Human Medicines Regulations 2012 Advisory Bodies

Annual Report 2016

Commission on Human Medicines

British Pharmacopoeia Commission

Medicines & Healthcare products Regulatory Agency

HUMAN MEDICINES REGULATIONS 2012
ADVISORY BODIES ANNUAL REPORT 2016

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Commission on Human Medicines

British Pharmacopoeia Commission

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FOREWORD BY THE PARLIAMENTARY UNDER SECRETARY OF STATE FOR LIFE SCIENCES

It gives me great pleasure to present the Annual Reports for 2016 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 a copy of the code of practice governing conflicts of interest.

On behalf of all Health Ministers I would like to thank the Chairs and Members of both Expert Committees and all those who contribute to their many expert advisory groups and working parties whose professional expertise, commitment and hard work plays a vital role in ensuring that the medicines we take continue to meet the highest standards of safety, quality and efficacy.

Lord O'Shaughnessy

COMMISSION ON HUMAN MEDICINES ANNUAL REPORT 2016

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 11 Expert Advisory Groups (EAGs) that report to the Commission, their remits and membership are listed at **Appendix II**.

4. The Commission warmly congratulates **Professor Martin Gore**, member of the CHM and Chair of the Oncology and Haematology EAG, on receiving a CBE for services to oncology in the Queen's Birthday Honours 2016.

5. The Commission warmly congratulates **Professor Derek Calam**, former member of the CHM, former chair and current member of the Chemistry, Pharmacy and Standards EAG, on receiving a CBE for services to public

health and the regulation of medicines in the Queen's Birthday Honours 2016.

6. The Commission warmly congratulates **Professor Andrew George**, member of the Clinical Trials, Vaccines and Biologicals EAG, on receiving an MBE for services to Research Participants and the Ethical Governance of Clinical Research in the New Year's Honours List 2017.

7. The Commission warmly congratulates **Professor Mary Lumsden**, vice-chair of the Medicines for Women's Health EAG, on receiving an OBE for services to women's health in the New Year's Honours List 2017.

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

Expert Advisory Groups 2016

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

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

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

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

Infection (IEAG)
Chaired by **Professor Jonathan Friedland**

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

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

Oncology and Haematology (OHEAG)
Chaired by **Professor Martin Gore**

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

Patient and Public Engagement (PPEEAG)
Chaired *Pro Tem* by **Mr Phil Willan**

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

Working Groups 2016

Aquiette Ad Hoc Stakeholder Group
Chaired by **Professor Kevin M G Taylor**

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

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

Paracetamol Expert Working Group
Chaired by **Professor Sir Ian V D Weller**

Sildenafil Stakeholder Group
Chaired by **Professor Kevin M G Taylor**

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

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

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

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

THE CODE OF PRACTICE

11. Members of the Commission on Human Medicines and its Expert Advisory Groups are required to comply with a Code of Practice on

Declaration of Interests in the Pharmaceutical Industry. The Code of Practice and Member's Interests are provided later in this document and are also made public at the following linked address on www.gov.uk: Code of Practice for Chairmen and Members of the Commission on Human Medicines, certain Committees and Expert Advisory Groups.

MEETINGS

12. The Commission held 11 meetings during 2016. Two day meetings were held in July and October. One day meetings normally lasted between five and six hours. Meetings were held at the Medicines and Healthcare Products Regulatory Agency, 151 Buckingham Palace Road, London, SW1W 9SZ.

SECRETARIAT

13. 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

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

FIRST CONSIDERATION BY THE COMMISSION

15. The Commission considered and advised on a total of 121 applications for marketing authorisations. The table below shows the outcome for National, Mutual Recognition, Decentralised and Centralised applications for new active substances and abridged applications at first consideration (i.e. before appeals).

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

	Grant advised	Grant not advised
New Active Substances	**7**	**29**
Abridged Applications	**6**	**29**

16. The Commission was extensively involved in applications made through the European Centralised Procedure. The Commission considered 27 new active substances, or new combinations of active substances, via the Centralised Procedure.

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

18. The Commission considered an average of nine applications at each of its 11 meetings in 2016, in addition to clinical trial applications, appeals, reclassifications, pharmacovigilance issues and other matters.

APPEALS

19. The Commission considered a total of three pre-hearings covering five applications. Of these, one pre-hearing covering three applications was approved at the pre-hearing stage, on condition that the product particulars were amended. Two pre-hearings covering two applications were not approved. One of these proceeded to an oral hearing, which took place in January 2017.

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

EXTERNAL STAKEHOLDERS

21. The Commission received the following as observers:

Professor Alan Boyd BSc MB ChB FRSB PFPM
President of the Faculty of Pharmaceutical Medicine

Ms Mandy East
National Coordinator, Anaphylaxis Campaign

Dr Christopher Gale
NIHR Clinical Trials Fellow, Imperial College London Clinical Trials Unit

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

Dr Linda Landells
Associate Director – Technology Appraisals, National Institute for Health and Care Excellence (NICE)

Dr Ailsa Oswald MBChB (Hons) BSc (Hons)
Academic Foundation Doctor

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

Professor Jon Williamson
Professor of Reasoning, Inference and Scientific Method
Department of Philosophy, SECL, University of Kent

CONSIDERATION OF OTHER MATTERS

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

WIDENING ACCESS TO MEDICINES FOR PARAMEDICS AND DIAGNOSTIC RADIOGRAPHERS

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

Following a request from NHS England, Professor Ralston met the Medical Director and Chief Allied Health Professionals in April to discuss

next steps. Participants concluded that the establishment of an ad-hoc group to consider the options for independent prescribing by paramedics and diagnostic radiographers in more detail would be the best approach.

CHM endorsed setting up a CHM led ad-hoc group with additional expertise from the relevant Royal Colleges at their meeting in June. The ad-hoc group have had an initial meeting and further meetings are planned in 2017.

SAFETY OF MARKETED MEDICINES

Sodium valproate and developmental disorders – update on implementation of risk minimisation

24. The Commission advised on the ongoing communications and stakeholder engagement subsequent to the regulatory action taken in 2015 to strengthen warnings about the risks of developmental disorders in children born to mothers who took sodium valproate in pregnancy. The EU wide review which completed in 2014 introduced warnings to the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) about the magnitude and nature of developmental disorders associated with exposure to valproate in pregnancy. Additional risk minimisation measures and subsequent interaction with stakeholders in the UK led to development of a toolkit which comprises a patient card, carton warning and healthcare professional booklets, patient guides and a prescriber checklist. The Commission welcomed the ongoing work that the MHRA was undertaking with the professional bodies, voluntary organisations, Department of Health, NICE and the BNF on this issue and advised on the need to raise levels of awareness of the risks of valproate during pregnancy among GPs and about the action that they should take to ensure patients stable on valproate have regular medication reviews. The Commission considered the initial results of studies under way to monitor the effectiveness of the risk minimisation measures and advised continued close monitoring of the progress following regulatory action, raising patient and healthcare professional awareness and appropriate changes in prescribing to reflect the latest evidence of harms in pregnancy.

Gadolinium containing contrast agents and deposition in brain tissue

25. The Commission considered the evidence on the deposition of gadolinium in brain tissue following exposures to gadolinium-containing contrast agents (GdCAs) in the context of an ongoing EU wide review The Commission advised that that evidence showed that gadolinium accumulated in the brain after repeated exposures to GdCAs, and that there was evidence of a differential risk with the linear agents having the most robust evidence of deposition in brain tissue. The Commission took into account the uncertainties with regard to the form of gadolinium deposited in the brain, the mechanism for crossing the blood-brain barrier

and the potential for adverse clinical consequences. After consideration and discussion, the Commission advised that in view of the greater potential for deposition in brain tissue associated with the linear agents and identified risks across the class:

- the benefit-risk balance was negative for the linear agents Magnevist (gadopentetic acid), Omniscan (gadodiamide), Optimark (gadoversetamide), and Multihance (gadobenic acid); for these agents suspension of the MAs was considered appropriate
- the benefit-risk balance was positive for the liver-specific linear agent Primovist, and for the macrocyclic agents Dotarem (gadoteric acid), Gadovist (gadobutrol), and Prohance (gadoteridol)
- statements to minimise excessive or unnecessary use should be included in the SmPC and PIL for those agents with a positive benefit-risk balance as long as they did not discourage use of those agents where it provided important advantages compared with an unenhanced MRI scan
- further studies to investigate possible mechanisms of the brain deposition and possible clinical effects would be important.

Warfarin and Miconazole Gel – drug Interaction

26. Following a Coroner's Regulation 28 Report to Prevent Future Deaths (PFD) under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013, raising concerns about a suspected drug interaction between miconazole oral gel and warfarin following the death of an elderly female from an intracerebral haemorrhage, the Commission advised that the potential for a drug interaction between miconazole and warfarin was well-established and was referred to in the product information for all miconazole-containing products. Nonetheless, there may be a perception amongst healthcare professionals and patients that an oral gel had only a local effect and would not pose a risk of drug interactions. The Commission advised that there was sufficient evidence to support regulatory action and that the miconazole product information could be improved by making warnings about concurrent use with warfarin more prominent and detailed. An article[1] was published in Drug Safety Update to remind healthcare professionals of the interaction. The Commission advised that consideration should be given to an appropriate warning on the outer carton of miconazole oral gel. In addition, the Commission suggested that the PIL should advise patients to tell their doctor or dentist about other medicines they are taking. The Commission also recommended that further consideration should be given to the legal status of the oral miconazole gel and whether reclassification from a pharmacy (P) to a prescription-only medicine (POM) would be effective in minimising risk.

[1] https://www.gov.uk/drug-safety-update/topical-miconazole-including-oral-gel-reminder-of-potential-for-serious-interactions-with-warfarin

Brimonidine tartrate (Mirvaso) and symptom exacerbation

27. The Commission considered the balance of risks and benefits of brimonidine tartrate (Mirvaso) which is indicated for the symptomatic treatment of facial erythema of rosacea in adult patients, following a number of reports of symptom exacerbation. The Commission advised that while the efficacy of Mirvaso was modest, it was the only topical treatment licensed specifically to treat erythema in rosacea and there was a group of patients who benefited from treatment, and while the reported incidence of symptom exacerbation was high the cases were generally not severe and recovered on stopping treatment. The Commission advised that the balance of risks and benefits of Mirvaso remained positive in its licensed indications and that a gradual dose escalation on treatment initiation was a potentially useful measure in minimising the risk of side effects. An article was published in Drug Safety Update[2].

MEDICINES AVAILABLE WITHOUT PRESCRIPTION

28. The Commission considered three applications for reclassification during the year which were all to reclassify products from Prescription Only (POM) to Pharmacy Only (P) availability. In all three cases the Commission advised against the change in legal status, having been informed by a stakeholder group (see below) in one case which related to a new therapeutic area for pharmacy availability.

Ad Hoc Reclassification Stakeholder Groups

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

    In 2016 two ad hoc stakeholder groups were established and met to consider POM to P reclassification applications and the Commission agreed to proposals to convene one further stakeholder group concerning the reclassification of a POM product within a new therapeutic area for pharmacy availability.

[2] https://www.gov.uk/drug-safety-update/brimonidine-gel-mirvaso-risk-of-exacerbation-of-rosacea

THE COMMISSION'S EXPERT ADVISORY GROUPS (EAGs)

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

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

31. The CDRRAEAG convened once via teleconference in 2016 and provided advice by written correspondence on seven occasions.

32. In February, the EAG provided written comments on an application to extend the indications of a medicine indicated for the treatment of type 2 diabetes mellitus.

33. Also in February, the EAG provided written comments on a medicine for the symptomatic treatment of adult patients with chronic obstructive pulmonary disease, a long-term disease of the airways in the lungs often caused by cigarette smoking.

34. In April, the EAG provided written comments on a safety signal related to a medicine for the treatment of type 2 diabetes mellitus in adults.

35. In May, the EAG provided written comments on an application to extend the indication for a medicine currently indicated for the treatment of type 2 diabetes mellitus in adults when diet and exercise changes alone have not been enough to control blood glucose (sugar).

36. Also in May, the EAG provided written comments on a report from the clinical trial of a medicine for the treatment of chronic thromboembolic pulmonary hypertension (CTEPH) and the pulmonary arterial hypertension (PAH) in adult patients, which is high blood pressure in the blood vessels to, from and within the lungs.

37. In November, the EAG convened via teleconference and made recommendations on a reclassification application concerning a medicine used for the treatment of overactive bladder symptoms.

