approaches for Documentary and Physical Standards for Biotechnological Products (BIO-DPS) was established and its inaugural meeting was held in May.

5. A comprehensive review of membership of the Expert Advisory Groups, Panels of Experts and Working Parties was undertaken during the year. A significant number of expressions of interest were received from individuals keen to become involved in the work of the BP. The terms of office for all newly appointed and re-appointed members will run from 1st January 2019 to 31st December 2022.

## CODE OF PRACTICE

6. 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

7. The British Pharmacopoeia Commission met three times during 2018. Twenty meetings of the Expert Advisory Groups, Panels of Experts and Working Parties were also held during the year. Until June, these meetings were held at the Medicines and Healthcare products Regulatory Agency (MHRA), 151, Buckingham Palace Road, London SW1W 9SZ. The MHRA relocated to a new site in July and subsequent meetings were held at 10 South Colonnade, Canary Wharf, London E14 4PU. The November meeting of the British Pharmacopoeia Commission was held at the National Institute for Biological Standards and Control (NIBSC), South Mimms, Potters Bar, Hertfordshire EN6 3QG. This enabled members of the Commission to learn more about the work undertaken at NIBSC, particularly how this related to the work of the Expert Advisory Group on Biological and Biotechnological Products.

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

## SECRETARIAT

9. 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

10. 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

11. 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 2018

12. Following publication of the British Pharmacopoeia 2018, three online updates were issued providing users with the text of Supplements 9.3 to 9.5 of the 9th Edition of the European Pharmacopoeia.

### British Pharmacopoeia 2019

13. The British Pharmacopoeia 2019 was published in August 2018. This new edition is available as a package containing the five volumes of the British Pharmacopoeia 2019, the one volume of the British Pharmacopoeia (Veterinary) 2019 and access to the electronic versions of both publications (online BP and offline download format).

14. 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 2019 is 1st January 2019.

15. All monographs published within the 9th Edition of the European Pharmacopoeia, as amended by Supplements 9.1 to 9.5, are included either in this edition of the British Pharmacopoeia or, where appropriate, in the associated edition of the British Pharmacopoeia (Veterinary). Monographs of the European Pharmacopoeia are clearly distinguished from those of national origin by means of a chaplet of stars that appears alongside the monograph title. Where appropriate, statements of relevance to UK usage, such as Action and use and the list of BP preparations, have been added to the European Pharmacopoeia monographs.

16. The British Pharmacopoeia 2019 contains 27 new monographs of national origin which were not published in previous editions. These include two new monographs for Traditional Herbal Medicines and four new monographs for unlicensed formulations. Nine new infrared reference spectra have been added to this edition.

17. The titles of 18 monographs were amended in the British Pharmacopoeia 2019. These included changes introduced as a result of the European Pharmacopoeia policy on specifying the degree of hydration in the monograph title. They also included changes to 14 national monographs following the decision of the British Pharmacopoeia Commission to amend the title of monographs containing split standard terms to reflect the current regulatory requirements for naming medicines. In these instances the former titles have been retained as subsidiary titles, which have the same legal weight as the main title, in accordance with established policy. This change in approach will be reflected in the title of new monographs and further changes to existing monographs will be made in future publications.

18. The General Monograph for Unlicensed Medicines was expanded to include general requirements for unlicensed Intraocular Injections. Additional guidance on these formulations was also included within Supplementary Chapter V F: Aseptic Preparation of Unlicensed Medicines.

19. Two new Appendices were added to harmonise with the European Pharmacopoeia: Appendix II L – Chemical Imaging; Appendix XV M – Substitution of in vivo Methods(s) by in vitro Method(s) for the Quality Control of Vaccines.

**British Pharmacopoeia (Veterinary) 2019**

20. The British Pharmacopoeia (Veterinary) 2019 was published as a companion volume to the British Pharmacopoeia 2019 in August 2018. 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) 2019 is 1st January 2019.

21. The British Pharmacopoeia (Veterinary) 2019 contains one new monograph of national origin which was not published in previous editions (Clenbuterol Injection). The titles of two monographs were amended, reflecting changes introduced by the European Pharmacopoeia. One new infrared reference spectrum has been added to this edition.

22. Efforts are being made to ensure that the British Pharmacopoeia (Veterinary) continues to provide authoritative quality standards for veterinary medicines in the UK and worldwide.

**British Approved Names 2017**

23. The second Supplement to British Approved Names 2017 (Supplement No. 2) was published in August 2018. The Supplement identifies and defines 22 new chemical and biological entities that are now used in medicines in the UK. The majority of the new names are for active substances used in medicinal products that have been licensed through the European Medicines Agency and have not previously been marketed in the UK.

**BP Online**

24. Access to the online version (www.pharmacopoeia.com) and the offline download edition of the publications is provided as a component of the complete British Pharmacopoeia 2019 package. An advantage of the offline download edition is that it is updated to include the European Pharmacopoeia Supplement updates at the same time as the online BP.

**Prices and Availability**

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

26. In addition, 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.

**Future Publications**

27. By the end of 2018 work was progressing on the preparation of the next editions of the British Pharmacopoeia and British Pharmacopoeia (Veterinary). These will be published during 2019 and will have an effective date of 1st January 2020.

28. A digital update to the British Pharmacopoeia 2019 was issued in December 2018 providing users with the text of Supplement 9.6 to the 9th Edition of the European Pharmacopoeia which came into effect on 1st January 2019. Further updates will be issued to coincide with the implementation of Supplements 9.7 and 9.8 on 1st April and 1st July 2019 respectively. These updates will only be available via the online BP and the offline download. The texts will subsequently be included in the BP 2020 publications.

29. The Secretariat continued to liaise closely with The Stationery Office regarding improved ways of working and further improving the BP website. A joint MHRA/TSO Innovation Board has been established to look at ways to improve current BP products and to develop future products. To support this work, user research has been commissioned which will provide an in depth understanding of user needs relating to the BP and chemical reference substances.

## OTHER PHARMACOPOEIAL MATTERS

### BP Website

30. 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.

31. Following the regular public consultation schedule for new and revised monographs, four three-month consultation periods were held during 2018. The opportunity to contribute to the monograph development process is appreciated by users.

### Biological Medicine

32. In 2017 the MHRA published its strategy relating to pharmacopoeial quality standards for biological medicines and the strategic work programme designed to implement the strategy. The strategy was developed in recognition of the important place of standardisation in the assurance of quality and the enabling of innovation. It committed the Agency to new exploratory areas of work for biotherapeutic and advanced therapy medicinal products (ATMPs). The Agency's combined expertise, through the incorporation of regulatory, pharmacopoeial and NIBSC physical standards functions, places it in a unique position to develop this work. The Strategy recognised the importance of engaging with stakeholders and international peer organisations and the need for mutual knowledge building.

33. In 2018 the MHRA continued to take measures to actively implement the new strategy, including the establishment of a new Working Party (BIO-DPS). The new Working Party is exploring the potential value of performance and class-based standards for biotechnological products, with the intention of providing robust, evidence-based recommendations to the Agency, the BP Commission and wider stakeholders. It has international expert membership and is making excellent progress through the collaborative approach taken.

34. The Agency has also engaged with stakeholders to understand their challenges regarding ATMPs, and how these could be addressed by documentary and physical standards. To this end, an informal stakeholder workshop was held in December attended by a range of stakeholders from the NHS, academia, the charity sector and industry. The attendee presentations and fruitful discussions provided excellent insight which will be built on further as the work progresses. This work directly responds to the objectives set out in the Advanced Therapies Manufacturing Taskforce report.

35. Engagement with users and knowledge building are key objectives of the strategy and the Agency has undertaken a programme of continual stakeholder engagement throughout the year, connecting with trade associations, international peer organisations, other UK government and standard setting organisations, the NHS and industry. Through this engagement mutual understanding has been developed, which will be built on further as the strategy continues to be implemented.

**Unlicensed Medicines**

36. Monographs that apply to specific unlicensed medicines are identified as such in the British Pharmacopoeia. If such products subsequently become licensed in the UK, this is reflected in an update to the relevant monograph.

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 Expert Advisory Group on Herbal and Complementary Medicines has continued to demonstrate the importance of producing monographs for herbal substances. This has seen the addition of a number of herbal monographs within the BP 2019 and a continued focus on targeting herbs that are routinely used in the UK market for Traditional Chinese Medicines and Ayurveda. The collaborative work involved closer working relationships with the Royal Botanic Gardens, Kew, and the University of Westminster. BP staff have also delivered numerous presentations and keynote speeches related to topics in the herbal industry.

40. The BP-NIBSC Herbal Project is scheduled to end during 2019. The BP will continue to be active in the field of herbal medicines through the Expert Advisory Group on Herbal and Complementary Medicines and through participation in the relevant Expert Groups of the European Pharmacopoeia.

**Nomenclature**

41. 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 formally adopted

as British Approved Names when they are first included in licensed medicines. 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 (79 and 80) were published by WHO during the year.

42. 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 690 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 continue to review 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)**

43. The AQbD Working Party has completed the feasibility study to investigate the application of Quality by Design concepts to analytical methods and the Pharmacopoeia. Significant learnings have been made relating to the Analytical Target Profile (ATP) concept. Several theoretical ATPs have been evaluated by the Laboratory, in collaboration with the Australian Therapeutic Goods Administration and statistical experts on the Working Party. The findings from the overall feasibility study are set to be published, including a possible consultation on a potential future pharmacopoeial standard developed using the knowledge gained from the study.

44. The BP has built on its global presence in AQbD, further developing collaborative relationships with peer organisations and presenting at international conferences. The BP will look to build on the relationships developed through our engagement to maximise the impact of any external publications.

**Liaison with Other UK Organisations**

45. The BP continues to work with academic institutions and has welcomed the opportunity to work and collaborate with universities as part of the process of establishing and revising monographs. A number of practical reports have been received and presented at our Expert Advisory Group meetings.

46. 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**

47. 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 has been undertaken by the Laboratory to support the Agency's response to the detection of *N*-nitrosoamines in valsartan and other angiotensin II receptor antagonist products for human use. This work, as part of a cross-European network, involved developing methods to detect the contaminants in active

substances and in drug products and the data obtained from this work informed the Agency's risk assessment and regulatory actions.

**BP Reference Materials**

48. Eighteen new BP Reference Materials were established to support the British Pharmacopoeia and British Pharmacopoeia (Veterinary) publications, 49 were replaced and 186 were re-tested to ascertain their continued stability.

49. In a major improvement for our customers this year the Laboratory was able to establish the new BPCRS materials required to support the BP 2019 and BP (Vet) 2019 at the time of publication (August 2018). This enabled customers to purchase these materials in advance of the monographs coming into force and to ensure they were ready to comply with the new and revised monographs.