38. In December, the EAG provided written comments on a medicine used for the treatment of patients with diabetes mellitus who require insulin to control blood glucose.

39. Also in December, the EAG provided written comments on a medicine used for the treatment of steroid sensitive nephrotic syndrome in patients aged between 2 and 18 years, a disease where the kidneys leak too much protein into urine, leading to lower levels of protein in the blood thus causing swelling in the body.

Chemistry, Pharmacy and Standards Expert Advisory Group (CPSEAG)

40. In 2016, the CPSEAG met 10 times and considered and advised on applications for new drugs, abridged applications, variations, written representations, pre-hearings and reclassifications. The EAG also provided advice by written correspondence on seven papers.

41. In January, the EAG provided written comments on the following:

- a medicine indicated for the treatment of Cerebrotendinous xanthomatosis (CTX), a rare condition in which patients cannot produce bile acid (normally produced by the liver from cholesterol, helping digestion and the absorption of fat and vitamins), resulting in a build-up of fatty deposits in various areas of the body and damage to the affected areas
- a medicine to treat Type 2 diabetes mellitus

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

- a medicine to increase appetite in patients with advanced cancer
- a medicine for the prevention and treatment of the bladder, kidney and other parts of the urinary tract
- two medicines indicated to treat thyroid hormone deficiency; produced by a small gland at the base of the neck.

The EAG considered and advised the Commission about a medicine indicated to treat thyroid hormone deficiency.

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

- a medicine indicated for the treatment of hepatitis C virus (HCV) infection in adults
- a medicine indicated for the treatment of severe plaque psoriasis, redness, scaling and thickness of the skin caused by skin cells being produced too quickly
- a medicine indicated for the treatment of renal cell carcinoma, kidney cancer
- a medicine indicated for the treatment of osteoporosis, when bones become thin and fragile, in postmenopausal women
- a medicine indicated for use in combination with other medicines for the treatment of adult patients with acute myeloid leukaemia (AML), cancer of blood forming cells in the bone marrow
- a medicine used to prevent and treat infections of the bladder, kidney and other parts of the urinary tract
- a medicine indicated for the treatment of severe psoriasis and other severe skin disorders where the skin has become thick and may be scaly
- a medicine indicated for contraception.
- a medicine indicated to treat thyroid hormone deficiency

- a medicine for the short-term symptomatic relief of acute sore throat.

The EAG also considered the company's response to questions and advised the Commission on a medicine for the treatment of acute gout, a type of arthritis where crystals of sodium urate form inside and around joints, in adults and familial Mediterranean fever, a hereditary inflammatory disorder, in children.

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

- a medicine indicated for the treatment of chronic hepatitis B in adults
- a medicine indicated for the treatment of low-risk localised prostate cancer
- two medicines indicated to treat various illnesses involving inflammation in the body and a number of different diseases of the immune system
- a medicine for the treatment of pancreatic cancer
- a medicine indicated for the treatment chronic heart failure.

The EAG also considered and made recommendations on:

- parametric release in lieu of sterility testing for nine sterile products.
- bioequivalence requirements for three medicines indicated to treat various illnesses involving inflammation in the body and a number of different diseases of the immune system.

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

- a medicine for the prevention and treatment of fungal infection of the mouth, oesophagus and intestinal tract
- a medicine for the relief of pain and swelling
- a medicine indicated for the local treatment of vaginal dryness in postmenopausal women with vaginal atrophy
- five medicines indicated for the treatment of glaucoma, raised pressure within the eye.

46. In May, the EAG also provided written comments on a medicine used in the treatment of epithelial ovarian cancer.

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

- a medicine indicated to treat advanced renal (kidney) cell cancer (RCC) in adults
- a medicine for use in the treatment of HIV infection

The EAG also considered and made recommendations on the following European Medicines Agency (EMA) Quality Working Party (QWP) documents:

- Draft Reflection paper on the dissolution specification for generic oral immediate release products. http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2016/04/WC500204724.pdf
- Draft Guideline on the sterilisation of the medicinal product, active substance, excipient and primary container. http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2016/04/WC500204724.pdf

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

- a radiopharmaceutical medicine indicated for the treatment of gastroenteropancreatic neuroendocrine tumours
- a medicine for the treatment of and prevention against acute or recurrent, lower urinary tract infections or inflammation of the renal pelvis
- a contraceptive vaginal ring used to prevent pregnancy
- a medicine used for the symptomatic treatment of moderate to severe pain
- a product for use in pre-operative skin disinfection prior to minor surgical procedures
- a product to treat patients with Chronic Lymphocytic Leukaemia (CLL), a type of cancer affecting white blood cells called lymphocytes and the lymph nodes. The product was discussed in the context of the UK Early Access to Medicine Scheme (EAMS).

The EAG also considered and made recommendations on proposed quality data requirements to demonstrate suitability of multidose containers for eye drops without antimicrobial preservatives.

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

- a medicine used in the treatment of adult patients with an enlarged spleen or with symptoms related to myelofibrosis, a rare form of blood cancer
- a medicine used in adults to control the level of potassium in the blood when it is too high

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

- a medicine indicated for the treatment of hepatitis B infection in adults
- a medicine to make mucus (phlegm) less sticky in patients with respiratory tract infections

- a medicine to reduce the amount of thyroid hormones in the thyroid gland
- on the container design for preservative free eye drops, used to treat glaucoma
- the proposed quality data requirements to demonstrate suitability of preservative-free eye drops in multidose containers
- supply of adrenaline auto-injectors to schools for emergency use in the event of one of the pupils having an anaphylactic reaction

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

- a medicine indicated for the treatment of breast cancer in patients with a history of brain metastases
- a medicine for the treatment of eye infections
- a medicine for the prevention and treatment of infections of the bladder, kidney and other parts of the urinary tract
- two medicines for the treatment of serious bacterial infections
- a medicine to relieve pain and inflammation in patients with arthritis and other inflammation in joints
- a medicine for the treatment of certain nasal skin and soft tissue infections
- two medicines for use in the treatment of hay fever and rhinitis
- a medicine used to remove excess iron or aluminium from the blood
- on parametric release in lieu of sterility testing for 24 Marketing Authorisations

In October, the EAG also provided written comments on a medicine indicated for the long term treatment of carcinoid syndrome, a rare cancer of the neuroendocrine system.

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

- a topical medicine indicated to relieve the symptom of pain caused by chronic anal fissures, a tear or open sore (ulcer) that develops in the lining of the anal canal
- a medicine for the treatment of progressive multiple sclerosis (MS), a condition which can affect the brain and/or spinal cord, causing a wide range of potential symptoms, including problems with vision, arm and leg movement, sensation and balance
- a medicine for the treatment of inhaled bacterial infections
- a diagnostic agent for liver assessment in adults under evaluation for liver surgery
- a medicine indicated for the treatment of early stage breast cancer
- a medicine indicated to treat thyroid hormone deficiency
- a medicine used to stop a prolonged, convulsive seizure (fit) in children and adolescents aged 10 to less than 18 years
- an anti-epileptic medicine for the treatment of epilepsy and for controlling and preventing seizures
- a medicine for the treatment of eye infections

- a topical medicine indicated to treat moderate to severe atopic dermatitis (eczema) in adults
- a medicine used to supplement magnesium levels when the level of magnesium in the body is too low
- the in-use shelf life of a medicine used to treat Parkinson's disease.

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

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

- a medicine for the treatment of adult patients with unresectable or metastatic melanoma, a type of skin cancer that has spread to other parts of the body or cannot be removed by surgery
- a medicine indicated to treat hypogonadotrophic hypogonadism (also called secondary hypogonadism), a condition in which the testicles do not produce enough testosterone
- a medicine for the treatment of children aged 2 to 18 years with Steroid Sensitive Nephrotic Syndrome (SSNS), a type of kidney disease
- a medicine indicated for severe forms of acne
- a medicine indicated for the treatment of hypercholesterolaemia (high cholesterol) and prevention of cardiovascular disease
- a medicine for the treatment of serious bacterial infections
- a medicine for the treatment of breast cancer in patients at risk of heart problems; cancer of the ovary and for use in combination with another medicine for Multiple Myeloma, a type of bone marrow cancer

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

- a medicine indicated for the sedation of children between the ages of 2 months and 5 years, under the supervision of a specialist
- a topical treatment indicated to relieve the symptom of pain caused by anal fissures, tears in the skin lining the anal canal.

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

54. The CTBVEAG met seven times in 2016, convened once via teleconference and provided advice by written correspondence on three occasions.

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

- A gene therapy treatment indicated for patients with relapsed or refractory CD19-positive B-cell acute lymphoblastic leukaemia (B-ALL)
- A medicine indicated for the treatment of steroid-resistant acute Graft-versus-Host Disease (GvHD) in adult patients who underwent allogeneic haematopoietic progenitor cell transplantation (HPCT).
- A medicine indicated for controlled ovarian stimulation for the development of multiple follicles in women undergoing assisted reproductive technologies (ART) such as an in vitro fertilisation (IVF) or intracytoplasmic sperm injection (ICSI) cycle.
- A medicine indicated for the treatment of patients with Non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukaemia (CLL), rheumatoid arthritis and granulomatosis with polyangiitis and microscopic polyangiitis combination with glucorticoids.

56. Also in January, the EAG considered and provided advice on a variation application concerning a medicine that may have been affected by a contamination incident.

57. In February, the EAG provided written comments on a treatment of high/risk/relapsed paediatric CD19+ acute lymphoblastic leukaemia, which is a common childhood cancer, and other haematological malignancies.

58. In March, the EAG convened and made recommendation on:

- A medicine indicated for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture. In postmenopausal women, a significant reduction in the incidence of vertebral and non-vertebral fractures but not hip fractures has been demonstrated. Treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at increased risk for fracture.
- A medicine indicated for the treatment of high/risk/relapsed paediatric CD19+ acute lymphoblastic leukaemia and other haematological malignancies.
- A medicine indicated for treatment of pain and anxiety.

59. Also in March, the EAG were briefed with regard to the Zika virus and the role that the EAG might play if clinical trial applications were submitted or scientific advice was requested.

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

- A treatment indicated for advanced solid tumours (post-meeting, the chair of the EAG provided further written comments)

- A medicine indicated for the reduction in duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy.

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

- A medicine indicated for the treatment of pain and anxiety, which had been previously discussed at the EAG's March meeting.
- A medicine indicated for use in adults with metastatic colorectal cancer whose disease has progressed following treatment with oxaliplatin and irinotecan based regimens.
- A medicine indicated in combination with doxorubicin for the treatment of adult patients with advanced soft tissue sarcoma who are not amenable to curative treatment with surgery of radiotherapy and who have not been previously treated with doxorubicin.

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

- A medicine indicated for the treatment of complex perianal fistula(s) in adult patients with non-active/mildly active luminal Crohn's disease, when fistula(s) have shown an inadequate response to at least one conventional or biologic therapy.
- A vaccine indicated for the prevention of dengue disease caused by dengue virus serotypes 1, 2, 3, and 4 in individuals 9 through 60 years of age living in endemic areas.

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

- A medicine indicated for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukaemia (ALL), which had been previously discussed at the EAG's January meeting.
- A medicine indicated for the reduction of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy, which had been previously discussed at the EAG's April meeting.

The EAG also discussed the future of the EAG's membership, highlighting that there were gaps for experts in cellular and advanced gene therapy.

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

- A treatment indicated for adults with relapsed or refractory B-cell precursor acute lymphoblastic leukaemia (ALL)
- A treatment indicated for relapsed CD19+ malignancy

The EAG also provided written comments on a medicine indicated for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, polyarticular juvenile idiopathic arthritis, enthesitis-related arthritis, axial spondyloarthritis, ankylosing spondylitis (AS), axial spondyloarthritis without readiographic evidence of AS, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa (HS), Crohn's disease, paediatric Crohn's disease and ulcerative colitis.

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

- A medicine indicated for the treatment of a variety of metastatic tumour types.
- A medicine indicated for the treatment of multiple myeloma in patients who have relapsed or are intolerant to at least two previous anti-myeloma therapies.
- A medicine indicated for the treatment of direct or indirect factor Za(FXa) inhibitor when reversal of anticoagulation is needed.
- A medicine indicated for the treatment of patients with diabetes mellitus who require insulin for the maintenance of glucose homeostasis.

Also in November, the EAG discussed and made recommendations on a paper concerning two vaccines that had been introduced to the national immunisation programme.

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

66. The GRIDEAG met once during 2016, and provided written comments and advice on five occasions.

67. In March the EAG convened and made recommendations on a medicine for the treatment of psoriasis, a skin condition causing red, flaky, crusty, patches of skin covered with silvery scales.

68. In March the EAG provided written comments on a medicine for the treatment of osteoporosis in postmenopausal women.

69. In March the EAG provided written comments on a medicine proposed for use in the treatment of Crohn's disease, an inflammatory disease of the bowel.

70. In August the EAG provided written comments on a medicine used in adults to control the level of potassium in the blood when it is too high.

71. In September the EAG provided written comments on draft CHMP guidelines on equivalence studies for the demonstration of therapeutic equivalence for products that are locally applied and locally acting in the gastrointestinal tract.

72. In October the EAG provided written comments on a medicine for the treatment of carcinoid syndrome to improve symptom control in adult patients with metastatic neuroendocrine tumours.

Infection Expert Advisory Group (IEAG)

73. In 2016, the IEAG met once via teleconference in July where the EAG considered and advised on one application for a new product. The EAG also provided written comments and advice on five papers.

74. In April, the EAG provided written comments on a medicine indicated for the treatment of chronic hepatitis B in adults.

75. In June, the EAG provided written comments on an issue of manufacturing a medicine in a non-dedicated manufacturing facility.

76. In July, the EAG convened via teleconference and considered and made recommendations on a cream indicated for the cutaneous treatment of impetigo, a highly contagious bacterial skin infection, in adults and children aged 2 months and older.

    Also in July, the EAG provided written comments on a medicine indicated for pre-operative skin disinfection prior to minor surgical procedures.

77. In October, the EAG provided written comments on a medicine indicated for the treatment of community-acquired pneumonia (CAP), anthrax and tularaemia, a rare but highly infectious disease that resides in small mammals.

78. In December, the EAG provided written comments on a paper examining the causal effects of an anti-fungal medicine on pregnant women.

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

79. The MWHEAG met on six occasions during the year, with 5 face to face meetings and 1 teleconference and provided comments by written communication on 4 further occasions.

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

    - the risk of arterial and venous thromboembolism with use of low dose combined hormonal contraception
    - migration of etonogestrel implants away from their site of insertion
    - use of dienogest-containing combined hormonal contraceptives for treatment of acne
    - use of fluconazole during pregnancy.

81. The MWHEAG considered and made recommendations on P availability of a medicine for women.

82. The MWHEAG considered and made recommendations on applications for new medicinal products for controlled ovarian stimulation during assisted reproduction, contraception, vaginal atrophy, osteoporosis, and secondary hypogonadism in men.

Neurology, Pain and Psychiatry Expert Advisory Group (NPPEAG)

83. The NPPEAG met on three occasions during 2016, with two face to face meetings and one teleconference and provided advice by written correspondence on 9 items.

84. In February, the EAG convened and provided recommendations on:

- an application to include a new indication for a medicine, currently indicated for the treatment of Ménière's syndrome, symptoms of which may include vertigo, tinnitus, hearing loss and nausea, to extend the indication to include the symptomatic treatment of vestibular vertigo origin.
- an application to change the indication of a slow release oral morphine sulphate product to the treatment of opioid dependence.
- the relative safety risks of drugs used for the treatment of opioid dependence.

85. Also in February the EAG provided written comments on an assessment of a clinical trial protocol for a medicine for the treatment of symptomatic chronic heart failure with reduced ejection fraction.

86. In March the EAG provided written comments to change the indication of a medicine currently indicated for the prolonged relief of severe and intractable pain.

87. Also in March the EAG provided written comments on safety updates of 3 products for the treatment of multiple sclerosis (MS) of which two products were on the risk of Progressive multifocal leukoencephalopathy (PML) and one on the risks of opportunistic infections and basal cell carcinoma.

88. In August, one neurologist provided written comments on a new medicine for the treatment of multiple sclerosis (MS) (primary and secondary) in adults.

89. Also in August the neurologists provided written comments on a new medicine for the treatment of relapsing remitting multiple sclerosis (RRMS) and primary progressive multiple sclerosis (PPMS) in adults.

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

- a new medicine for the treatment of relapsing remitting multiple sclerosis (RRMS) and primary progressive multiple sclerosis (PPMS) in adults.
- a new medicine for the treatment of schizophrenia in adults.

91. In October, one neurologist provided written comments on a new product for single disease modifying therapy for the treatment of adult patients with highly active relapsing-remitting multiple sclerosis (MS) as defined by clinical or imaging features.

92. Also in October, the neurologists provided written comments on a medicine for the treatment of adult patients with types of blood cancer called mantle cell lymphoma, chronic lymphocytic leukaemia, or Waldenström's macroglobulinaemia and the risk of progressive multifocal leukoencephalopathy (PML).

93. In November, the EAG convened via teleconference and made recommendations on:

- a risk management plan (RMP) for a medicine for the treatment of progressive multiple sclerosis (MS) (primary and secondary) in adults.
- a medicine for the control of tonic-clonic seizures, partial seizures or a combination of these, and the prevention and treatment of seizures occurring during or following neurosurgery and/or severe head injury.
- a medicine for the sedation of children undergoing painless diagnostic imaging procedures within a hospital setting.

94. In December, the EAG provided written comments on a Risk Management Plan for a medicine for the interferon beta item.

95. Also in December the EAG provided written comments on a new product for the treatment of Spinal Muscular Atrophy (SMA).

Oncology and Haematology Expert Advisory Group (OHEAG)

96. In 2016, the OHEAG met on one occasion and convened by teleconference on eight occasions. The EAG also provided written comments on nine papers.

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

- a medicine used to treat non-small cell lung cancer.
- a medicine used to treat advanced renal cell carcinoma (advanced kidney cancer) in adults.

98. In February, the EAG convened by teleconference and made recommendations on the following:

- a medicine indicated for the treatment of anorexia, cachexia or unintended weight loss in adult patients with non-small cell lung cancer (NSCLC).
- a medicine indicated for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.

99. Also in February the EAG provided written comments on the following:

    - a medicine indicated for the treatment of anorexia, cachexia or unintended weight loss in adult patients with non-small cell lung cancer (NSCLC).
    - a medicine indicated for the treatment of chronic lymphocytic leukaemia (CLL), a cancer of a type of white blood cells called lymphocytes.

100. In March the EAG convened by teleconference and made recommendations on the following:
    - a medicine for the treatment of relapsed or refractory acute myeloid leukaemia, a cancer of the blood which forms in cells within the bone marrow.

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

    - a medicine for the treatment of prostate cancer that has not spread to other parts of the body.
    - two medicines for the treatment of cancer within the tubules of the kidney.
    - a medicine for the treatment of tumours of the pancreas.

102. In May the EAG provided written comments on the following:

    - a medicine indicated for the first-line treatment of adults with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).
    - a medicine used to treat two types of blood cancer: chronic lymphocytic leukaemia (CLL) and follicular lymphoma.

103. In June, the EAG convened by teleconference and made recommendations on the following:

    - a medicine for the treatment of advanced renal cell carcinoma, a kidney cancer.
    - a medicine (used in combination with another anti-cancer medicine) for the treatment of adults with advanced soft tissue sarcoma, a malignant disease starting in the soft tissues, such as the muscles, fat or other tissues.

- a variation to a medicine for the treatment for chronic lymphocytic leukaemia (CLL), a type of blood cancer starting from certain white blood cells (lymphocytes) in the bone marrow.

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

- a product for the treatment of classical Hodgkin lymphoma (cHL), a cancer of the lymphatic system. The product was discussed in the context of the Early Access to Medicines Scheme (EAMS).
- a product for the treatment of chronic lymphocytic leukaemia (CLL), a type of cancer originating from certain cells in bone marrow. The product was discussed in the context of the Early Access to Medicines Scheme (EAMS).

105. Also in July, the EAG convened face-to-face and made recommendations on the following:

- a product for the treatment of acute lymphoblastic leukaemia (ALL), a cancer of blood where you have too many white blood cells.
- a product for the treatment of certain tumours (gastroenteropancreatic neuroendocrine tumours), which cannot be completely removed from your body during surgery or have spread to another part of the body.
- a product for the treatment of adult patients with an enlarged spleen or with symptoms related to myelofibrosis, a rare form of blood cancer.

106. In September, the EAG convened by teleconference and made recommendations on the following:

- a product for the treatment of breast cancer in people with a history of cancer cells spreading to the brain.
- a product for the treatment of advanced cancer of the head and neck in adults. The product was discussed in the context of the UK Early Access to Medicine Scheme (EAMS).

107. In October, the EAG convened by teleconference and made recommendations on the following:

- a product for the treatment of breast cancer.
- a variation to a medicine for the prevention of heart damage when certain medicines are used during breast cancer treatment in adults.

108. Also in October, the EAG provided written comments on a medicine indicated for the long-term treatment of a condition called ‘carcinoid

syndrome.' This is when a tumour, called a 'neuroendocrine tumour', releases a hormone called serotonin into your bloodstream.

109. In November the EAG provided written comments on the following:

- a medicine indicated for the treatment of adult patients ≥ 60 years of age with relapsed or refractory acute myeloid leukaemia (AML).
- a medicine indicated in combination with standard induction and consolidation chemotherapy followed by single agent maintenance therapy for adult patients with newly diagnosed acute myeloid leukaemia (AML) who are FLT3 mutation-positive.

110. In December, the EAG convened by teleconference and made recommendations on the following:

- a product for the treatment of adult patients with metastatic melanoma, skin cancer that has spread to other parts of the body.
- a product for the treatment of cancer that affects the bladder and the urinary system, called 'urothelial carcinoma'.

Paediatric Medicines Expert Advisory Group (PMEAG)

111. The Paediatric Medicines Expert Advisory Group (PMEAG) advises the Commission on the safety, quality and efficacy of medicines for paediatric use, including all matters relating to the implementation of the EU Paediatric Regulation. The PMEAG met 6 times in 2016 and provided advice through written correspondence for 10 papers.

Paediatric Investigation Plans

112. PMEAG advises on Paediatric Investigation Plans (PIPs) where UK is Rapporteur or Peer Reviewer. The PMEAG discussed 9 PIPs where the UK is Rapporteur and 6 where UK has acted as Peer Reviewer. In addition, EAG members commented through written procedures for 3 PIPs for which UK was Rapporteur. The advice given covered a range of therapeutic areas, including: oncology, neurology, psychiatry, infectious diseases, rare paediatric conditions and chronic autoimmune syndromes. Finally the PMEAG commented on ongoing regulatory actions with regards to the completed clinical development for a drug treating a rare genetic condition that primarily affects the nervous system of children.

113. The PMEAG reviewed the current status of all ongoing PIPs for antipsychotics, any discontinued development programmes and advised on regulatory actions having arisen from completed PIPs in this therapeutic field.

Work-sharing Procedures

114. The PMEAG considered products being assessed under work-sharing procedures, (coordinated at European level by Member States) for which

the UK was Rapporteur. These included 4 products with studies completed before the Regulation came into force (Article 45 procedure) and 1 product with studies completed afterwards (Article 46 procedure). The therapeutic areas for these procedures included drugs used for infectious diseases, gastrointestinal symptoms and paediatric arthritis.

Marketing Authorisation Applications Supported by Paediatric Data

115. The PMEAG advised on 1 application for a new product and 3 applications to add or extend paediatric use to an existing product. The products covered a range of indications including the treatment of arthritis, Steroid Sensitive Nephrotic Syndrome and hereditary angioedema.

Safety of Medicines in Children

116. In 2016 the PMEAG reviewed monthly statistics on adverse drug reactions in paediatric patients reported to MHRA, and an overview of all identified paediatric signals. They advised on the updated data with regards to an ongoing review of the safety of products for infant teething and for mouth ulcers in children. The PMEAG also considered the risk of seizures associated with the use of high dose of a drug used commonly during paediatric eye examinations and proposed reduction of posology for very young children and a clear warning for the PIL. The EAG advised on potential risks of psychiatric reactions associated with the use of a drug in children for bedwetting. The PMEAG considered the communication strategy and evaluation of outcome which have been developed in relation to informing prescribers of the risk of neurodevelopmental disorders in children from maternal exposure to sodium valproate (see above). The PMEAG advised on the availability of a medicine for the treatment of anaphylaxis in schools in an emergency and also on the minimum label requirements concerning the administration of medicines via feeding tubes.