50. The demand for these reference materials remained high throughout the year. 29234 vials were sold within the UK and to countries worldwide, representing a 2% decrease in sales from the previous year.

**European Pharmacopoeia**

51. The sixth and seventh Supplements to the 9th Edition of the European Pharmacopoeia (Supplements 9.6 and 9.7) were published in July 2018 and October 2018 respectively. Supplement 9.6 came into effect on 1st January 2019 and Supplement 9.7 will come into effect on 1st April 2019. The eighth Supplement (9.8) was published in January 2019 and will come into effect on 1st July 2019. The text of these publications will be included in the next editions of the British Pharmacopoeia or British Pharmacopoeia (Veterinary), as appropriate.

52. 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 four 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.

53. 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.

54. 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.

55. 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 2018, is included in **Appendix V**.

**International Liaison and Collaboration**

56. Liaison was maintained on a wide range of topics relating to pharmacopoeial matters and nomenclature with various international organisations and bodies including the World Health Organization (WHO), the Australian Therapeutic

Goods Administration Laboratories, the Canadian Health and Food Protection Branch, the United States Pharmacopeia (USP) and the United States Adopted Names (USAN) Council.

57. Following the UK's decision to exit the European Union, there have been some questions about the future of the British Pharmacopoeia. The BP will continue to be part of the Medicines and Healthcare products Regulatory Agency's public health role. The UK was a founding member of the Convention on the Elaboration of a European Pharmacopoeia and will continue to be a member of the European Pharmacopoeia in any EU Exit scenario, as the UK will continue to be a member of the Council of Europe in its own right. The standards of the European Pharmacopoeia will continue to be adopted in the UK and the European Pharmacopoeia will continue to be reproduced in the BP for the convenience of users.

58. Representatives from the BP attended a number of technical meetings in order to support the work of the European Pharmacopoeia. A number of issues had been discussed including the approach to dissolution testing in finished product monographs, proposals to increase the number of finished product monographs through adaptation of current national monographs and ways to improve collaboration between National Pharmacopoeial Authorities and National Competent Authorities.

59. BP staff attended the annual meeting of the EDQM Official Medicines Control Laboratory (OMCL) Network, held in Bosnia. Participants at the meeting highlighted recent testing and surveillance experiences and discussed the co-ordination of future work. The next OMCL meeting, which will be held in May 2019, will be hosted jointly by the MHRA and NIBSC and will be organised in conjunction with the EDQM. The meeting will provide an opportunity for the UK to highlight its OMCL activities and to demonstrate the continuing co-operation between the UK and Europe.

60. The Co-operation Agreement between the BP/MHRA and the Croatian Agency for Medicinal Products and Medical Devices (HALMED) was renewed in February. This agreement allows HALMED to reproduce texts from the British Pharmacopoeia relating to unlicensed medicines in the Croatian Pharmacopoeia.

61. BP Staff attended the Ninth International Meeting of World Pharmacopoeias which was organised by the World Health Organization and was held in Vietnam in April. A wide range of items were discussed, including: the guidelines on Good Pharmacopoeial Practices and how to increase awareness of the document; advances in technology; the establishment of reference materials; the on-going project to update monographs in the International Pharmacopoeia containing microbiological methods of Assay with HPLC methods; collaborating models between pharmacopoeias.

62. During the meeting the renewed Co-operation Agreement between the BP/MHRA and WHO, which had been finalised in December 2017, was formally exchanged. This agreement will enable the continued collaboration between the two organisations. The meeting also provided BP staff with an opportunity to hold meetings with representatives from the Chinese Pharmacopoeia, the Indian Pharmacopoeia, the Brazilian Pharmacopoeia, the State Pharmacopoeia of the Ukraine and the South Korean Pharmacopoeia. These informal meetings

focussed on current and potential future collaboration opportunities between the BP and these organisations.

63. 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.

64. The BP attended the WHO Consultation on Screening Technology, Sampling and Specifications for Medicines in May, during which monographs that were being jointly developed by the BP and the International Pharmacopoeia were discussed.

65. BP staff attended the 66th and 67th WHO Consultations on International Non-proprietary Names (May and October). The number of names requested for biological substances continues to increase, with about half of new names requested now being for biologicals.

66. BP staff participated in a number of discussions throughout the year with representatives from the United States Pharmacopeia to expand the current successful joint working between the BP and the USP. A wide range of topics were discussed, including: Global Health monographs; the draft Memorandum of Understanding between the two organisations; the BP/MHRA Biologicals consultation and the future of biological standards in the BP and the USP; international collaboration; progress on the Up-to-date programme, which is aimed at updating monographs containing outdated technology; issues for discussion at future International Meetings of the World Pharmacopoeias; stakeholder engagement.

67. A representative from the BP attended the USP Workshop on Analytical Procedure Lifecycle which included a presentation on the BP/MHRA Analytical Quality by Design feasibility study and participation in a number of workshops on novel concepts and their potential applications to improve manufacturing controls for the benefit of patients.

68. Good progress has been made on informal harmonisation projects. The BP 2019 saw the publication of Moxifloxacin Tablets, the first monograph developed through an informal harmonisation process with the International Pharmacopoeia, and publication of the first informally harmonised revised monograph, Tetracaine Eye Drops, through collaboration with the USP via their Up-to-date programme. A further six informally harmonised monographs are in the later stages of the process, through collaboration with the USP and the International Pharmacopoeia, and are expected to be published in the BP 2020.

69. The BP participated in the Joint Compendial Industry (JCI) Meeting organised in association with the US Consumer Healthcare Products Association. Updates on current and future BP activities were provided and positive feedback was received regarding the early availability of the new BPCRS required to support the BP 2019 monographs and the close engagement of the BP with stakeholders.

70. BP staff attended the Drug Information Association CMC Workshop in Basel which had addressed current challenging topics within the global pharmaceutical

and biopharmaceutical arena. A presentation was given on “MHRA Perspectives on Pharmacopoeial Standards for Biological Medicines”.

71. Staff from the BP-NIBSC Herbals Laboratory participated in a number of international meetings at which the work of the group was highlighted. These included the Plant ID meeting in Barcelona, the purpose of which was to start a Marie Curie Initial Training Network which would focus on the molecular identification of plants, the USP-FDA Workshop on DNA Standards for Botanical Identification and the second International Congress on DNA Technology for Authentication, Quality Control and Conservation of Herbal Medicines held in Hong Kong.

## ACKNOWLEDGEMENTS

72. The Commission wishes to place on record its sincere thanks to Dr Brian Matthews, who retired from the British Pharmacopoeia Commission at the end of the year after 9 years of service. Dr Matthews would also be retiring from his roles as Vice-Chair of the Expert Advisory Group on Pharmacy, Chair of the Panel of Experts on Excipients and member of the Panel of Experts on Microbiology. Dr Matthews had made a significant contribution to the work of the British Pharmacopoeia Commission over many years and his enthusiasm and expertise would be missed.

73. The Commission wishes to express its gratitude to all Expert Advisory Group, Panel and Working Party members for the invaluable contribution they have made towards the continuing improvement of standards in the British Pharmacopoeia and to members of the United Kingdom delegation to the European Pharmacopoeia Commission and to UK members of its Groups of Experts and Working Parties who have unstintingly provided time, attention and expertise to the work of that Commission. In particular, the Commission wishes to acknowledge the contribution of those members who have now retired from the Expert Advisory Groups, Panels of Experts and Working Parties of the British Pharmacopoeia Commission.

74. 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 Transformation 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 and Social Care, from the National Institute for Biological Standards and Control and from the Veterinary Medicines Directorate.

75. The Commission wishes to acknowledge the advice of the publishing team at The Stationery Office in the production of the British Pharmacopoeia 2019, the British Pharmacopoeia (Veterinary) 2019 and Supplement No. 2 to British Approved Names 2017.

76. 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.

## OBITUARIES

77. It was with sadness and regret that the Commission learnt of the death of Dr Andrew Coulson, a serving member of the BP Commission, during the year. Dr Coulson had been an active and engaged member of the Commission since 2012 and had been the Vice-Chair of the Panel of Experts on Veterinary Medicines.

78. Members were also saddened to learn of the deaths of Dr Adrian Thomas and Mr Peter Murray, long-standing members of the Expert Advisory Groups on Biological and Biotechnological Products and Medicinal Chemicals MC2 respectively.

**APPENDIX I**

**MEMBERSHIP OF THE BRITISH PHARMACOPOEIA COMMISSION DURING 2018**

**Chair**

**Professor Kevin M G Taylor BPharm PhD FRPharmS**
Professor of Clinical Pharmaceutics, UCL School of 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[1] 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 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

**Dr Brian R Matthews[2] 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**

**Mr James Pound BSc**
Group Manager, British Pharmacopoeia and Laboratory Services, MHRA

[1]*Deceased.*
[2]*Retired, 31st December 2018.*

**APPENDIX II**

**MEMBERSHIP OF EXPERT ADVISORY GROUPS, PANELS OF EXPERTS AND WORKING PARTIES OF THE BRITISH PHARMACOPOEIA COMMISSION DURING 2018**

## Expert Advisory groups

| | |
|---|---|
| ABS: Antibiotics | R L Horder (**Chair**), G D Cook (**Vice-Chair**), G Blake, E Flahive, V Jaitely, W Mann, J Miller, M Pires, J Sumal, I R Williams |
| BIO: Biological and Biotechnological Products | P Varley (**Chair**), A-M Brady (**Vice-Chair**), L Bissett*, C Burns, 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[1], P Sheppard, P Stickings*, A H Thomas[2], R Thorpe, L Tsang, M Wadhwa* |
| HCM: Herbal and Complementary Medicines | M Simmonds (**Chair)**, R Middleton (**Vice-Chair**), L A Anderson, P Anderson, A Booker, C Leon, B Moore, M Pires, E Reich, M Rowan, A Slater, K Strohfeldt-Venables, J Sumal*, E Williamson, C Welham, K Zhao (*Corresponding members* SS Handa, A Krauss, Z-T Wang) |
| MC1: Medicinal Chemicals | A G Davidson (**Chair**), D Cairns (**Vice-Chair**), J C Berridge, E Bush, A J Caws, D Deutsch, P Fleming, E Gray, W J Lough, D J Malpas |
| MC2: Medicinal Chemicals | G Cook (**Chair**), C T Goddard (**Vice-Chair**), K Bracht, J Cowie, D Edwards[1], J Lim, J Miller, P Murray[2], A Ruggiero, M Turgoose[1], N Wynne (*Corresponding members* M Brits, W Sherwin) |
| MC3: Medicinal Chemicals | M Almond (**Chair)**, 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[1], K M G Taylor, S Wicks
(*Corresponding member* J Churchill)

ULM: Unlicensed Medicines — M G Lee (**Chair**), V Fenton-May (**Vice-Chair**), S Branch[1], D Caulfield, W Goddard, S Hartley, S Ho, 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**), R Cawthorne, D Deutsch,

DNA: Identification Techniques — A Slater (**Chair**), M Carine, 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[1], 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[2] **(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)

BIO-DPS: Alternative Approaches for Documentary and Physical Standards for Biotechnological Products — P Varley (**Chair**), A-M Brady (**Vice-Chair**), C Burns, B Cowper, N Czeloth, L Duhau, V Ganeva, C E Giartosio, A Ramzan, B Rellahan, M Wild

MCS: Microscopy (*Disbanded, 31st December 2018*) — 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]*Retired during the year*.
[2]*Deceased.*
** Specialist member*.