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

117. Regulatory guidance:
The PMEAG discussed and advised on a number of draft or revised guidance being developed at European or international level. The topics included: the risks associated with the presence of ethanol in medicines and the changes to the warnings in the Patient Information Leaflets (PILs), extrapolation principles for paediatric drug development, investigation of medicinal products in term and preterm neonates, paediatric waiver applications for fixed dose drug combination products in co-morbid cardiovascular disease; collecting and reporting information on the off-label use of medicines as part of routine pharmacovigilance activities, Inventory of paediatric respiratory medicines, collaboration framework with academia and the ICH E11(R1) guideline on clinical investigation of medicinal products in the paediatric population. The

PMEAG commented on the EMA's 10 year Report on the experience acquired as a result of the application of the Paediatric Regulation.

118. Discontinuations of paediatric medicinal products:
In 2016, the PMEAG gave advice on the clinical implications of the proposed discontinuation of 3 medicinal products for children. These included products used for patients with breathing difficulties including wheezing and asthma and the supply of syringes used for the delivery of an oral vitamin product.

Patient and Public Engagement Expert Advisory Group (PPEEAG)

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

Pharmacovigilance Expert Advisory Group (PEAG)

120. The Commission's Pharmacovigilance Expert Advisory Group (PEAG) membership includes expertise in pharmacovigilance, clinical pharmacology, toxicology, epidemiology, general practice, nursing, pharmacy and also includes lay representation.

121. In February 2016 the Commission agreed revised Terms of Reference for the PEAG. These now include an additional responsibility to review and advise MHRA on applications for Type II Yellow Card data, which fall outside of Freedom of Information provisions. This had previously been the responsibility of the Independent Scientific Advisory Committee for MHRA database research (ISAC).

122. The PEAG met on 6 occasions during 2016 (5 face to face meetings and one teleconference) and provided advice by written procedure on a further four occasions. The PEAG considered papers on the following drug safety issues:

- Drug-drug interaction between warfarin and miconazole oral gel leading to serious bleeding events
- Factor VIII products – risk of inhibitor development with recombinant factor VIII products compared to plasma derived factor VIII products
- Direct acting anti-viral medicines for Hepatitis C – risk of Hepatitis B reactivation and hepatocellular carcinoma recurrence
- Riociguat – signal of increased mortality and serious adverse events in patients with pulmonary hypertension associated with idiopathic interstitial pneumonia
- Fluoroquinolone antibiotics and risk of retinal detachment
- Fluoroquinolone antibiotics and risk of aortic dissection and aneurysm
- Fluoroquinolone antibiotics and risk of uveitis

- SSRI and SNRI antidepressants and risk of Autism Spectrum Disorder in children following maternal exposure during pregnancy
- SSRI and SNRI antidepressants and risk of akathisia, aggression or suicide
- Paracetamol – use during pregnancy and neurodevelopmental disorders
- Ingenol mebutate and risk of skin cancer
- Ibrutinib and progressive multifocal leukoencephalopathy (PML)
- Methadone and buprenorphine – relative risk of fatal poisoning

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

124. The PEAG gave advice on 8 Risk Management Plans (RMPs) including one for a new product being considered under the Early Access to Medicines Scheme (EAMS). The PEAG considered preliminary data on the effectiveness of the risk minimisation measures implemented following the 2014 EU-wide review of sodium valproate and the risk of neurodevelopmental disorders in children exposed to sodium valproate during pregnancy. The PEAG also noted the results of a Clinical Practice Research Database (CPRD) study which examined prescribing trends of renin-angiotensin system blockers in the UK following safety advice against concomitant use issued in 2014. In addition to the monthly Yellow Card reporting statistics, and in accordance with its new Terms of Reference the PEAG also reviewed one application for Type II Yellow Card Data.

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

Hormone Pregnancy Tests Expert Working Group

126. The CHM's Expert Working Group (EWG) on Hormone Pregnancy Tests (HPTs) and adverse effects in pregnancy, convened in 2015, met on three occasions in 2016. Having already considered their remit and work plan, and the social, medical and legal context from the time HPTs had been available in the UK (1950s-1970s), in 2016 the Group has focused on the scientific evidence for a possible association. The Group has considered in detail the pharmacology, pharmacokinetic and non-clinical data on the components of Primodos, the most widely used HPT in the UK. Presentations from visiting experts have discussed pre-clinical data, advances in understanding the aetiologies of congenital anomalies, and

advances in data capture in pregnancy. Further meetings to consider additional analyses of ADR data and epidemiological studies, an updated review of historical documentation and lessons learnt are planned for 2017 when the Group is expected to conclude.

Independent Prescribing Ad Hoc Group

127. The IPAHG met in December 2016 to discuss proposals for independent prescribing by paramedics. A second meeting is due to take place in 2017.

Paracetamol Expert Working Group

128. The Ad Hoc Paracetamol Expert Group was reconvened in January and April 2016 to consider the data for an off-label shortened 2-bag regimen for intravenous N-acetylcysteine (NAC) to treat paracetamol overdose published in the Lancet (the Scottish and Newcastle Antiemetic Pre-treatment for paracetamol poisoning (SNAP) study[3]). The Expert Group also reviewed the safety profile of NAC since the CHM's simplified guidance on the treatment of paracetamol overdose was implemented in September 2012. The Expert Group considered all available data, and took evidence and views from invited experts, including the lead author of the SNAP study.

129. The CHM considered the conclusions and recommendations of the Expert Group at its meeting in October 2016. CHM concluded that there was insufficient evidence of efficacy to add information about the off-label shortened 2-bag dose regimen used in the SNAP study to the product information for intravenous NAC. The CHM endorsed the view of the Ad Hoc Expert Group that the pattern of potential adverse drug reactions associated with NAC is well established, and no new safety issues have been identified since the 2012 guidance was implemented, and agreed that the authorised NAC product information reflects the safety profile. The CHM concluded that the benefits of the authorised 3-bag dose regimen continue to outweigh the risks. CHM also agreed that prescribing information for intravenous NAC should be updated to advise that continued treatment with NAC beyond the standard 21 hour treatment may be necessary depending on the clinical evaluation of the individual patient. The CHM advice on this issue was communicated to health professionals in the UK in the January edition of Drug Safety Update[4].

[3] Bateman DN, et al. Reduction of adverse effects from intravenous acetylcysteine treatment for paracetamol poisoning: a randomised controlled trial. Lancet 2014; 383: 697–704.

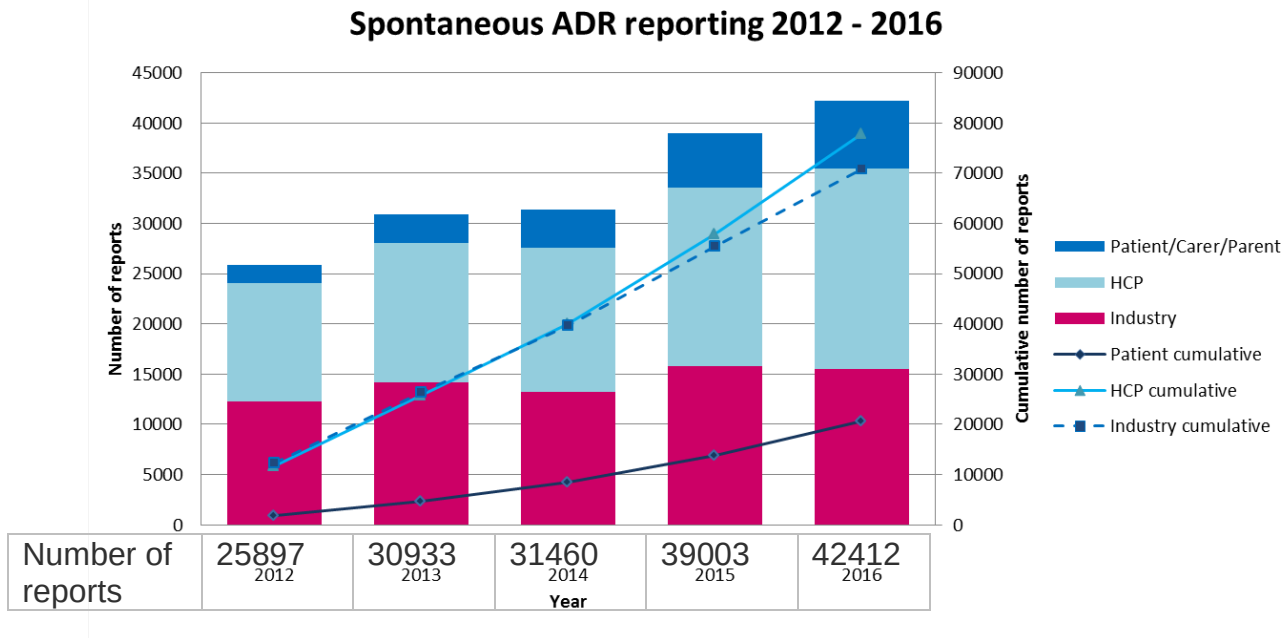
[4] https://www.gov.uk/drug-safety-update/intravenous-n-acetylcysteine-nac-for-paracetamol-overdose-reminder-of-authorised-dose-regimen-possible-need-for-continued-treatment-with-nac.

REPORTING OF SUSPECTED ADVERSE DRUG REACTIONS 2016

130. Suspected Adverse Drug Reactions (ADRs) to medicinal products and vaccines are reported to the CHM and MHRA on a voluntary basis by healthcare professionals, coroners and patients through the Yellow Card Scheme. Reports are also submitted as a legal requirement by pharmaceutical companies holding Marketing Authorisations. Information collected through the Yellow Card Scheme is an important means of monitoring drug safety in clinical practice, acting as an early warning system for the identification of previously unrecognised adverse reactions and increasing knowledge of known ADRs.

131. The total number of UK spontaneous ADR reports received from pharmaceutical companies, healthcare professionals and patients over a five year period between 1 January 2012 and 31 December 2016 is shown in Figure 1. The number of suspected ADR reports has increased by 66% (16,515 reports) over the five year period. Overall the annual number of reports received since 2012 shows an increasing trend, as depicted by the cumulative lines on the graph, with the Scheme receiving its highest ever number, over 42,000 ADR reports, in 2016. The total number of UK spontaneous suspected ADR reports increased by 8% (3,237 reports) in 2016 when compared to the previous year.

Figure 1 – Graph showing the number of UK reports of spontaneous suspected Adverse Drug Reactions received between 2012 and 2016 from industry, healthcare professionals and patients.



132. Of the total number of reports received in 2016, 47% (20,210) of reports were received directly from healthcare professionals, 37% (15,473) from pharmaceutical industry, and 16% (6,729) from members of the public (patients, parents and carers). The number of both patient reports and healthcare professional reports has increased in the past 5 years (Figure

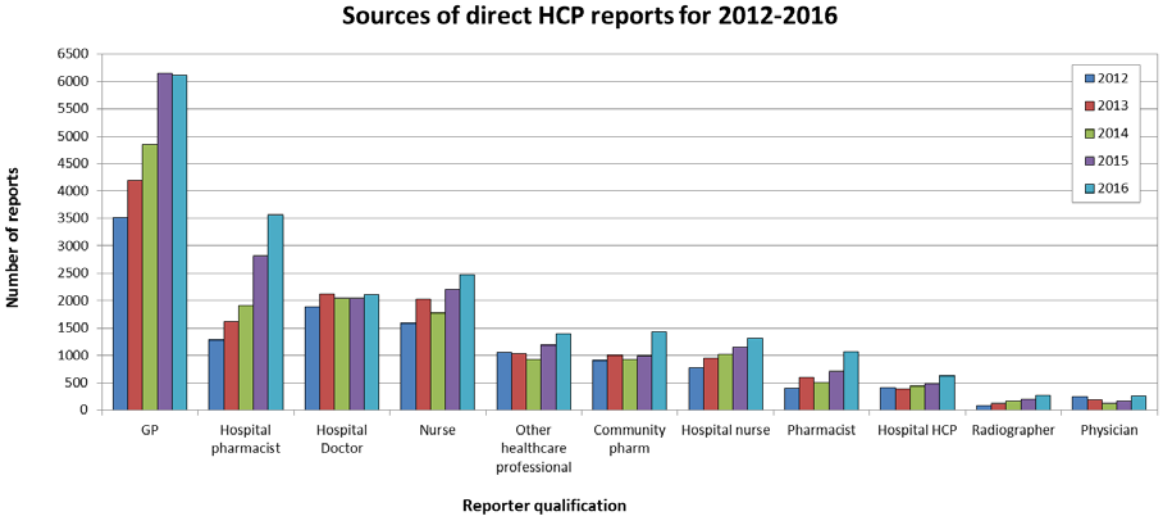
1). This reflects planned strategic efforts to improve the quantity and quality of reports from these groups.

Healthcare Professional ADR Reporting

133. In 2016, building upon the momentum of previous targeted campaigns, the MHRA worked collaboratively with a number of healthcare professional organisations such as medical Royal Colleges to promote Yellow Card reporting to their membership, for example through promotional articles within their organisations' newsletters. A series of quick reference guides, including an infographic, and supporting information for pharmacists was developed with the Royal Pharmaceutical Society. Topics included pharmacovigilance, additional monitoring (the Black Triangle), and the safe and effective use of medicines.

134. A breakdown of direct healthcare professional reports by reporter qualification between 2012 and 2016 is shown in Figure 2.

Figure 2 – Graph showing the number of direct ADR reports received from HCPs between 2012 and 2016 by reporter qualification.
**Other health professionals include: dentists, optometrists, coroners, healthcare assistants, paramedics, chiropodists, medical students and other non-specified health professionals.*



135. GPs continue to be the cornerstone of the Yellow Card Scheme, reporting the highest proportion of all suspected direct healthcare professional reports. The number of reports from GPs in 2016 (6,120) has remained consistent with that received in 2015, representing 30%.

136. In 2016, Yellow Cards completed by hospital pharmacists accounted for the second largest proportion of all direct healthcare professional reports (3,560 reports, 17.5%). It is encouraging to note that the number of

Yellow Cards received from hospital pharmacists has almost tripled between 2012 and 2016. MHRA has worked with MiDataBank to promote pharmacist reporting at the MiDataBank annual conference. Additionally, many of the 464 Medication Safety Officers in hospital trusts are based in hospital pharmacy and champion the Scheme and promote reporting locally.

137. To increase engagement with healthcare professionals and demonstrate greater transparency with regards to the data collected through the Yellow Card Scheme, in October 2016 the MHRA launched interactive Drug Analysis Profiles (iDAPs) which replaced the static Drug Analysis Prints previously available on the MHRA website. The new iDAPs are more clearly displayed and user-friendly than the former static pdf files which were previously published. Each iDAP provides the complete data comprising all spontaneous suspected adverse drug reactions which have been reported to the MHRA for a drug substance. iDAPs enable users to interact with the data in different ways so they can understand more about the types of reactions that have been reported, and the type of patient who has experienced them. DAPs are currently available for 2,150 active substances and over 2,300 visitors viewed the interactive profiles in December 2016 on www.yellowcard.mhra.gov.uk/idap. Feedback received from healthcare professionals as well as members of the public and the pharmaceutical industry has all been positive and users say they appreciate the opportunity to look at the Yellow Card data in which they are particularly interested.

Patient ADR Reporting

138. 2016 saw the highest ever proportion of Yellow Card reports from patients, parents and carers, with 6,729 reports received making up 16% of all direct reports. Overall there has been a 23% increase in patient, parent and carer reports compared to 2015. The MHRA and its 5 Yellow Card Centres have made significant efforts to proactively encourage the reporting of suspected ADRs from this important reporter group via engagement to reach patients through their associations, organisations, consultative forums and patient conferences.

139. Standard wording within patient information leaflets to encourage reporting of any suspected side effects to medicines also contributes to raising awareness of the Scheme. Data taken from our Yellow Card website, “where did you hear about us”, suggests an increase of 58% (from 1,174 reports in 2015 to 1,855 reports in 2016) in those selecting the “Patient Information Leaflet” category as the source of information. This builds upon the foundations of previous campaign and strategic work resulting in messages and information about ADR reporting in trusted places such as patient organisations and health information websites, e.g. NHS Choices.

140. The MHRA led a social media campaign in November 2016 to raise general awareness of the Yellow Card Scheme with the public. The

campaign formed part of the European Commission Joint Action project Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE), and focused specifically on raising awareness of national ADR reporting systems. The campaign was the first of its kind, with 21 Member States taking part. Initial findings for the UK showed that each day more than 72,000 people saw the key messages on a number of social media channels as well as the MHRA and other stakeholder websites. At the centre of the campaign was an animation and supporting infographics to promote ADR reporting that reached nearly 2.6 million people. The animation shows the story of a patient who experiences a suspected adverse reaction when taking a medicine and how reports made by patients or healthcare professionals to the medicines regulator may benefit future patients by making medicines safer.

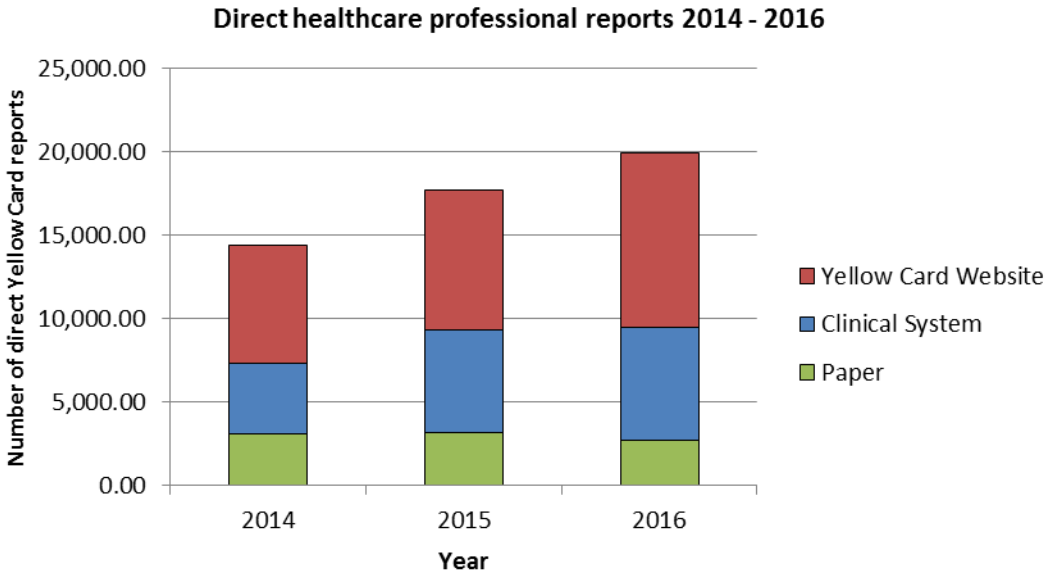
Electronic ADR Reporting

141. The MHRA's strategy to strengthen reporting of ADRs through the Scheme has a strong focus on making reporting convenient to access and easy to use. Over the last 5 years we have seen an increase in overall numbers of reports and within that an increase in the percentage of these reports being received electronically. Several projects are under way to facilitate electronic reporting through integration of Yellow Card into clinical IT systems used by healthcare professionals. The Yellow Card reporting function was incorporated into the GP Systems of Choice (GPSoC) contractual framework in 2012 using an Information Standards Board standard (ISB 1582). It is now mandatory for all GP systems in England to include the capability to report a Yellow Card. Direct electronic reporting from GP IT systems began in 2010 with SystmOne and the same functionality was launched in Vision in England and Wales in 2016. The roll-out in Vision throughout the rest of the UK will continue into 2017 in collaboration with Scottish Health Boards and accompanied by promotional activities.

142. The ISB standard has also been tested throughout 2016 with a number of suppliers outside the primary care setting. Cerner's Millennium system is a clinical IT system for hospitals which first incorporated the Yellow Card function in 2011 at Newcastle NHS Foundation Trust. Cerner have updated their Yellow Card package available in Millennium and this is ready to be released in 2017 across all UK Cerner Trusts. MiDatabank is a clinical system used in Medicines Information Centres and is a further system that has integrated direct electronic Yellow Card reporting, bringing the total of systems with such integrated functionality to four.

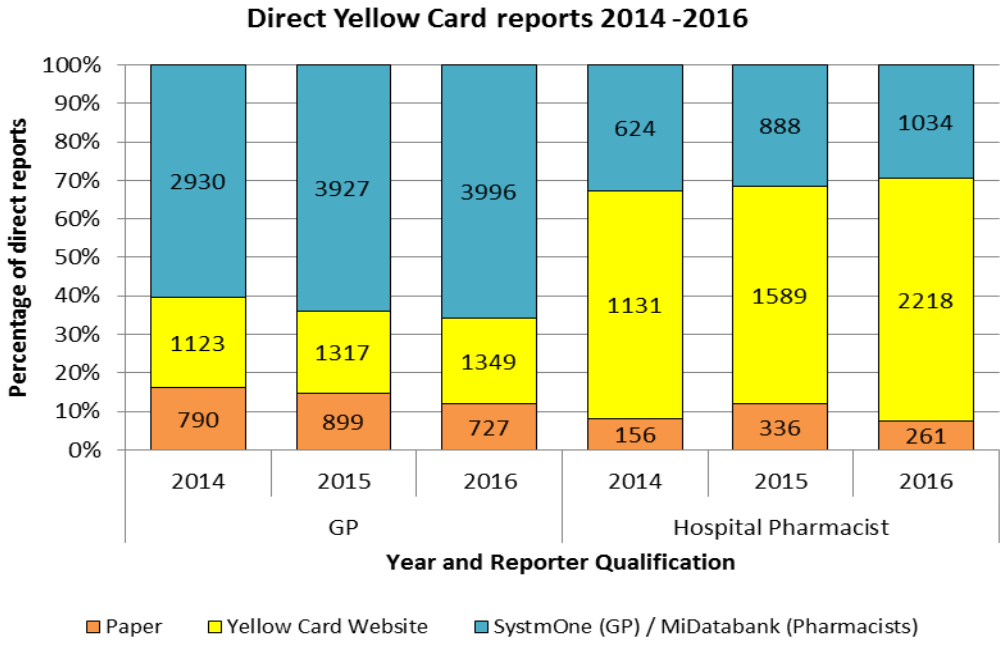
143. Electronic reporting via both the Yellow Card website and clinical systems continues to increase in use amongst healthcare professionals as seen in Figure 3 below.

Figure 3 - Graph showing the breakdown of the 3 main ways in which healthcare professionals reported suspected ADRs directly to the Yellow Card Scheme between 2014 and 2016.



144. In 2016, 86% of all direct healthcare professional reports were received electronically (52% by the Yellow Card website, 34% via clinical systems) and 14% by paper forms (Figure 3). This was an increase compared to 2015, when 82% of reports from healthcare professionals were received electronically. Figure 4 shows the impact of electronic reporting on the number of reports received from GPs and hospital pharmacists from 2014 to 2016; both groups have seen an increasing number of reports from clinical systems over the past 3 years.

Figure 4 - Graph showing the breakdown of Yellow Card reports reported by GPs and hospital pharmacists by reporting method between 2014 and 2016.



145. In 2016, we received 3996 Yellow Card reports from GPs via SystmOne, an increase of 69 reports from 2015. These reports contributed 14.8% of all directly reported Yellow Cards in 2016.

146. The majority of hospital pharmacist reports are electronic, with 29% (1,032 reports) being reported directly from the MiDataBank system used within 128 different Medicines Information Centres, whilst 62% (2,218) were reported through the MHRA's electronic Yellow Card website. Reports via the MHRA's website have increased by 40% compared to 2015, and reports via MiDataBank have increased by 16% compared to 2015.

147. Electronic reporting is also the most popular way of reporting for members of the public; in 2016, the MHRA received 6,729 suspected ADR reports from patients, parent and carers, of which 89% were reported via the online Yellow Card reporting tool.

Use of Mobile Technology

148. The Yellow Card reporting app was launched in 2015 and since then 247 reports have been reported via the app, with 183 reports made in 2016. The app is free to access (available on iOS and Android) and was developed as part of the European Innovative Medicines Initiative WEB-RADR project co-ordinated by MHRA. The Yellow Card app allows patients, carers and healthcare professionals to report directly via their mobile device without using the Yellow Card website or paper forms. Users can also select specific medicines or vaccines to track and receive news and alerts. The app has been downloaded 2,974 times on iOS and 596 times on Android in total. A promotional poster about the app was also provided in 2016 for Yellow Card Centres to raise awareness and to encourage downloads.