## APPENDIX III

## MEMBERS OF THE BRITISH PHARMACOPOEIA COMMISSION STAFF DURING 2018

#### SECRETARY AND SCIENTIFIC DIRECTOR

Mr J Pound

#### SECRETARIAT

Mr A Gibb (*Editor-in-Chief, from November*)
Mr S Young (*Head of Analytical Science*)
Ms H Corns
Mr P Crowley
Mr L Elanganathan (*until July*)
Mr A Evans
Dr A Gardiner
Ms S Gomersal
Dr G Kemp
Dr C Lenihan
Ms G Li-Ship
Mr S Maddocks
Mr H Makwana
Dr K Radi (*until July*)
Dr F J Swanson
Ms M-L Wall
Mr M Whaley

#### DHSC STAFF

Ms N Clothier (*from October*)
Mr T Gladwin (*March to August*)
Mr J Parker (*until February*)

#### NIBSC BASED STAFF

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

#### LABORATORY MANAGEMENT BOARD

Mr J Pound (*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
Ms A Korzeniowska (*until November*)
Miss J Paine
Ms U Rothna
Ms N Siddika (*from December*)

## APPENDIX IV

## BRITISH PHARMACOPOEIA COMMISSION PUBLICATIONS DURING 2018

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

### British Pharmacopoeia 2019 package

Consisting of:-

British Pharmacopoeia 2019

British Pharmacopoeia (Veterinary) 2019

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

BP Download Edition (single-user licence)

*(Subscription price £1000; £875 for print, online or download edition only)*

### Individual BP Monograph (only supplied electronically)

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

### British Approved Names

British Approved Names 2017: Supplement No. 2

*(Price £20)*

## APPENDIX V

## EUROPEAN PHARMACOPOEIA COMMISSION

### MEMBERS OF THE UNITED KINGDOM DELEGATION DURING 2018

Main: A G Davidson, J Pound, K M G Taylor

Alternates: R L Horder, S Young

### MEMBERS OF GROUPS OF EXPERTS FROM THE UNITED KINGDOM DURING 2018

| | | |
|---|---|---|
| Group 1 | Microbiology | V Fenton-May (***Chair***), I Venet |
| Group 6 | Biological Substances | B Cowper (*Specialist*), C Burns |
| Group 6B | Human Blood and Blood Products | A R Hubbard |
| Group 7 | Antibiotics | 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[1], A Lucatelli |
| Group 12 | Dosage Forms and Methods | R L Horder (***Chair***), S Wicks |
| 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, D Sesardic (*Specialist*), P Stickings |
| Group 15V | Veterinary Sera and Vaccines | A-M Brady *(Specialist*), R Cooney |
| 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 2018:**

| | |
|---|---|
| Alkyl Mesilates (*dormant group*) | J Midgley (***Chair***) |
| Allergens | A Cook |
| Bacterial Endotoxins Test | K Nordgren |
| Chairs of Chemical Groups | A G Davidson, M G Lee |
| Chromatographic Separation Techniques | S Young |
| Dialysis Solutions | M G Lee (***Chair***) |
| Extracts | L Anderson, M Pires |
| Excipient Performance | C Mroz |
| Gene Therapy Products | Y Zhao |
| General Methods | S Boland, E Gray, O McPolin (*Specialist*) |
| 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, A Nunn |
| Pharmaceutical Preparations (*dormant group*) | V Fenton-May (***Chair***), M G Lee |
| Procedure 4 for Biologicals | M Wadhwa, L Both |
| Pyrrolizidine Alkaloids | S MacDonald |
| 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 | C Lenihan |
| 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 | Abbvie | Department was recruiting centre in clinical trial. I was local PI | No | None |
| | | | Abbvie | Unrestricted grant to support educational event | | |
| | | | Amgen | Department is recruiting centre in clinical trial. I am local PI | Yes | |
| | | | Amgen | Unrestricted grant to support educational event | No | |
| | | | Astra Zeneca | Department is recruiting centre in an observational study of patients with SLE. I am local PI. | Yes | |
| | | | Cellgene | Unrestricted grant to support educational event | No | |
| | | | Consilient health | Unrestricted grant to support educational event | No | |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| MEMBER | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | Eli Lilly | Department was a recruiting centre in a clinical trial. I was local PI | No | |
| | | | Eli Lilly | Eli Lilly have donated Teriparatide for an NIHR supported clinical trial where I am PI. | Yes | |
| | | | Eli Lilly | Department is recruiting centre in an observational study. I am a sub-investigator. | Yes | |
| | | | Internis | Unrestricted grant to support educational event | No | |
| | | | Internis | Unrestricted grant to support educational event | No | |
| | | | Kyowa Kirin | Department is recruiting centre in an observational study of patients with X-linked hypophosphataemic rickets. I am local PI | Yes | |
| | | | Kyowa Kirin & Ultragenyx | Department is recruiting centre in clinical trial. I am local PI | Yes | |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| | | | Pfizer | Unrestricted grant to support educational event | No | |
| | | | Sanofi-Genzyme | Unrestricted grant to support educational event | No | |
| Ms Susan Bradford | None | None | None | None | | None |
| Professor Jamie Coleman | None | None | None | None | | None |
| Dr J Colin Forfar | None | None | Weatherden | Advice only | No | My wife is a director of Bioexcel ltd whose clients may include members of the Pharmaceutical Industry.<br>My daughter is a prescribing General Practitioner. |
| Dr Jamie Fraser | None | None | None | None | | None |
| Professor Jonathan S Friedland | None | None | Astra Zeneca | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | None |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| MEMBER | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | Chiesi Limited | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |
| | | | EDIXOMED LIMITED | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |
| | | | FairCourt Capital | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| MEMBER | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | Fondazione PENTA ONLUS | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |
| | | | GlaxoSmithKline | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |
| | | | Gilead Sciences Ltd. | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| | | | Healthcare Diagnostics Ltd. | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |
| | | | LDN Pharma | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |
| | | | Merck Serono Ltd | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| MEMBER | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | McColl's Retail Group | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |
| | | | Pfizer UK | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |
| | | | QuantuMDX Group Ltd | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| MEMBER | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| Dr Richard JC Gilson | | | ViiV | My department is a clinical site for trials sponsored by ViiV, who have provided research funds and donated drug to the department (received by UCL and Central and North West London NHS Trust). I am a co-investigator on these studies. | No | None |
| | | | Gilead Sciences | My department is a clinical site for trials sponsored by ViiV, who have provided research funds and donated drug to the department (received by UCL and Central and North West London NHS Foundation Trust). I am a co-investigator on these studies, except for one study, for which I am the | No | |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| MEMBER | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | | local principal investigator. | | |
| | | | Merck | My department is a clinical site for trials sponsored by Merck, who have provided research funds and donated drug to the department (received by Central and North West London NHS Foundation Trust). | No | |
| | | | Janssen | My department is a clinical site for trials sponsored by Merck, who have provided research funds and donated drug to the department (received by Central and North West London NHS Foundation Trust). | No | |
| | | | Mylan | My department is a clinical site for a trial funded by the NHS, using a drug purchased from Mylan. 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** |
| | | | | receives research funds to support this trial, for which I am the local principal investigator (funds paid to Central and North West London NHS Foundation Trust). | | |
| | | | Glaxo SmithKline | My department is a clinical site for trials sponsored by GSK, who have provided research funds and donated drug to the department (funds paid to Central and North West London NHS Foundation Trust). | No | |
| Professor Martin Gore | None | None | None | None | | None |
| Professor Malcolm R Macleod | None | None | Janssen Pharmaceutica NV | Co-supervise 2 PhD students; 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 2-stage application. In stage 1 academic consortia submit proposals against the bid, |
| | | | AbbVie Inc. | 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 |
| | | | Boehringer Ingelheim International GmbH | Co-applicants on funded IMI consortium – see additional information | Yes | 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% finding from the EU, with 50% coming in cash or in kind from the EFPIA partners listed above, with total resource of around €9m. 2 junior researchers would be shared between |
| | | | 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 | |
| | | | Pfizer Limited | Co-applicants on funded IMI consortium – see additional information | Yes | |
| | | | PsychoGenics Inc. | 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 | |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| | | | Sanofi-Aventis Research and Development | Co-applicants on funded IMI consortium – see additional information | Yes | 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. |
| Dr Rebecca Mann | None | None | None | None | | None |
| Professor Sarah Meredith | None | None | Abbott | Grant & Product donated for a trial<br>Financial support for a virology sub-study (no drug) | Yes | None |
| | | | Astellas | Grant & Product donated for a trial | Yes | |
| | | | AstraZeneca | Grant & Product donated for a trial<br>Drug supply and financial support | Yes | |
| | | | Bayer | Grant & Product donated for a trial | Yes | |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| MEMBER | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | Boehringer Ingelhein, Bris/ol-Myers Squibb | Grant & Product donated for a trial | Yes | |
| | | | Cipla | Product donated for a trial | Yes | |
| | | | Gilead Sciences | Grant & Product donated for a trial | Yes | |
| | | | GlaxaSmithKline | Grant & Product donated for a trial | Yes | |
| | | | Janssen | Grant & Product donated for a trial | Yes | |
| | | | Janssen-Cilag | Grant & Product donated for a trial | Yes | |
| | | | Lilly | Product donated for a trial | Yes | |
| | | | Merck | Grant & Product donated for a trial | Yes | |
| | | | Pilatus | Product donated for a trial | Yes | |
| | | | Roche | Grant & Product donated for a trial | Yes | |
| | | | Sanofi-Aventis | Grant & Product donated for a trial | Yes | |
| | | | Sanofi Pasteur | Product donated for a trial | Yes | |
| | | | Tibotec | Product donated for a trial | Yes | |
| | | | Vireo | Product donated for a trial | Yes | |
| | | | WHO/GDF | Product donated for a trial | Yes | |
| | | | Emergent Bioso/utions | Product donated for a trial | Yes | |
| | | | Ctovis | Product donated for a trial | Yes | |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| | | | Emcure | Product donated for a trial | Yes | |
| | | | FIT Biotech | Product donated for a trial | Yes | |
| | | | INSERM-ANRS | Product donated for a trial | Yes | |
| | | | Merck-Serono | Grant & Product donated for a trial | Yes | |
| | | | Takeda | Product donated for a trial | Yes | |
| Dr Siraj Misbah | None | None | None | None | | None |
| Professor David G C Owens | None | None | None | None | | None |
| Professor Sir Munir Pirmohamed | None | None | Eli Lilly | Research grant to support clinical training fellowships jointly with MRC | Yes | None |
| | | | Novartis | Research grant to support clinical training fellowships jointly with MRC | Yes | |
| | | | Roche | Research grant to support clinical training fellowships jointly with MRC | Yes | |
| | | | UCB Pharma | Research grant to support clinical training fellowships jointly with MRC | Yes | |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| | | | Astra Zeneca | Research grant to support PHD in drug interactions | Yes | |
| | | | BMS (Bristol Myers Squibb) | Unrestricted educational grant to support UK Pharmacogenetics and Stratified Medicine network open meeting | Yes | |
| Professor Shirley Price | None | None | None | None | | None |
| Professor Kevin M G Taylor | None | None | AstraZeneca | Contribution to EPSRC Doctoral Training Centre in my department | | None |
| | | | Boots | Contribution to EPSRC Doctoral Training Centre in my department | | |
| | | | Pfizer | Contribution to EPSRC Doctoral Training Centre in my department | | |
| | | | GlaxoSmithKline | Contribution to EPSRC Doctoral Training Centre in my department | | |
| | | | Quadrant | Contribution to EPSRC Doctoral Training Centre in my department | | |
| Professor Angela E Thomas | None | None | Pfizer | Other: travel and accommodation support | No | None |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| | | | | as speaker at nursing meeting (International Conference on Cancer Nursing, Auckland 2018) to which Pfizer had contributed funding. The company had no direct contact with me or control or influence over content of lecture | | |
| Professor Helen M Ward | None | None | None | None | | 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 | Research grant to institution, on which I am co-applicant | Yes | |
| Dr Martin Wilson | None | None | None | None | | I am involved with 4 pieces of Research in 2018 none of which have drug company sponsors. |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| MEMBER | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | | | | PD MED trial<br>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 Specialist Association. Hosted by Birmingham Clinical Trials Unit<br>Running since 1999. I am the local principle investigator (taking over from my predecessor in 2005) this involves follow up of a single patient. |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| MEMBER | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | | | | 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 principle investigator with assessments carried out by PD Nurse and Research nurse<br>Prescribing Outcomes from implementing Enhanced Medication Summaries (POEMS) Funded by CSO grant I am on advisory board for this study<br>PD COMM<br>A multicentre randomised |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| MEMBER | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | | | | control trial to compare clinical and cost effectiveness of SALT input in Parkinson's disease<br>I am local principle investigator<br>Funded by National Institute for Health Research Health Technology Assessment programme (HTA 10/135/02)<br>Other<br>I am regular speaker at Royal Colleges, Regional Speciality meetings on a range of subjects including management of Polypharmacy. I receive travel and accommodation reimbursement. None of the meetings have been solely drug sponsored.<br>I spoke to a patient group at a Parkinson's Disease society sponsored event in |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| MEMBER | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | | | | 2018. I received no fees or reimbursement for this. |