E-Cigarette Reporting

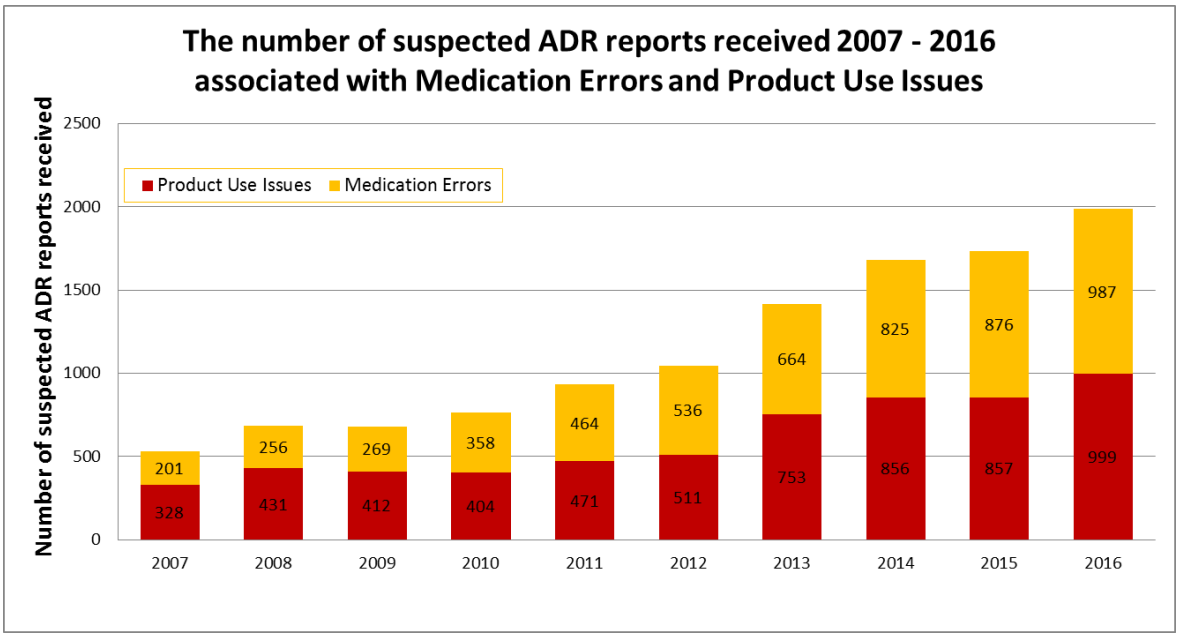
149. In 2016 the MHRA was designated the UK competent authority for the regulation of nicotine containing e-cigarettes and refills under the terms of the Tobacco Products Directive which came into force on the 20th May 2016. A new reporting form on the Yellow Card website was launched for consumers and healthcare professionals to report side effects and safety concerns for these products. Between 20th May and the end of the year we received 15 adverse incident reports and 2 reports of product safety concerns. We have been liaising with Trading Standards authorities to share the reports regarding product device-related safety concerns. With public communications planned in 2017 about reporting Yellow Cards for e-cigarettes, it is anticipated that there will be an increase in the number of reports.

National Medication Safety Network of Medication Safety Officers in England

150. Since 2014 the National Medication Safety Network, operating in conjunction with NHS Improvement, has been in place and is intended as a forum for discussing potential and recognised safety issues and for identifying trends and actions to improve the safe use of medicines. By the end of 2016, the National Medication Safety Network had a total of 464 registered Medication Safety Officers (MSOs) in England. The MSOs encompass nearly all hospital pharmacists, and themselves continue to report as well as encourage reporting within their trusts.

151. The main focus of the network's activity is medication error. Figure 5 shows that the number of UK spontaneous Yellow Card reports received associated with medication errors over a ten year period between 1 January 2007 and 31 December 2016 has steadily increased in line with overall reporting.

Figure 5 – Graph showing the number of UK spontaneous suspected Adverse Drug Reaction reports associated with medication errors received between 2007 and 2016.



152. Data from the National Reporting and Learning System (NRLS) is shared with the MHRA for analysis on a weekly basis. Of the 9,514 reports received between November 2015 – November 2016, 33% (3,173) were valid cases reporting a conventional ADR or harm associated with a medication error. Efforts have been made through the monthly web conferences and communication with the Network to focus on increasing reporting, and improving coding and quality of medication error reports.

153. The 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, online information forums and web events based on regions, clinical specialty or healthcare setting. MHRA is continuing to work with the UK Devolved Administrations (Scotland, Northern Ireland and Wales) to share learnings from this initiative and to promote similar initiatives UK-wide.

154. The MHRA also acknowledges the importance of working with local risk management system suppliers which facilitate reporting to the NRLS. In collaboration, a system supplier Ulysses, which runs the Safeguard Risk Management system present in over 100 health service organisations and trusts, has built Yellow Card reporting as a standalone functionality within their Safeguard dashboard so that suspected ADRs can be reported and sent to MHRA directly. This will be launched for pilot in early 2017 with key reporting sites. The second phase will consist of integrating the Yellow Card fields into the existing medication incident reporting process prior to national roll out. This will ensure all relevant information is requested and captured for pharmacovigilance purposes.

Signal Detection

155. The MHRA signal management system is designed for the timely detection of new and changing drug safety issues. Changes in the frequency of ADRs already known to be associated with drugs are also closely monitored through the signal detection process. The drug-event combinations from Yellow Card reports are assessed on a weekly basis to identify potential safety signals. In 2016, there were a total of 68 validated signals – potential signals that have been identified by a statistical algorithm or from external sources which subsequently require additional detailed investigation and review. Once evaluated, these validated signals result in appropriate regulatory action such as updates to product information, and may also contribute to wider reviews alongside other sources of data. Each signal is prioritised and assigned a timeframe during which a regulatory position on the action required is reached. A breakdown of the signals and assigned priorities is provided in Table 1.

Table 1: Number of signals assessed in 2016

	Signal Priority			
	Top	Increased	Standard	Not prioritised
Number of signals	0	10	57	1

156. In 2016, ADR reports received from members of the public contributed towards 14 signals being detected, including 2 signals which directly stimulated regulatory action. One example of a signal to which members of the public contributed was migration of the Nexplanon implant, which

led to communication to healthcare professionals and an article in Drug Safety Update. Another was the signal of apremilast and suicidal ideation which resulted in updates to product information, healthcare professional communication and a Drug Safety Update.

UK Yellow Card Centres

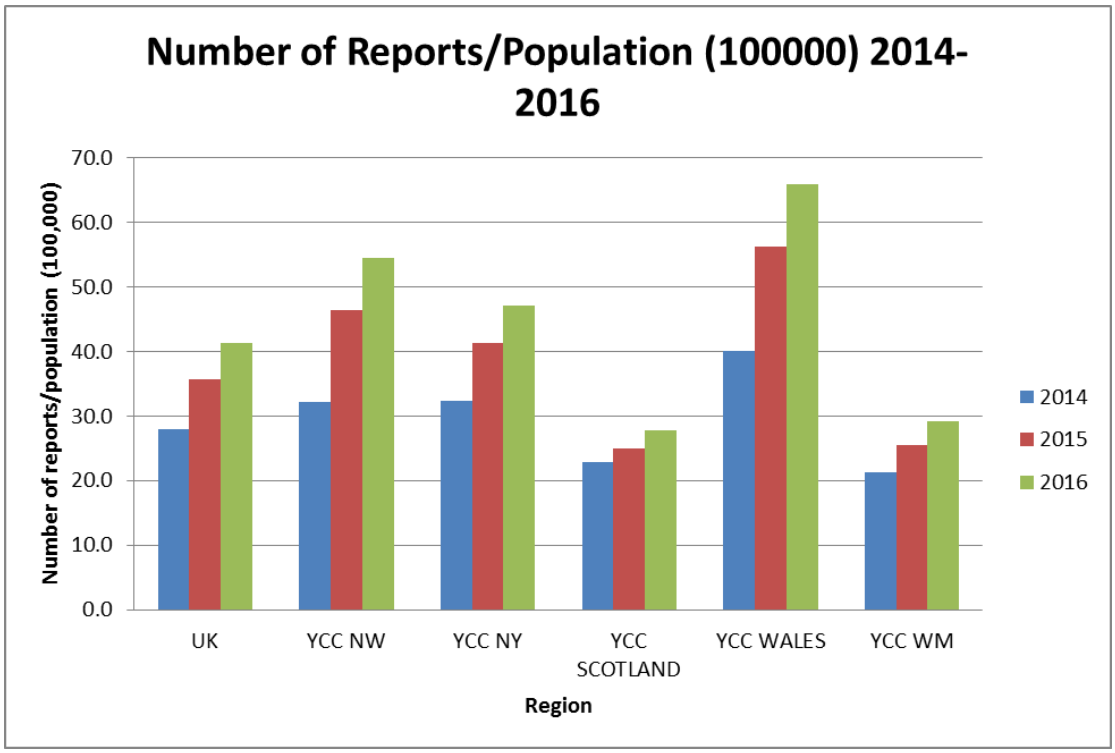
157. The Yellow Card Scheme operates throughout the United Kingdom. To strengthen reporting in certain regional areas, five Yellow Card Centres (YCCs) operate in Wales, the West Midlands, Scotland, Northern & Yorkshire, and the North West. The YCCs undertake valuable work relating to a number of areas including academic research, the promotion of the Yellow Card Scheme, improving ADR reporting through the Yellow Card Scheme and communicating drug safety messages locally.

158. The YCCs are involved in various programmes that aim to increase ADR reporting in their specific region, including the establishment of nominated hospital pharmacists or pharmacy technicians as ‘ADR Champions’. The YCC Wales Champions Scheme, developed in 2013, has continued its success in promoting the Yellow Card Scheme within the hospital sector in 2016. The Wales YCC intends to expand the scheme in 2017 beyond pharmacists to include nurses and doctors as champions. Successful Champions Schemes have also been organised by YCC West Midlands and YCC North West. YCC Scotland are planning to pilot a Champions Scheme in 2017.

159. The YCCs continue to provide valuable educational services for current healthcare professionals, as well as postgraduate and undergraduate students, local charities and support groups.

160. The impact of the YCCs’ efforts can be seen from the reporting rates from these regions in Figure 6. In 2017, 3 YCCs had a higher number of reports per 100,000 people than the UK average (41): Northern & Yorkshire (47), North West (55) and Wales (66). Overall, all YCCs have seen further increases in reporting rates in 2016 and we expect this to continue in 2017.

Figure 6 – Graph showing the number of reports per population for each Yellow Card Centre between 2014 and 2016



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

Appendix I

MEMBERSHIP OF THE COMMISSION ON HUMAN MEDICINES (CHM)

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

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

Dr J Colin Forfar[5] BSc (Hons) MBChB PhD MD MA FRCP FRCP (Edin)
Consultant Physician and Cardiologist, John Radcliffe Hospital, Oxford

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

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 Richard JC Gilson 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

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

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

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

[5] Re-appointed 01/01/2016-31/12/2018

Dr Siraj Misbah[6] MBBS (Hons) MSc FRCP FRCPath
Consultant Clinical Immunologist, Lead for Clinical Immunology, Oxford University Hospitals

Professor David G C Owens[7] MD (Hons) FRCP FRCPsych
Professor of Clinical Psychiatry, Edinburgh University

Professor Sir Munir Pirmohamed[8] 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 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[9] BPharm PhD FRPharmS
Chair of the British Pharmacopoeia Commission and Professor of Clinical Pharmaceutics, UCL School of Pharmacy, London

Professor Angela E Thomas[10] MB BS PhD FRCPE FRCPath FRCPCH **(Vice-Chair)**
Consultant Paediatric Haematologist, Royal Hospital for Sick Children, Edinburgh

Professor Helen M Ward[11] MSc BSc (Hons) RGN RCN Nurse Practitioner PGCEA PG Cert NMP
Associate Professor, Non-Medical Prescribing, London South Bank University

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

Dr Martin Wilson[12] MB ChB, MPhil (Glasgow), FRCP(Edin)
Consultant Physician in Care of the Elderly, Raigmore Hospital, Inverness

[6] Re-appointed 01/07/2016-30/06/2020
[7] Re-appointed 01/01/2016-31/12/2018
[8] Re-appointed 01/01/2016-31/12/2018
[9] Re-appointed 01/01/2016-31/12/2018
[10] Re-appointed 01/01/2016-31/12/2018
[11] Appointed 28/03/2016-27/03/2020
[12] Appointed 28/03/2016-27/03/2020

Invited Experts to Commission Meetings

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

Dr Robert J Boyle MB ChB MRCP PhD
Clinical Senior Lecturer in Paediatric Allergy, Imperial College London

Professor Jamie Coleman MBChB MD MA (Med Ed) FRCP FBPhS
Professor in Clinical Pharmacology and Medical Education, School of Medicine, University of Birmingham

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

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

Prof Wladyslaw M W Gedroyc MBBS MRCP FRCR
Consultant Radiologist, Imperial College Healthcare NHS Trust and Medical Director, Magnetic Resonance Imaging, St Mary's Hospital

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

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

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

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

Professor Anthony G Wilson MB BCH BAO DCH PhD FRCP
Professor of Rheumatology, Medical School, University of Sheffield **(via Teleconference)**

Observers of Commission Meetings

Mr Edson Sinuhé Torres Ballato BSc
Chemist Bacteriologist Parasitologist

Professor Alan Boyd BSc MB ChB FRSB PFPM
President of the Faculty of Pharmaceutical Medicine

Ms Imelda Rocío Guzmán Cervantes BSc, M Eng
Pharmaceutical Chemistry Biologist. Master in Engineering

Ms Mandy East
National Coordinator, Anaphylaxis Campaign

Dr Christopher Gale
NIHR Clinical Trials Fellow, Imperial Clinical Trials Unit

Mr Edgardo Arenas Gasca BA
Economist, Liaison of International Affairs

Ms Marlen Rodriguez Jimenez BSc
Pharmaceutical Chemistry Biologist

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

Dr Linda Landells
Associate Director – Technology Appraisals
National Institute for Health and Care Excellence

Dr Ailsa Oswald MBChB (Hons) BSc (Hons)
Academic Foundation Doctor

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

Ms Claudia Ramirez Torres BSc
Pharmaceutical Chemistry Biologist

Ms Adriana Hernández Trejo BSc
Pharmaceutical Chemistry Biologist

Professor Jon Williamson
Professor of Reasoning, Inference and Scientific Method
Department of Philosophy, SECL, University of Kent

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

Ms Rebecca Blessing
Section Head - Non-Medical Prescribing and General Prescribing Issues, Department of Health

Ms Katy Lindfield
Senior Executive Officer, Disabled and Ill Child Services Team

Ms Patricia Parris
Policy Officer, Disabled and Ill Child Services Team

Mr John Wright
Business Manager, Clinical & Cost Effectiveness, Department of Health

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[13] 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[14] MRCP DM FRCPCH
Consultant Respiratory Paediatrician, Respiratory/Cystic Fibrosis Unit, Children's Hospital for Wales, Cardiff

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

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

Professor Wasim Hanif[15] MD FRCP
Professor of Diabetes & Endocrinology, Head of Service Diabetes, University Hospital Birmingham

Dr Philip W Ind[16] BA Cantab MB BChir MA Cantab FRCP
Consultant Respiratory and General Physician, Adjunct Reader NHLI, Imperial School of Medicine

[13] Re-appointed 01/01/2016-31/12/2018
[14] Re-appointed 12/11/2016-11/11/2018
[15] End of appointment 14 May 2016
[16] Re-appointed 12/11/2016-11/11/2018

Professor Alan G Jardine[17] BSc MD FRCP
Professor of Renal Medicine, University of Glasgow

Dr Patrick Mark[18] MB CHB (Hons) PhD FRCP
Clinical Reader/Honorary Consultant Nephrologist
University of Glasgow/Queen Elizabeth University Hospital, Glasgow

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

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

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

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

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

Professor Sarah Wild[19] 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

[17] End of appointment 11/11/2016
[18] Appointed 08/12/2016-07/12/2020
[19] Appointed 15/07/2016-14/07/2020

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

Members

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

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

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

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

Professor Ruth Duncan[21] 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

[20] Re-appointed 01/01/2016-31/12/2018
[21] Re-appointed 08/12/2016-07/12/2020

Dr Gillian M Hawksworth[22] MBE PhD FFRPS FRPharmS (Hon) DSc
Academic Community Pharmacist, Visiting Fellow at University of Huddersfield & Past President of the RPSGB

Miss Carol E Knott[23] MRPharmS MBA MIHM
Lay Representative. Director of Windcliff Management Ltd

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

Mr Robert Lowe[24] BPharmS MRPharmS
Practising Hospital Pharmacist, Specialist Pharmacy Services - East of England

Professor Christopher Marriott 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[25] 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[26] PhD BSc DSc FRPharmS CChem FRSC FAAPS
Emeritus Professor of Pharmaceutics, Bradford University

[22] Re-appointed 11/11/2016-10/11/2019
[23] Re-appointed 08/12/2016-07/12/2020
[24] Re-appointed 11/11/2016-10/11/2019
[25] Re-appointed 13/02/2016-12/02/2020
[26] Re-appointed 11/11/2016-10/11/2019

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

Remit

To advise the Commission on:

- First time in human (FTIM) studies with new compounds acting (directly or indirectly) via the immune system with a novel target or a novel mechanism of action or having a secondary potential effect on the immune system via a mechanism of action which currently is not well characterised
- FTIM studies with novel compounds acting via a possible or likely species specific mechanism
- Any FTIM studies which are otherwise seen as requiring expert advice
- Other clinical trials involving classes of compound where MHRA may wish to seek external expert advice or CHM may wish to have oversight
- Whether a product's mechanism of action is novel and comes within the scope of the EAG
- Pre-meeting scientific advice documentation for within scope compounds
- Other clinical trials where MHRA may wish to seek advice or where there is a difficult risk benefit balance
- Other clinical trials involving products where a new class safety issue has been identified
- The quality, safety and efficacy of medicinal products of biological or biotechnological origin including vaccines which are the subject of marketing authorisation applications; and to advise on such other matters as are referred to it.

Chair

Professor Angela E Thomas[27] MB BS PhD FRCPE FRCPath FRCPCH
Consultant Paediatric Haematologist, Royal Hospital for Sick Children, Edinburgh

Members

Professor Farzin Farzaneh[28] DPhil FRCPath FRSB
Professor of Molecular Medicine, King's College London
Honorary Consultant in Specialist Medicine, King's College Hospital NHS Trust

[27] Re-appointed 01/01/2016-31/12/2018
[28] Appointed 03/11/2016-02/11/2020

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

Dr Elwyn Griffiths[29] BSc PhD DSc CChem FRSC
Consultant in Biologicals and Vaccines, World Health Organization; Formerly Director General, Biologics and Genetic Therapies Directorate, Health Canada, Ottawa, Canada

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

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

Dr Siraj Misbah[30] MBBS (Hons) MSc FRCP FRCPath
Consultant Clinical Immunologist, Lead for Clinical Immunology, Oxford University Hospitals

Professor B Kevin Park[31] BSc PhD FMedSci FRCP (Hon) FBTS
Director of MRC Centre for Drug Safety Science, Professor of Pharmacology & Head of Institute of Translational Medicine, University of Liverpool

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

Dr Stephen Poole PhD
Consultant: Biological Medicines and Vaccines

Dr Peter F Searle[32] BA PhD
Institute of Clinical Sciences, University of Birmingham

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

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

[29] Re-appointed 06/12/2016-31/12/2017
[30] Re-appointed 01/07/2016-30/06/2020
[31] Re-appointed 19/05/2016-18/05/2018
[32] End of appointment 14/05/2016

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

Remit

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

Chair

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

Members

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

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

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

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

Professor Kevin Moore[33] BSc MB BS PhD FRCP
Professor of Hepatology, Royal Free Hospital, London

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

[33] End of Appointment 13/10/2016

MEMBERSHIP OF THE INFECTION EXPERT ADVISORY GROUP

Remit

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

Chair

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

Members

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

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

Dr Richard JC Gilson MD FRCP
Reader in Sexual Health and HIV and Honorary Consultant 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[34] 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[35] FRCP FRCPath
Consultant Microbiologist (Clinical Lead), Oxford University Hospitals NHS Foundation Trust

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

[34] Re-appointed 24/03/2016-23/03/2019
[35] Appointed 09/09/2016-08/09/2020

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

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

Dr Matthias Schmid[36] MD FRCP DTMH
Consultant Physician & Honorary Clinical Senior Lecturer, Head of Department of Infection & Tropical Medicine, Royal Victoria Infirmary

Ms Hilary A Shenton[37] CPFA
Lay Representative. Retired Secretary to the School of Medicine, University of Sheffield

[36] Appointed 09/09/2016-08/09/2020
[37] Re-appointed 24/03/2016-23/03/2019

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[38] 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

Dr E Jane Dickson[39] MB BChir FSRH
Consultant in Sexual and Reproductive Healthcare Contraception, Sexual Health and Community Gynaecology, Oxleas NHS Foundation Trust

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

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

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

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

Carolyn, Lady Roberts[40] HV Cert MSc DUniv
Member of the Ethox Foundation – Oxford Foundation for Ethics and Communication in Healthcare Practice.

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

[38] Re-appointed 11/04/2016-10/04/2020
[39] Retired 23/09/2016
[40] Retired 31/10/2016

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

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[41] MD (Hons) FRCP FRCPsych
Professor of Clinical Psychiatry, Edinburgh University

Members

Professor Thomas R. E. Barnes[42] MD FRCPsych DSc
Professor of Clinical Psychiatry, Imperial College London

Professor Naomi Fineberg[43] BA Hons MB BS MA MRCPsych
Consultant in General Adult Psychiatry, Hertfordshire Partnership NHS

Dr Anthony L Johnson[44] BSc PhD CStat
Honorary Senior Research Associate, MRC Clinical Trials Unit at University College London

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

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

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

Dr Fergus Rugg-Gunn[45] MB BS MRCP PhD
Consultant Neurologist, National Hospital for Neurology and Neurosurgery, Queen Square, London

[41] Re-appointed 01/01/2016-31/12/2018
[42] Appointed 08/12/2016-07/12/2020
[43] Appointed 08/12/2016-07/12/2020
[44] Re-appointed 14/02/2016-06/10/2017
[45] Appointed 21/01/2016-20/01/2020

Professor Peter A G Sandercock[46] MA DM FRCPE FMedSci
Professor of Medical Neurology and Honorary Consultant Neurologist, University of Edinburgh

Dr Catherine F Stannard[47] MB ChB FRCA FFPMRCA
Consultant in Complex Pain/Pain Transformation Programme Clinical Lead
NHS Gloucestershire CCG, Senior Research Fellowship at the Institute of Psychiatry, Psychology and Neurosciences at King's College London.

Professor Eric A Taylor[48] MA MB FRCP FRCPsych (Hon) FMedSci
Emeritus Professor of Child & Adolescent Psychiatry, King's College London Institute of Psychiatry

Dr Christopher Weir[49] 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

[46] Retired 24/02/2016
[47] Re-appointed 09/12/2016-08/12/2018
[48] End of appointment 12/11/2016
[49] Re-appointed 09/12/2016-08/12/2018

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

Members

Professor Mark D Bower[50] MA MB BChir PhD FRCP FRCPath
Consultant Medical Oncologist, Chelsea & Westminster Hospital, London

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

Dr Hugo Ford[51] 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

Professor Angela E Thomas[52] MB BS PhD FRCPE FRCPath FRCPCH **(Vice Chair)**
Consultant Paediatric Haematologist, Royal Hospital for Sick Children, Edinburgh

Invited Expert

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

[50] Resigned 12/09/2016
[51] Appointed 03/11/2016-02/11/2020
[52] Re-appointed 01/01/2016-31/12/2018

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 BMBS FRCPCH
Consultant Paediatrician, Taunton and Somerset NHS Foundation Trust

Members

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

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

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

Dr Steven Cunningham MBChB PhD FRCPCH FRCP **(Vice Chair)**
Consultant and Honorary Reader in Paediatric Respiratory Medicine, Consultant Paediatric Endocrinologist, UCL Institute of Child Health

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

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

Professor Nigel Klein[53] 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[54] MB ChB MBA
GP Principle

[53] Re-appointed 14/09/2016-13/09/2018
[54] Re-appointed 15/07/2016-14/07/2017

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 Jane Tizard[55] MBBS FRCP FRCPCH
Consultant Paediatric Nephrologist, Bristol Royal Hospital for Children

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

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

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

Mrs Madeleine Wang[56] BA (Hons)
Lay Representative. Patient Advocate

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

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

[55] End of appointment 11/11/2016
[56] End of appointment 11/11/2016

MEMBERSHIP OF THE PATIENT AND PUBLIC ENGAGEMENT EXPERT ADVISORY GROUP

Remit (Under Revision)

To advise the Commission on:

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

Chair *Pro Tem*

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

Members

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

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

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

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

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

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

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

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

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

External Experts

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

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

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

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

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

Members

Dr Robert C G Bracchi[58] BSc MB BCh MD FRCGP
Retired General Practitioner

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

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

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

Professor Alison B Ewing[59] BSc MSc MIPharmM FFRRPS FRPharmS
Clinical Director of Pharmacy, Royal Liverpool and Broadgreen University Hospital NHS Trust; Professor of Pharmacy Innovation, Liverpool John Moores University

[57] Re-appointed 01/01/2016-31/12/2018
[58] End of appointment 11/11/2016
[59] End of appointment 11/11/2016

Ms Amanda Lee[60] RGN RM RNP MSc (NURS) BSc (Hons) Dip HEd PG Cert ANNP
PhD Student & Academic Lecturer Health Professional Studies, University of Hull

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

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

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

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

Ms Christine Randall[61] BPharm MRPharmS
Assistant Director, North West Medicines Information Centre

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

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

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

[60] Re-appointment 24/03/2016-23/03/2017
[61] Appointed 07/10/2016-06/10/2020

THE COMMISSION'S WORKING GROUPS

MEMBERSHIP OF THE AQUIETTE AD HOC STAKEHOLDER GROUP

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

Chair

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

Members

Dr Martin Duerden B Med Sci, DRCOG, Dip Ther, DPH, FRCGP
Member of National Stakeholder Platform, Honorary Senior Research Fellow, Centre for Health Economics and Medicines Evaluation, Bangor University.