## CARDIOVASCULAR, DIABETES, RENAL, RESPIRATORY & ALLERGY 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 J Colin Forfar (Chair) | None | None | Weatherden | Advice only | No | My wife is a director of Bioexcel ltd whose clients may include members of the Pharmaceutical Industry.<br>My daughter is a prescribing General Practitioner. |
| Dr Amanda Adler | None | None | None | None | | None |
| Dr Iolo J Doull | GSK | I was part of a scientific organizing committee for a Global Paediatric Forum to improve the care of children with respiratory | None | None | No | None |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| | | disorders. The meeting was supported by GSK, from whom I received a fee. | | | | |
| Dr John Firth | None | None | AMGEN | Support of renal anaemia service / research and renal mineral and bone disease studies and of renal educational meetings. | No | None |
| | | | ASTELLAS | Support of renal transplantation service / research and of renal educational meetings. | No | |
| | | | GENZYME | Support of renal mineral and bone disease studies and of renal educational meetings. | No | |
| | | | NOVARTIS | Support of renal transplantation service / research and of renal educational meetings. | No | |
| | | | ROCHE | Support of renal transplantation and renal | No | |

| MEMBER | PERSONAL INTERESTS NAME OF COMPANY | PERSONAL INTERESTS NATURE OF INTERESTS | NON-PERSONAL INTERESTS NAME OF COMPANY | NON-PERSONAL INTERESTS NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
|---|---|---|---|---|---|---|
| | | | | anaemia service / research and renal mineral and bone disease studies and of renal educational meetings. | | |
| | | | SHIRE | Support of renal mineral and bone disease studies and of renal educational meetings. | No | |
| | | | WYETH | Support of renal transplantation service / research and of renal educational meetings. | No | |
| Dr Andrew Grace | None | None | None | None | | None |
| Dr Philip W Ind | None | None | None | None | | I have attended occasional Divisional meetings where snack breakfast e.g. fruit or croissant was provided e.g. 17/4/18 sponsored by Boehringer.<br>More recently some of the Hospital Medical Staff Rounds have had a snack lunch provided. |
| Dr Patrick Mark | Vifor | Consultancy, Speaker fees | Boehringer Ingelheim | Research grant | Yes | None |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| | Novartis | Speaker fees | AstraZeneca | National Lead for clinical trial (no financial reward) | Yes | |
| | Pfizer | Speaker fees | | | | |
| | Bristol Myers Squibb | Speaker fees | | | | |
| Professor Theresa McDonagh | NOVARTIS | Fees and consultancy | NOVARTIS | Preceptorship fees foe KCH | No | |
| | VIFOR | Fees and Consultancy | | | | |
| | ASTRA-ZENECA | Fees | | | | |
| Professor Ann Millar | None | None | None | None | | None |
| Dr Hilary Pinnock | Teva | Honorarium of £300 | 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 interested Pharmaceutical Companies |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT | ADDITIONAL INFORMATION |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | | |
| | | | | | | 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.<br>Scottish Allergy and Respiratory Academy. (A national training programme and resource in allergic and respiratory disorders for healthcare professionals in primary, secondary and tertiary care and other interested individuals). I am course co-ordinator for this initiative which is supported |

| MEMBER | PERSONAL INTERESTS NAME OF COMPANY | PERSONAL INTERESTS NATURE OF INTERESTS | NON-PERSONAL INTERESTS NAME OF COMPANY | NON-PERSONAL INTERESTS NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
|---|---|---|---|---|---|---|
| | | | | | | by unrestricted educational grants from respiratory interested Pharmaceutical Companies |
| Dr Pallav L Shah | Olympus | Consultancy | ERBE, Medtronic, Olympus, PneumRX/BTG, Pulmonx, Boston Scientific, Nuvaria, Fischer & paykel, Broncus | sponsor Imperial college for bronchoscopy course | No | None |
| | PneumRX/BTG | Lecture/workshop/consultancy | Pulmonx | RCT with endobronchial valves Royal Brompton Hospital reimbursed for clinical trial expenses | Yes | |
| | Pulmonx | Consultancy/lecture | Nuvaira | RCT with vagal nerve ablation Royal Brompton Hospital and Chelsea & Westminster Hospital reimbursed for clinical trial expenses | Yes | |
| | Nuvaira | Consultancy/lecture | 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** |
| | CSA Medical | Consultancy/lecture | Gala therapeutics | Developing clinical trial protocol | Yes | |
| Dr Caroline Vaughan | None | None | None | None | | None |
| Professor Sarah Wild | Novo Nordisk | Accommodation and dinner provided as part of unrestricted educational grant during attendance at biannual meetings of the Scottish Study Group for Care of Diabetes in the Young in role as member of Steering Group | None | None | | None |
| Mr Phil Willan | None | None | None | None | | None |

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

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| Professor Kevin M G Taylor (Chair) | None | None | AstraZeneca | Contribution to EPSRC Doctoral Training Centre in my department | | None |
| | | | Boots | Contribution to EPSRC Doctoral Training Centre in my department | | |
| | | | Pfizer | Contribution to EPSRC Doctoral Training Centre in my department | | |
| | | | GlaxoSmithKline | Contribution to EPSRC Doctoral Training Centre in my department | | |
| | | | Quadrant | Contribution to EPSRC Doctoral Training Centre in my department | | |
| Professor Michael E Aulton | Actelion | Fees. Patent advice. | None | None | No | None |
| Professor Graham Buckton | Teva/Actavis | Consultancy | None | | Yes | None |
| | GSK | Consultancy | | | No | |
| | APOTEX | Consultancy | | | Yes | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | AUROBINDO | Consultancy | | | Yes | |
| | GENENTECH | Consultancy | | | | |
| | Dr. Reddy's, Sun | Consultancy | | | No | |
| | Silvergate | Consultancy | | | No | |
| | PAR | Consultancy | | | No | |
| | Impax | Consultancy | | | Yes | |
| | Gilead | Consultancy | | | Yes | |
| Professor Brian J Clark | None | None | None | None | | None |
| Professor Ruth Duncan | None | None | None | None | | None |
| Mr V'Iain G Fenton-May | None | None | None | None | | None |
| Professor Geoffrey W Hanlon | None | None | None | None | | None |
| Dr Gillian M Hawksworth | None | None | None | None | | None |
| Miss Carol E Knott | Windcliff Management Ltd | Owner and managing director. Undergoing project work across the NHS, private hospitals and pharma industry | None | None | Yes | None |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | Nottingham West Clinical Commissioning Group | Lay Member and Chair of Finance and Performance Committee | | | Yes | |
| | Baxter Healthcare | Shareholder (less than £20,000) | | | Yes | |
| | BMI Park Hospital Nottingham | Locum pharmacist | | | Yes | |
| Dr Majella Lane | None | None | None | None | | 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 | | None |
| Professor Christopher Marriott | Remedica Ltd | Directorship, Fees | None | None | | My wife, Ann Marriott, holds shares in Halation Ltd and Vectura Ltd. |
| | Halation Ltd | Directorship, Shares, Fees | | | | |
| | Vectura Ltd | Shares | | | | |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| Professor Yvonne Perrie | Colorcon | Grant to Aston University, Paper published. | None | None | | None |
| | GSK | EU Grant to University of Strathclyde. | | | | |
| | AMRI | Knowledge exchange research contracts from company to University of Strathclyde. | | | | |
| | Encap/Capsugel/Lonza | KTP Grant to University of Strathclyde. | | | | |
| | Lamellar Biomedical | KTP Grant to University of Strathclyde. | | | | |
| | Pfizer Inc, Astrazeneca, Precision Nanosystems, Centre for | Contract for grant signed in Dec 2017 (started March 2018) which includes | | | | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | process Innovation Ltd, Malvern Instruments, Croda. | contributions from listed companies to University of Strathclyde. | | | | |
| | Diagenode | Grant to Aston University. | | | | |
| | Microfluidics | Equipment loan to University of Strathclyde. | | | | |
| | Academy of Pharmaceutical Sciences (APSGB) | Exec Board member (non-salary). | | | | |
| | Precision Nanosystems | Advisory Board member (non-salary). | | | | |
| | Controlled Release Society | Society Secretary (non-salary). | | | | |
| Ms Hilary A Shenton | None | None | None | None | | None |
| Professor Michael D Threadgill | None | None | None | None | | None |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| Professor Peter York | Nektar Therapeutics | Shares | Boehringer Ingelheim | Funded project at CrystecPharma | No | None |
| | CrystecPharma | Director, Shares | | | | |
| | 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 | Pfizer | Other: travel and accommodation support as speaker at nursing meeting (International Conference on Cancer Nursing, Auckland 2018) to which Pfizer had contributed funding. The company had no direct contact with me or control or influence over content of lecture | No | None |
| Professor Farzin Farzaneh | Cellectis, France | Consultancy | None | None | | None |
| | Autolus, UK | Consultancy payments and shares in the company | | | | |
| | CellVec | Consultancy | | | | |
| | Syncona | Consultancy | | | | |
| Dr Helen J Lachmann | | | | | | |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| Dr Siraj Misbah | None | None | None | None | | None |
| Professor B Kevin Park | None | None | GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED (UK) | Quantitative assessment of drug-protein adduct formation and function (pi grant) | Yes | None |
| | | | JANSSEN PHARMACEUTICALS (BELGIUM) | Mitochondrial toxicity research | Yes | |
| | | | MERCK & CO., INC. (USA) | To examine the potential preclinical value of mechanism-based biomarkers of dill over more established and widely accepted clinical 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 dill assay in preclinical | Yes | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | | studies (cdss dill project) (pi grant) | | |
| | | | WELLCOME TRUST (UK) | Multi-modal high resolution preclinical pet+spect+ctscanner (co-i grant) | Yes | |
| | | | EMD SERONO RESEARCH & DEVELOPMENT INSTITUTE INC | Consultancy | Yes | |
| Professor Andrew Pollard | None | None | Gilead/Sanofi Pasteur/GSK/Astra Zeneca | Grant to Oxford University | No | Non-commercial: Grants from Bill & Melinda Gates Found'n on typhoid vaccines (Tybar-CV, Bharat Biotech, 2013-2021); from MRC on paratyphoid vaccine (U. Maryland; from 2018-)); from NHIR (2015-2018) on IVIG in encephalitis (supply/distribution funding agreement with CSL Behring) & AMR equipment grant 2017/8; Grant from the Gavi on pneumococcal vaccines in Nepal (2013- |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT | ADDITIONAL INFORMATION |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | | |
| | | | | | | 2020). European Commission (EC): grant (EUCLIDS; 2011-2017) on fever with Bexsero (supply agreement, Novartis/GSK); (ADITEC, 2011-2016) on influenza vaccines (FluAd, Novartis). EC IMI grants (EBOVAC), on Ebola vaccine (Janssen; 2015-current); (PERISCOPE) on pertussis vaccines (2016-current); (RESCEU) on RSV biomarkers (2016-Current). EC H2020 grant (PERFORM) on pneumococcal carriage (2016-2020). Grants from Innovate UK to develop plague, zika, Q fever vaccines (2016-2019). Grant from Meningitis Res Found'n on a booster of Bexsero in teens (2018-current), from BMA on RSV, and MRC on novel |

| MEMBER | PERSONAL INTERESTS NAME OF COMPANY | PERSONAL INTERESTS NATURE OF INTERESTS | NON-PERSONAL INTERESTS NAME OF COMPANY | NON-PERSONAL INTERESTS NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
|---|---|---|---|---|---|---|
| | | | | | | meningococcal vaccine.. Chair of UK Dept. Health's Joint C'ttee on Vacc. & Imms & the EMA vaccines SAG, and is a member of the WHO's SAGE. |
| Dr Robin Thorpe | None | None | None | None | | None |
| Professor Marc Turner | Scottish National Blood Transfusion Service | Medical Director | None | None | | None |
| | Cell and Gene Therapy Catapult | Non-Executive Director | None | None | | |
| Mrs Madeleine Wang | None | None | None | None | | None |
| Professor Christopher Weir | None | None | ReNeuron Ltd | DSMB membership, resulting in income to my department | Yes | None |

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

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| Professor Anthony G Wilson (Chair) | UCB | Advisory board - fee | None | None | | None |
| | Diurnal | Consultancy - fee | | | | |
| | Biogen | Advisory board and lecture - fees | | | | |
| | Abbvie | Advisory board - fee | | | | |
| | Amgen | Advisory board - fee | | | | |
| Professor Michael Ardern-Jones | None | None | Unilever | Grant funding PhD student | No | I undertake commercial clinical trials on behalf of my employer/NHS Trust to investigate products under development:<br>Currently engaged with: Regeneron / Sanofi; Leo; Amgen; Abbvie<br>I am an invited speaker due 2019: |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | | | | Sanofi – course<br>Sanofi – EAACI Satellite symposium<br>I have accepted travel/conference fees from Janssen / J&J for 2019.<br>I have organized clinical meetings on behalf of the British Society for Medical Dermatology, which have been sponsored. |
| Dr Ian Barrison | GSK | Shares | None | None | | None |
| Dr Andrew Carmichael | None | None | None | None | | None |
| Mr David Chandler | None | None | None | None | | I'm employed by a patient charity, but the charity has a policy not to receive any funding or financial support whether monetary, in kind or via a third parties from pharmaceutical companies or other commercial organisations. Any events or meetings I attend in relation to my work for the charity are funded by the charity, this includes: |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | | | | registration fees, travel, subsistence and accommodation. 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 specialty, 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. |
| Professor Kevin Moore | | | | | | |
| Professor Celia Moss | None | None | None | None | | I organize an annual course for my department for which I receive no payment other than a fee for each lecture given by me. The course receives sponsorship from a variety of pharmaceutical |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | | | | companies who have no influence over the programme, and course material includes a declaration that the course does not endorse products of those companies. Sponsorship money is paid into a hospital Charitable Trust Fund used to support research, academic activities and staff and patient amenities. Sponsors for the 2018 course were Leo Pharma, Dermal Laboratories, CD Medical, La Roche-Posay, Almirall, Intrpharm Laboratories, Espere Healthcare and Molnlyke.<br>As an invited speaker at the meeting DERMACON 2018 in Kolkata, my travel and accommodation expenses were paid for by the meeting which was |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT | ADDITIONAL INFORMATION |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | | |
| | | | | | | supported by numerous pharmaceutical companies with whom I had no direct contact.<br>I am a medical advisory board member of the Ichthyosis Support Group and the Ectodermal Dysplasia Support Group but I receive no payment from them.<br>My immediate family has no personal or non-personal interests in the pharmaceutical industry. |
| Dr Frances MK Williams | None | None | None | None | | 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 | Astra Zeneca | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | None |
| | | | Chiesi Limited | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |
| | | | EDIXOMED LIMITED | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |
| | | | FairCourt Capital | The commercial company is a sponsor / funder of | Yes | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | | research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | | |
| | | | Fondazione PENTA ONLUS | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |
| | | | GlaxoSmithKline | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |
| | | | Gilead Sciences Ltd. | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | Healthcare Diagnostics Ltd. | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |
| | | | LDN Pharma | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |
| | | | Merck Serono Ltd | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |
| | | | McColl's Retail Group | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of | Yes | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | | which I am generally unaware of the topic) | | |
| | | | Pfizer UK | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |
| | | | QuantuMDX Group Ltd | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |
| Professor David Dockrell | None | None | GSK | Grant Investigating NRF2 agonists in macrophage innate responses in COPD | No | I have participated in Advisory Boards for ViiV on the use of NRTI sparing integrase inhibitor containing antiretroviral regimens in 2018 |
| Dr Andrew Freedman | GILEAD | Invited Lecturer (remunerated) on postgraduate | None | None | | None |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| | | training course in HIV Medicine in Saudi Arabia – programme organised by independent training company, but sponsored by Gilead | | | | |
| | GILEAD | Participated in remunerated Advisory Board | | | | |
| Dr Richard JC Gilson | | | ViiV | My department is a clinical site for trials sponsored by ViiV, who have provided research funds and donated drug to the department (received by UCL and Central and North West London NHS Trust). I am a co-investigator on these studies. | No | None |
| | | | Gilead Sciences | My department is a clinical site for trials sponsored by | No | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | | ViiV, who have provided research funds and donated drug to the department (received by UCL and Central and North West London NHS Foundation Trust). I am a co-investigator on these studies, except for one study, for which I am the local principal investigator. | | |
| | | | Merck | My department is a clinical site for trials sponsored by Merck, who have provided research funds and donated drug to the department (received by Central and North West London NHS Foundation Trust). | No | |
| | | | Janssen | My department is a clinical site for trials sponsored by Merck, who have provided research funds and donated drug to the department (received by Central and North West London NHS Foundation Trust). | No | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | Mylan | My department is a clinical site for a trial funded by the NHS, using a drug purchased from Mylan. My department receives research funds to support this trial, for which I am the local principal investigator (funds paid to Central and North West London NHS Foundation Trust). | No | |
| | | | Glaxo SmithKline | My department is a clinical site for trials sponsored by GSK, who have provided research funds and donated drug to the department (funds paid to Central and North West London NHS Foundation Trust). | No | |
| Dr Richard Hobson<br>Dr Susan Hopkins | None | None | None | None | | None |
| Dr Katie Jeffery | None | None | None | None | | None |
| Professor Martin Lombard | | | | | | |
| Dr Hermione Lyall<br>Professor Kevin Moore | None | None | None | None | | None |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| Dr Matthias Schmid | None | None | None | None | | 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, MSD to help with funding of those meets. |
| Ms Hilary A Shenton | None | None | None | None | | 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 | | None |
| Mrs Claire Bellone | None | None | None | None | | None |
| Professor Philip Hannaford | None | None | None | None | | None |
| Ms Linda Pepper | None | None | None | None | | None |
| Professor Siobhan Quenby | None | None | None | None | | None |
| Dr Clare Spencer | None | None | None | None | | None |
| Ms Julia Louise Tassano-Edgecombe | None | None | None | None | | None |
| Professor Jonathan H Tobias | None | None | None | None | | None |
| Dr Diana Wellesley | None | None | None | None | | None |

# NEUROLOGY, PAIN & 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 | | None |
| Professor Thomas R. E. Barnes | Gedeon Richter | Advisory board member | None | None | | Co-editor of The Maudsley Prescribing Guidelines in Psychiatry, 13th edition 2018 |
| | Newron Pharmaceuticals | Consultancy | | | | Co-head of the Prescribing Observatory for Mental Health, Centre for Quality Improvement, The Royal College of Psychiatrists. |
| Professor Naomi Fineberg | British association for psychopharmacology | Travel expenses for delivering educational masterclasses on treating anxiety disorders | 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 world psychiatric association scientific section on |
| | European College Of Neuropsychopharma-Cology (Ecnp) | Research meetings and symposia touching upon medication related to ocd | Eu Horizon 2020 | Grant supporting research into problematic internet usage | | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | and related psychiatric disorders - travel and subsistence expenses to attend the meetings. | | | | anxiety, ocd and related disorders i work as a medical lead of an nhs england service providing pharmacological treatment for obsessive compulsive disorders. I act as an |
| | Royal College Of Psychiatrists | Invited conference Lecturer; travel Expenses to attend Meeting touching upon Medication related to Ocd and related Psychiatric disorders | Nihr | Research grant, touching upon treatment of ocd | | unpaid medical adviser and trustee to national consumer charities for ocd and related disorders. I chair the world psychiatric association scientific section on anxiety, ocd and related disorders. I have contributed to the british association for psychopharmacology (bap) treatment guidelines for anxiety disorders (2014) and the nice treatment guidelines including the most recent update (2013). |
| | Oxford University Press | Pocketbook obsessive compulsive and related disorders - royalties | | | | |
| | Sun Pharma | Personal: fees and expenses to deliver three day | | | | No personal interests in the pharmaceutical industry are held by my partner or |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | masterclass on anxiety and ocd in india touching upon medication related to ocd and related psychiatric disorders | | | | any adult members of my immediate household.. I have contributed to the british association for 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. |
| | International College Of Neuropsychopharmacology | Invited conference Lecturer; travel Expenses to attend Meeting and symposia touching upon medication related to ocd and related psychiatric disorders | | | | |
| | Taylor And Francis | Personal fees for editorial duties | | | | |
| | International Society For Th Study Of | Registration fees to attend meeting as lecturer | | | | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | Behavioural Addiction | | | | | |
| | Eu Horizon 2020 | Travel Expenses to attend Meetings a nd symposia touching upon medication related to ocd and related psychiatric disorders | | | | |
| Dr David Hunt | None | None | None | None | | None |
| Professor Malcolm R Macleod | None | None | Janssen Pharmaceutica NV | Co-supervise 2 PhD students; 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 2 stage application. In stage 1 academic consortia submit 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 |
| | | | 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 | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | 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 | 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% finding from the EU, with 50% coming in cash or in kind from the EFPIA partners listed above, with total resource of 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 |
| | | | Pfizer Limited | Co-applicants on funded IMI consortium – see additional information | Yes | |
| | | | PsychoGenics Inc. | 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 | |
| | | | Sanofi-Aventis Research and Development | Co-applicants on funded IMI consortium – see additional information | Yes | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | | | | from Janssen. This is described in the application and will be further described in the consortium agreement. |
| Professor John T O'Brien | TauRx | Personal fees for consultancy | None | None | | None |
| | Axon | Personal fees for consultancy | | | | |
| | Eisai | Personal fees for consultancy | | | | |
| | GE Healthcare | Personal fees for consultancy | | | | |
| Dr Waqar Rashid | Roche | Occasional consultancy to advise regarding Multiple sclerosis disease area. Non-promotional. | None | None | | None |
| Dr Fergus Rugg-Gunn | None | None | None | None | | None |
| Dr Aditya Sharma | None | None | None | None | | None |
| Dr Catherine F Stannard | None | None | None | None | | None |
| Professor Christopher Weir | None | None | ReNeuron Ltd | DSMB membership, resulting in income to my department | Yes | None |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | Celgene | DSMB membership, resulting in income to my department | Yes | |
| | | | Eli Lilly | 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 | | None |
| Professor David Bowen | | | CELGENE | My department receives funding for the MEDALLIST clinical trial | No | Throughout 2018 I was a registered Expert at the European Medicines Agency. I participated in a Scientific Advice procedure for a novel AML drug. |
| | | | ASTEX | My department receives funding for the ASTRAL-3 clinical trial | No | I also share a patent for Siglec-9 binding agents. |
| Professor Stephen Devereux | None | None | None | None | | None |
| Dr Hugo Ford | None | None | None | None | | None |
| Dr Chris Gallagher | None | None | None | None | | None |
| Dr Robert Marcus | Roche<br>Gilead | Lecture fees<br>Consultancy | None | None | | None |
| Dr Geoff Shenton | None | None | None | None | | None |
| Professor Angela E Thomas | None | None | Pfizer | Other: travel and accommodation support as speaker at nursing meeting (International Conference on Cancer | No | None |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | | Nursing, Auckland 2018) to which Pfizer had contributed funding. The company had no direct contact with me or control or influence over content of lecture | | |

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

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| Dr Rebecca Mann (Chair) | None | None | None | None | | None |
| Dr Eileen M Baildam | None | None | None | None | | None |
| Mrs Catrin Barker | None | None | None | None | | As Chief Pharmacist at Alder hey Children's NHS FT, I oversee the conduct of clinical research involving Investigational Medicinal products. These studies may be commercial or non-commercial. The pharmacy department do not receive direct payment from any sponsor. All research income is managed and allocated through the Research division |
| Dr Helen Burdett | None | None | None | None | | None |
| Professor J Helen Cross | None | None | GW Pharma | Investigator on studies, advisory board, speaker, all monies to department | No | None |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | Zogenix | Investigator on studies, advisory board, speaker, all monies to department | No | |
| | | | Nutricia | Speaker, all monies to department | No | |
| | | | Vitaflo | Investigator on studies, all monies to department | Yes | |
| | | | Marinius | Investigator on studies, all monies to department | Yes | |
| Professor Steven Cunningham | None | None | Ablynx (SANOFI) Pharmaceuticals | Consultancy with fees paid to the University of Edinburgh | No | None |
| | | | Janssen Pharmaceuticals | Data Safety Monitoring Board with fees paid to the University of Edinburgh | No | |
| | | | Pulmocide | Consultancy with fees paid to the University of Edinburgh | No | |
| | | | ReViral | Consultancy with fees paid to the University of Edinburgh | No | |
| | | | Boehringer Ingelheim | Consultancy with fees paid to the University of Edinburgh | No | |
| | | | Vertex Pharmaceuticals | Consultancy with fees paid to the University of Edinburgh | Yes | |
| Dr Meriel Jenney | None | None | None | None | | None |
| Dr Caroline Jones | None | None | Alexion | PI for registry strudy at Alder Hey Children's Hospital | No | None |
| Professor Nigel Klein | None | None | None | None | | None |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| Dr Rubin Minhas | None | None | None | None | | None |
| Professor Marie-Louise Newell | Crucell BVm a Janssen pharmaceutical company of Johnson&Johnson | Member of the DSMB for phase II trial | None | None | | None |
| Professor Anthony Nunn | None | None | None | None | | I am a registered scientific expert with EMA and a member of the EMA PDCO Formulation Working Group and the EMA 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 |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT | ADDITIONAL INFORMATION |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | | |
| | | | | | | reformulation 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 medicines and pharmacology) - not product specific. |
| Ms Sara Payne | PHG Foundation | Associate (PT) | None | None | | I work as an associate at PHG on general cutting edge health policy issues and workshops |
| Dr Guido Pieles | Canon Medical System | Consultancy | Canon Medical System Ltd | University Collaboration lead researcher | | None |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| Professor Heather M Wallace | None | None | NovaBiotics | Shares (less than 0.01 % of company) | No | None |
| | | | CellProTx | Director | No | |
| | | | Antoxis | Shares (less than 0.1 % of company) | No | |
| Dr Mark Whiting | None | None | None | None | | None |
| Dr Morris Zwi | None | None | None | None | | 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 | Eli Lilly | Research grant to support clinical training fellowships jointly with MRC | Yes | None |
| | | | Novartis | Research grant to support clinical training fellowships jointly with MRC | Yes | |
| | | | Roche | Research grant to support clinical training fellowships jointly with MRC | Yes | |
| | | | UCB Pharma | Research grant to support clinical training fellowships jointly with MRC | Yes | |
| | | | Astra Zeneca | Research grant to support PHD in drug interactions | Yes | |
| | | | BMS (Bristol Myers Squibb ) | Unrestricted educational grant to support UK Pharmacogenetics and Stratified Medicine network open meeting | Yes | |
| Professor Darren Ashcroft | None | None | AbbVie<br>Celgene<br>MedImmune<br>Becton Dickinson | MRC Stratified Medicine<br>Research Grant: Psoriasis Stratification to Optimise Relevant Therapy (PSORT). | Yes | None |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | Novartis<br>GSK/Stiefel<br>Pfizer<br>Qiagen<br>Sanquin<br>Janssen<br>Eli Lilly | Several industry partners making funding contributions | | |
| | | | Leo Foundation<br>Eli Lilly<br>Abbvie<br>Novartis<br>UCB<br>Almiral<br>Celgene | Research grant to support the development of the Global Psoriasis Atlas. | | |
| Professor Ann Daly | None | None | Boehringer Ingelheim Pharmaceuticals | Consultancy managed by Newcastle University | No | None |
| | | | Gedeon Richter/Preglem | Consultancy managed by Newcastle University | Yes | |
| | | | Probiodrug AG | Consultancy managed by Newcastle University | Yes | |
| Professor Ian J Douglas | GlaxoSmith Kline | Shares | GlaxoSmithKline | Methodology research grant | Yes | None |
| Dr Daniel Hawcutt | None | None | None | None | | None |
| Ms Susan Hunneyball | None | None | None | None | | None |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| Professor Simon R J Maxwell | None | None | None | None | | None |
| Dr Karen Miller | None | None | None | None | | None |
| Dr Rupert Payne | None | None | None | None | | I am consultant editor for the journal Prescriber |
| Ms Christine Randall | None | None | None | None | | None |
| Dr Ruben Thanacoody | None | None | None | None | | None |
| Mr Phil Willan | None | None | None | None | | None |

## CHRONIC LIVER DISEASE WORKING GROUP:

Declaration of interest for Chronical Liver Disease Working Group was not collected as the remit of this group is to propose guidelines on the treatment of PBC, PSC and Fatty Liver Disease.

## EMOLLIENT EXPERT GROUP:

Declaration of interest for Emollient Expert Group was not collected as there are many products and MAH's/manufacturers, the topics of this group will be considered generic discussions in terms of products and companies.

## GENTAMICIN 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 John Firth | None | None | AMGEN | Support of renal anaemia service / research and renal mineral and bone disease studies and of renal educational meetings. | No | None |
| | | | ASTELLAS | Support of renal transplantation service / research and of renal educational meetings. | No | |
| | | | GENZYME | Support of renal mineral and bone disease studies and of renal educational meetings. | No | |
| | | | NOVARTIS | Support of renal transplantation service / research and of renal educational meetings. | No | |
| | | | ROCHE | Support of renal transplantation and renal anaemia service / research and renal mineral and bone disease studies and of renal educational meetings. | No | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | SHIRE | Support of renal mineral and bone disease studies and of renal educational meetings. | No | |
| | | | WYETH | Support of renal transplantation service / research and of renal educational meetings. | No | |
| Dr Andrew Freedman | GILEAD | Invited Lecturer (remunerated) on postgraduate training course in HIV Medicine in Saudi Arabia – programme organised by independent training company, but sponsored by Gilead | None | None | | None |
| Professor Jonathan S Friedland | None | None | Astra Zeneca | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of | Yes | None |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | | which I am generally unaware of the topic) | | |
| | | | Chiesi Limited | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |
| | | | EDIXOMED LIMITED | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |
| | | | FairCourt Capital | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |
| | | | Fondazione PENTA ONLUS | The commercial company is a sponsor / funder of research at St. George's, | Yes | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | | University of London which does not involve me (and of which I am generally unaware of the topic) | | |
| | | | GlaxoSmithKline | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |
| | | | Gilead Sciences Ltd. | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |
| | | | Healthcare Diagnostics Ltd. | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | LDN Pharma | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |
| | | | Merck Serono Ltd | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |
| | | | McColl's Retail Group | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |
| | | | Pfizer UK | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of | Yes | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | | which I am generally unaware of the topic) | | |
| | | | QuantuMDX Group Ltd | The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic) | Yes | |
| Dr Patrick Mark | Vifor | Consultancy, Speaker fees | Boehringer Ingelheim | Research grant | Yes | None |
| | Novartis | Speaker fees | AstraZeneca | National Lead for clinical trial (no financial reward) | Yes | |
| | Pfizer | Speaker fees | | | | |
| | Bristol Myers Squibb | Speaker fees | | | | |

## LAXATIVES AD HOC EXPERT 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 | Pfizer | Other: travel and accommodation support as speaker at nursing meeting (International Conference on Cancer Nursing, Auckland 2018) to which Pfizer had contributed funding. The company had no direct contact with me or control or influence over content of lecture | No | None |
| Dr Qamar Abbas | None | None | Teva | I understand that my Medical Director has carried out lectures for Teva, UK for which Hospice received a payment on donation in last 5 years | Yes | I regularly teach on topic of constialion in Pallialive Care but do not receive any payment for that. That teaching could be to community, Hospice and Hospital Community staff and medical and nursing student at hospice. |
| Dr Rachel Bryant-Waugh | None | None | None | None | | None |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| Dr Matthew Cahill | None | None | None | None | | None |
| Ms Anne Cawdron | None | None | None | None | | None |
| Dr Richard Cooper | Boots | I was an employee of The Boots Company as a sales assistant during the period 1987-1990 and then undertook my pre-registration training year placement with the company 1990-1991 for which I was paid the standard pre-registration fee. | None | None | | None |
| Professor Peter Crome | None | None | None | None | | None |
| Ms Zoe Girdis | Boots | Worked for Boots as a Pharmacist from 2001-2008 | None | None | | None |
| Dr Pippa Hugo | None | None | None | None | | I was a member of the NICE Guideline Group for |

| MEMBER | PERSONAL INTERESTS NAME OF COMPANY | PERSONAL INTERESTS NATURE OF INTERESTS | NON-PERSONAL INTERESTS NAME OF COMPANY | NON-PERSONAL INTERESTS NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
|---|---|---|---|---|---|---|
| | | | | | | Eating Disorders in 2004. As part of the review of treatment and management of eating disorders the Group reviewed the evidence with respect to misuse of laxatives in patients with eating disorders. The review did not include a review of specific products. |
| Professor Raymond Playford | Reckitt Benckiser Group Plc Ord | Ordinary shares had been purchased at market rate with value approximately £4,000. Following discussion with MHRA, to prevent any possible conflict of interest I sold | None | None | | I continue as a director and shareholder of two limited companies called Nutritional Bioscience Ltd and RPF Ltd neither of which deals with herbal products or pharmaceutical companies. I am an external consultant and receive consultancy payments as well as funding for research activities from Pantheryx, a US based company that |

| MEMBER | PERSONAL INTERESTS NAME OF COMPANY | PERSONAL INTERESTS NATURE OF INTERESTS | NON-PERSONAL INTERESTS NAME OF COMPANY | NON-PERSONAL INTERESTS NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
|---|---|---|---|---|---|---|
| | | these shares in May 2018 | | | | deals with bovine colostrum but not herbal or pharmaceutical products. |
| Dr Paul Robinson | None | None | None | None | | None |
| Ms June Rogers | None | None | Bladder and Bowel UK | I work as a Specialist Continence Advisor for Bladder and\| Bowel UK, which is part of the charity Disabled Living. Disabled Living receives a number of non specific educational grants to support the work of the charity and has currently received a non specific educational grant from Ferring pharmaceuticals. The charity also hosts a number of educational events throughout the year which are supported by company exhibitions when a range of companies, including Ferring and Reckitt Benckiser have exhibited in the past | Yes | I was a member of the NICE Guideline group re Childhood Constipation in 2010 and the NICE Quality Standard re Childhood Constipation in 2015 |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | Nocturia | I attended a European meeting re Nocturia in 2017 and my travel was sponsored by Ferring Pharmaceuticals | No | |
| Mrs Hilary Shenton | None | None | None | None | | None |
| Dr Caroline Vaughan | None | None | None | None | | None |
| Mr Hadar Zaman | None | None | None | None | | None |
| Dr Natalia Zarate-Lopez | None | None | None | None | | None |

## MEMBERSHIP OF THE RAXONE PATIENT 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 | Weatherden | Advice only | No | My wife is a director of Bioexcel ltd whose clients may include members of the Pharmaceutical Industry.<br>My daughter is a prescribing General Practitioner. |
| Dr Rebecca Mann | None | None | None | None | | None |
| Professor Stuart Ralston | None | None | Abbvie | Department was recruiting centre in clinical trial. I was local PI | No | None |
| | | | Abbvie | Unrestricted grant to support educational event | | |
| | | | Amgen | Department is recruiting centre in clinical trial. I am local PI | Yes | |
| | | | Amgen | Unrestricted grant to support educational event | No | |
| | | | Astra Zeneca | Department is recruiting centre in an observational study of patients with SLE. I am local PI. | Yes | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | Cellgene | Unrestricted grant to support educational event | No | |
| | | | Consilient health | Unrestricted grant to support educational event | No | |
| | | | Eli Lilly | Department was a recruiting centre in a clinical trial. I was local PI | No | |
| | | | Eli Lilly | Eli Lilly have donated Teriparatide for an NIHR supported clinical trial where I am PI. | Yes | |
| | | | Eli Lilly | Department is recruiting centre in an observational study. I am a sub-investigator. | Yes | |
| | | | Internis | Unrestricted grant to support educational event | No | |
| | | | Internis | Unrestricted grant to support educational event | No | |
| | | | Kyowa Kirin | Department is recruiting centre in an observational study of patients with X-linked hypophosphataemic rickets. I am local PI | Yes | |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| | | | Kyowa Kirin & Ultragenyx | Department is recruiting centre in clinical trial. I am local PI | Yes | |
| | | | Pfizer | Unrestricted grant to support educational event | No | |
| | | | Sanofi-Genzyme | Unrestricted grant to support educational event | No | |
| Mrs Madeleine Wang | None | None | None | None | | None |

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

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| Professor Sir Munir Pirmohamed (Chair) | None | None | Eli Lilly | Research grant to support clinical training fellowships jointly with MRC | Yes | None |
| | | | Novartis | Research grant to support clinical training fellowships jointly with MRC | Yes | |
| | | | Roche | Research grant to support clinical training fellowships jointly with MRC | Yes | |
| | | | UCB Pharma | Research grant to support clinical training fellowships jointly with MRC | Yes | |
| | | | Astra Zeneca | Research grant to support PHD in drug interactions | Yes | |
| | | | BMS (Bristol Myers Squibb) | Unrestricted educational grant to support UK Pharmacogenetics and Stratified Medicine network open meeting | Yes | |
| Professor J Helen Cross | None | None | GW Pharma | Investigator on studies, advisory board, speaker, all monies to department | No | None |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | Zogenix | Investigator on studies, advisory board, speaker, all monies to department | No | |
| | | | Nutricia | Speaker, all monies to department | No | |
| | | | Vitaflo | Investigator on studies, all monies to department | Yes | |
| | | | Marinius | Investigator on studies, all monies to department | Yes | |
| Dr Martin Duerden<br>Professor Jayne Lawrence<br>Dr John Paul Leach | None | None | None | None | | None |
| Dr Janine Lynch | None | None | None | None | | None |
| Dr Rebecca Mann | None | None | None | None | | None |
| Dr Karen Miller | None | None | None | None | | None |
| Professor Catherine Nelson-Piercy | Sanofi | I have received travel costs from Sanofi but not in the last 12 months | Sanofi | My department received an educational grant from Sanofi to fund a meeting January 2017 | No | None |
| Professor David G C Owens<br>Ms Clare Pelham | None | None | None | None | | None |
| Dr Fergus Rugg-Gunn | None | None | None | None | | None |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| Professor Philip Smith | None | None | None | None | | I have not personally written on this, but I am co-editor of Practical Neurology which included an editorial and two commentaries on sodium valproate use in women of childbearing age, to coincide with the change in licensing in April 2018 |
| Mrs Madeleine Wang | None | None | None | None | | None |
| Professor Thomas R. E. Barnes | Gedeon Richter | Advisory board member | None | None | | Co-editor of The Maudsley Prescribing Guidelines in Psychiatry, 13th edition 2018 |

## ZEBRAFISH TOXICOLOGY AD HOC EXPERT 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 Alan Boobis (Chair) | GlaxoSmithKline R & D Ltd | Member of Devlopability Advisory Group to provide generic advice on the pre-clinical toxicity testing of candidate human medicines. 09/2010-12/2011 | GlaxoSmithKline/MRC-CASE | studentship on mechanisms of drug-induced mitochondrial toxicity, 2012-2015 (academic supervisor) | No | |
| | GlaxoWellcome | presentations and reviews on the pharmacokinetics and toxicology of inhaled glucocorticoids (e.g. | Imperial College London/GlaxoSmithKline Alliance | Academic Alternative Discovery Initiative, the use of PET imaging to investigate neutrophil activation in smoking, 2007-2008 (co-PI) | No | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | fluticasone), 1996-1998 | | | | |
| | | | Imperial College London/GlaxoSmithKline Alliance | Academic Alternative Discovery Initiative, the development and application of imaging techniques to assess the efficacy of therapeutic intervention in COPD, 2005-2007 (co-PI) | No | |
| | | | Glaxo-Wellcome/BBRC-CASE | studentship on the relationship between inflammation and subsequent fibrosis in the lungs of rabbits, 1995-1998 (academic co-supervisor) | No | |
| | | | Glaxo-Wellcome, Pfizer Central Research and Sanofi Winthrop Ltd | Consortium of pharmaceutical companies including Glaxo-Wellcome, Pfizer Central Research and Sanofi Winthrop Ltd, research support to study the use of human liver samples in the in vitro metabolism of drugs, 1992-1998 | No | |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| Professor Len Levy | None | None | None | None | | None |
| Professor Aldert Piersma | None | None | None | None | | None |
| Professor Marysia Placzek | None | None | None | None | | None |
| Professor Andy Smith | Sanofi | 2004 I gave a talk on the potential and pitfalls of toxicogenomics at a Sanofi away meeting. I had overnight accommodation but no fee. | Fhone-Poulence (later Aventis) | In mid-1990's I had a small grant from Rhone-Poulence (later Aventis) on detecting endocrine disruptors. | No | None |
| Professor Stephen Wilson | None | None | None | None | | None |
| Dr Leo T.M. van der Ven | None | None | None | None | | None |

## EXTERNAL COMMISSION EXPERT ADVISORY PANEL: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| Professor Leon Aarons | Eli Lilly | Consultancy | Astra Zeneca | Studentship | No | None |
| | | | Astra Zeneca | Research Funding | No | |
| | | | Eli Lilly | Studentship | Yes | |
| | | | Roche | Studentship | Yes | |
| Professor Christopher 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. | | | | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT | ADDITIONAL INFORMATION |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | | |
| | Pfizer | Fesoterodine - Meeting participant, lecturer, consultant, advisor. | | | | |
| Professor Peter Clayton | None | None | Ammonnett Pharma LLC (US) | Consultancy – advising on design of clinical trial | Yes | Secretary General of the European Society for Paediatric Endocrinology: Sept 2015 – Oct 2018. ESPE has sponsorship agreements with Pharma (Pfizer, NovoNordisk, Ferring, Lilly, Ipsen, Merck, Sandoz, Alexion, Ultragenix) |
| Dr Thomas Clutton-Brock | None | None | None | None | | None |
| Professor Peter Crome | None | None | None | None | | None |
| Professor Karen Forbes | None | None | None | None | | None |
| Dr Clive Grattan | Novartis | Omalizumab - Fee for | None | None | | None |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | chairing a meeting | | | | |
| Professor Paul Griffiths | None | None | None | None | | None |
| Professor Nedim Hadzic | Alexion | Ad hoc consultancy fees | None | None | | None |
| Professor Freddie Hamdy | None | None | None | None | | None |
| Dr Nigel Hoggard | None | None | None | None | | None |
| Professor David Isenberg | None | None | Astra Zeneca | Consultancy - Honoraria passed onto a local arthiritis charity | No | None |
| | | | 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 | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | | Sanofi | Consultancy - Honoraria passed onto a local arthiritis charity | No | |
| Professor Colin Kennedy | None | None | None | None | | None |
| Professor Karen Luker | None | None | None | None | | None |
| Professor Robert Pickard | None | None | None | None | | None |
| Professor Stephen Powis | None | None | None | None | | None |
| Professor Shakeel Qureshi | Venus Medtech | Venus P-Valve - Consultancy and PI for CE study in Europe | None | None | | None |
| | Numed Inc | Tyshak Balloons - Constulancy | | | | |
| | Occlutech | Variety of Devices, eg | | | | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | 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, 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, |
| | Diurnal | Shares | Angelini | Consultancy fee | No | |
| | Zilico | Shares | AbbVie | Consultancy fee | No | |

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

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | WHETHER CURRENT | ADDITIONAL INFORMATION |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | | |
| | | | | | | 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: Certara, Janssen, Eli Lilly, Merck, Genentech and Takeda. |
| Dr Lindsey Rylah | None | None | None | None | | None |
| Dr Andrew Scarsbrook | None | None | Blue Earth Diagnostics | 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, | | | | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | Speaker Honorarium & Expenses | | | | |
| | Teva | Colistin - Speaker Honorarium & Expenses | | | | |
| | Novartis | Inhaled tombramycin - Speaker Honorarium & Expenses | | | | |
| Professor Paul Stewart | None | None | None | None | | None |
| Professor Gilbert Thompson | Astra Zeneca | Shares | None | None | | None |
| | Glaxo Smith Kline | Shares | | | | |
| | Shire | Shares | | | | |
| Dr David Tuthill | None | None | None | None | | None |
| Dr David Wheeler | Amgen | Speaker fees | AstraZeneca | Fees paid to department for staff training | Yes | None |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | AstraZeneca | Consultancy | | | | |
| | Boehringer Ingelheim | Consultancy | | | | |
| | Kyowa Hakko Kirin | Speaker fees | | | | |
| | Vifor Fresenius | Consultancy | | | | |
| Professor Alistair R W Williams | Bayer | Consultancy - Vilaprisan | None | None | | None |
| | Gegeon Richter | Consultancy - Esmya (ulipristal acetate) | | | | |
| | HRA Pharma | Consultancy - Ulipristal acetate | | | | |
| | ASKA Pharmaceutical Co Ltd | Consultancy - Ulipristal acetate | | | | |
| Professor Sir Nicholas Wright | None | None | None | None | | None |

# OPHTHALMIC EXTERNAL EXPERT PANEL: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| Dr Sajjad Ahmad | 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 | | 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 |

| MEMBER | PERSONAL INTERESTS NAME OF COMPANY | PERSONAL INTERESTS NATURE OF INTERESTS | NON-PERSONAL INTERESTS NAME OF COMPANY | NON-PERSONAL INTERESTS NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
|---|---|---|---|---|---|---|
| | | | | | | 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 | | None |
| Professor Paul N Bishop | Acucela Inc | Optogenetic gene therapy treatment in preclinical development - Consultancy, technology licensed to Acucela Inc through University of Manchester and as an | None | None | | None |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | | inventor have financial interests | | | | |
| | Astra Zeneca | AZD4547 - Consultancy | | | | |
| Professor Baljean Dhillon | | | | | | |
| Ms Cecilia H Fenerty | None | None | None | None | | 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 | | | | |

| MEMBER | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| | NAME OF COMPANY | NATURE OF INTERESTS | NAME OF COMPANY | NATURE OF INTERESTS | WHETHER CURRENT | ADDITIONAL INFORMATION |
| | Bayer | Eylea - Advisory board panels, travel expenses and Investigator-initiated grants | | | | |
| | Novartis | Lucentis - Advisory board panels and travel expenses | | | | |
| Mr Teifion Emlyn James | | | | | | |
| Professor Sir Peng T Khaw | Santen | Speaker fee, advisory board | None | None | | None |
| | National Medical Research Council Singapore | Grant panel | | | | |
| | Novartis | Advisory board & fees | | | | |
| | Alcon | Scientific selection panel | | | | |
| | Valid Insight Interview | Honorarium | | | | |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| | Aerie Pharmaceuticals | Advisory Board | | | | |
| | Radiance Therapeutics | Founder | | | | |
| | Optceutics | Founder | | | | |
| Mr Anthony King | | | | | | |
| Mr Martin McKibbin | | | | | | |
| Mr David P.S. O'Brart | Alcon Inc | Cataract surgery - consultancy fee | Alcon Inc | Cataract surgery - noncommercial research grant | | None |
| | Sooft Italia SPA | Corneal collagen cross linking surgery - consultancy fee | Alcon Inc | Cataract surgery intraocular lens study - noncommercial research grant | | None |
| Professor Sunil Shah | Presbyopia Treatments Ltd | Shares | None | None | | None |
| | The Laser and Lens Network Ltd | Dormont | | | | |
| | The Eye Doctors Ltd | Shares | | | | |
| | SS Laser Consultancy Ltd | Shares | | | | |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| | Visual Entrepreneurs Ltd | Dormont | | | | |
| | Eye-Docs Ltd | Shares | | | | |
| | Allergan | Consultancy | | | | |
| | Shire | Consultancy | | | | |
| Miss Laura Steeples | | | | | | |

## 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 INTEREST | WHETHER CURRENT | ADDITIONAL INFORMATION |
| Prof K Taylor (Chair) | None | | AstraZeneca | Contribution to EPSRC Doctoral Training Centre in own department (until 30:09:18) | No | |
| | | | Boots | Contribution to EPSRC Doctoral Training Centre in own department (until 30:09:18) | No | |
| | | | GlaxoSmithKline | Contribution to EPSRC Doctoral Training Centre in own department (until 30:09:18) | No | |
| | | | Pfizer | Contribution to EPSRC Doctoral Training Centre in own department (until 30:09:18) | No | |
| | | | Quadrant | Contribution to EPSRC Doctoral Training Centre in own department (until 30:09:18) | No | |
| Prof M Almond | GlaxoSmithKline | Salary, Shares (immediate | None | | | |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTEREST** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| | | family member) | | | | |
| Dr J Beaman | Pfizer | Salary, Shares | None | | | |
| Dr A-M Brady | Bayer | Consultancy (specific product) | Biologicals journal | Section Editor (unpaid) | Yes | |
| | AstraZeneca | Shares (immediate family member) | VAC2VAC Working Party | Member (unpaid) | Yes | |
| | GlaxoSmithKline | Shares (immediate family member) | | | | |
| | Vernalis | Shares (immediate family member) | | | | |
| Dr G D Cook | Pfizer | Salary, Shares | None | | | |
| Prof A G Davidson (Vice-Chair) | None | | None | | | |
| Dr A Gleadle | Tesco PLC | Shares | None | | | |
| | AstraZeneca (Medimmune) | Salary (other person) | | | | |
| Dr M G Lee | None | | None | | | |
| Mr R Lowe | None | | None | | | |
| Dr B R Matthews | None | | None | | | |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTEREST** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| Prof J Miller | None | | None | | | |
| Ms S Palser | None | | None | | | |
| Prof M Simmonds | Pharmakos (SEM spin out from University of Cambridge and Royal Botanic Gardens, Kew) | Research funding (non-specific products) | Chase Sun China | Research Grant | No | |
| | | | Tasly China | Research Grant | No | |
| | | | Purapharm, Hong Kong | Research Grant | Yes | |
| Dr R Torano | GlaxoSmithKline | Salary, Shares | None | | | |
| Dr P Varley | AstraZeneca (Medimmune) | Salary, Shares | None | | | |

**Contact for information about these reports:**
**Zhirui Huang**
**MHRA, 10 South Colonnade, Canary Wharf, London E14 4PU**
**020 3080 6060**


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