Ruth Wakeman FFRPS MRPharmS
Assistant Director of Professional Development and Support, Royal Pharmaceutical Society

Invited Experts

Mrs Anne Cawdron BPharm
Superintendent Pharmacist, Member of Royal Pharmaceutical Society, Independent member of Community Pharmacy West Yorkshire Local Pharmaceutical Committee
Stainland Pharmacy, West Yorkshire

Ms Lilian Ethapemi (TC)
Continence Nurse Specialist, St Charles Centre For Health and Wellbeing

Ms Elaine Hazell
Clinical nurse Specialist, functional Urology.

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

MEMBERSHIP OF THE HORMONE PREGNANCY TESTS WORKING GROUP

Chair

Dr Ailsa Gebbie MB ChB FRCOG FRCPE FFSRH
Consultant Gynaecologist and Director of the Clinical Effectiveness Unit of the Faculty of Sexual and Reproductive Health, Chalmers Centre, Edinburgh

Members

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

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

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

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

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

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

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

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

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

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

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

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

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

Invited Experts

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

Mr Nick Dobrik
Thalidomide Campaigner

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

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

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

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

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

Professor Dr med Christof Schaefer
Pharmakovigilanzzentrum Embryonaltoxikologie, Charité-Universitätsmedizin Berlin

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

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

Visiting Experts

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

Observers

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

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

MEMBERSHIP OF THE INDEPENDENT PRESCRIBING AD HOC GROUP

Chair

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

Members

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

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

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

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

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

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

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

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

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

Dr Raman Uberoi
President of the British Society for Interventional Radiology
Honorary Senior Lecturer and Consultant Interventional Radiologist, John Radcliffe Hospital, Oxford **(second meeting only)**

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

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

MEMBERSHIP OF THE PARACETAMOL EXPERT WORKING GROUP

Chair

Professor Sir Ian V D Weller BSC MBBS MD FRCP (Hon) FRCP (Glas)
Emeritus Professor of Sexually Transmitted Diseases, Research Department of
Infection and Population Health, University College London

Members

Mr Simon Denegri
NIHR National Director for Patients and the Public and Chair, INVOLVE

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

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

Dr Marianne Gillings BPharm(Hons) MBBS MRCP(UK) PGDip(MedTox) FRCEM
Locum Consultant in Emergency Medicine, Gloucestershire Hospitals, NHS Foundation Trust and Member of the Royal College of Emergency Medicine Toxicology Steering Group

Professor Keith Hawton FMedSci, DSc., FRCPsych
Professor of Psychiatry and Consultant Psychiatrist, University of Oxford

Dr Corinne Hayes
Consultant Paediatrician, Royal Devon & Exeter NHS Foundation Trust

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

Dr Rebecca Maxwell MB Bch BAO FRCEM PGDipMedTox
Consultant in Emergency Medicine Editorial Lead, RCFN

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

Mr Jerry Nolan
Head of Nursing Practice, Royal College of Nursing

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

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

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

Carolyn, Lady Roberts HV Cert MSc DUniv
Member of the Ethox Foundation – Oxford Foundation for Ethics and Communication in
Healthcare Practice.

Dr J P Thompson BMedSci MBChB FRCP FBTS FEAPCCT
Clinical Senior Lecturer, Department of Pharmacology, Therapeutics & Toxicology,
Cardiff University, and Director NPIS Cardiff Unit.

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

Invited Experts

Professor Nicholas (Nick) Bateman BSc MBBS MD FRCP FRCPE FBPharmS FBTS FAACT FEAPCCT
Honorary Professor of Clinical Toxicology, University of Edinburgh

Professor Kim Dalhoff MD, DMSc, FEAPCCT
Professor of Clinical Pharmacology (Clinical Toxicology), Department of Clinical Pharmacology, Bispebjerg and Frederiksberg University Hospital

Professor Paul Dargan MB BS FRCPE FACMT FRCP FAACT FEAPCCT FBPhS Professor of Clinical Toxicology, King's College London and Consultant Physician, Guy's and St Thomas' NHS Foundation Trust, London

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

Professor Laurie Prescott MD, FRCPE, FRCP, FFPM, DCPSA, FRSE
Retired Consultant Physician and Emeritus Professor of Clinical Pharmacology, University of Edinburgh

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

DoH Representative

Mrs Gul Root Bsc(Hons) MRPharmS DMS FFPH FRSPH
Principal Pharmaceutical Officer, Department of Health, London

MEMBERSHIP OF THE SILDENAFIL AD HOC STAKEHOLDER GROUP

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

Chair

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

Members

Dr Martin Duerden B Med Sci, DRCOG, Dip Ther, DPH, FRCGP
Member of National Stakeholder Platform, Honorary Senior Research Fellow, Centre for Health Economics and Medicines Evaluation, Bangor University.

Ruth Wakeman FFRPS MRPharmS
Assistant Director of Professional Development and Support, Royal Pharmaceutical Society

Invited Experts

Dr Robert Bracchi BSc MB BCh MD FRCGP
Retired General Practitioner

Ms Karen Briggs
Andrology Clinical Nurse Specialist at Guy's and St Thomas Hospital

Mrs Anne Cawdron BPharm
Superintendent Pharmacist, Member of Royal Pharmaceutical Society, Independent member of Community Pharmacy West Yorkshire Local Pharmaceutical Committee
Stainland Pharmacy, West Yorkshire

Dr David Edwards
GP/Specialist in male and female sexual health. Past President of the British Society for Sexual Medicine.

Ms Sue Thompson
Specialist Urology Nurse Practitioner
Peterborough and Stamford Hospitals NHS Foundation Trust

Mr Hadar Zaman
Lecturer in Pharmacy Practice (University of Bradford)/Community Pharmacist

Appendix III

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

Dermatology

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

Diabetology/Endocrinology

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

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

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

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

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

Nurse

Professor Karen Luker 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

Dr Alison Thomson[62] BSc MSc PhD
Senior Lecturer, Strathclyde Institute of Pharmacy & Biomedical Sciences, University of Strathclyde and Area Pharmacy Specialist, Western Infirmary Glasgow

Radiology/Nuclear Medicine

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

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

[62] Retired 31/12/2016

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

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

Urology

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

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

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

Appendix IV

COMMISSION ON HUMAN MEDICINES/EXPERT ADVISORY GROUPS SECRETARIAT

Commission on Human Medicines (CHM)

Dr K Prasad
Principle Assessor, Licensing

Ms S Morgan
Principal Assessor, Pharmacovigilance

Ms S Singh
Secretary

Ms F Norris
Assistant Secretary

Chemistry, Pharmacy and Standards Expert Advisory Group (CPSEAG)

Dr L A Anderson
Principal Assessor

Ms E Agca
Secretary

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

Dr J Bonnerjea
Principal Assessor, Licensing (Biologicals)

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

Dr P Bryan
Principal Assessor, VRMM

Ms F Norris
Secretary

Pharmacovigilance Expert Advisory Group

Ms C Davies
Principal Assessor

Mr F Huckle
Secretary **(until 31st July 2016)**

Ms N Nolen
Secretary **(from 1st August 2016)**

Appendix V

Glossary of Acronyms and Abbreviations

ABHI: Association of British Healthcare Industries

ABPI: Association of the British Pharmaceutical Industry

ABRHP: Advisory Board on the Registration of Homeopathic Products

ADHD: Attention Deficit Hyperactivity Disorder

ADR: Adverse Drug Reaction

AI: Adverse Incident

AIMDD: Active Implantable Medical Devices Directive

AITS: Adverse Incident Tracking System

ANDPB: Advisory Non-Departmental Public Body

AR: Assessment Report

ALB: Arms Length Body

ARM: Application to Reclassify a Medicine

ASMF: Active Substance Manufacturer

ASPR: Anonymised Single Patient Report

ART: Assisted Reproductive Technology

ATC: Anatomical, Therapeutic, Chemical

AT: Assistive Technology

ATE: Arterial Thromboembolic Events

BAN: British Approved Names.

BCPNN: Bayesian Confidence Propagation Neural Network

BGMA: British Generic Manufacturers Association

BHMA: British Herbal Medicines Association

BIR: British Institute of Radiology

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

BMA: British Medical Association

BNF: British National Formulary

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

BP: British Pharmacopoeia

BPC: British Pharmacopoeia Commission

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

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

BSE: Bovine Spongiform Encephalopathy

BSI: British Standards Institution

BVEAG: Biologicals and Vaccines Expert Advisory Group

CA: Competent Authority

CAS: Current Awareness Service

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

CCG: Clinical Commissioning Group

CD: Controlled Drug

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

CDF: Competence Development Framework

CDRH: The Centre for Devices and Radiological Health

CE(O): Chief Executive (Officer)

CE MARK: European mark of approval for medical devices.

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

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

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

CFC: Chlorofluorocarbons

CHM: Commission on Human Medicines

CHMP: Committee for Medicinal Products for Human Use

CI: Confidence Interval

CIOMS: Council for International Organisations of Medical Sciences

CJD: Creutzfeldt-Jakob Disease

CLIN: Clinical Devices division of the MHRA

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

CMS: Concerned Member State

COMMS: Communications division of the MHRA

COPD: Chronic Obstructive Pulmonary Disease

CP: Chinese Pharmacopoeia

CPD: Continuing Professional Development

CPRD: Clinical Practice Research Datalink

CPSEAG: Chemistry, Pharmacy and Standards Expert Advisory Group

CQC: Care Quality Commission

CR: Computed Radiology

CSD: Committee on the Safety of Devices

CT: Computed tomography

CTA: Clinical Trial Authorisation

CTD: Clinical Trials Directive

CTD: Common Technical Document

CTEAG: Clinical Trials Expert Advisory Group

CVMP: Committee for Veterinary Medicinal Products

DA: Designating Authority

DAE: Discontinuation due to Asthma-related Event

DAP: Drug Analysis Print

DB: Device Bulletin

DCP: De-Centralised Procedure

DDL: Dear Doctor Letter

DDPS: Detailed Description of Pharmacovigilance System

DDX: Doctors and Dentist exemptions

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

DG: Directorate General [of the European Commission]

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

DH: Department of Health

DIRC: Departmental Industrial Relations Council

DMF: Drug Master File

DMRC: Defective Medicines Report Centre

DR: Digital Radiology

DSMB: Data and Safety and Monitoring Board

DSRU: Drug Safety Research Unit

DSU: Drug Safety Update

DTS: Device Technology & Safety division of the MHRA

E2B: Data elements for individual case safety reports.

EAG: Expert Advisory Group

EBGM: Empirical Bayes Geometric Mean

EC: *see EU*

ECG: Electrocardiogram

ECPHIN: European Community Pharmaceutical Information Network

eCTD: Electronic Common Technical Document

EDQM: European Directorate for the Quality of Medicines & Healthcare

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

EFTA: European Free Trade Association

EFPIA: European Federation of Pharmaceutical Industries Associations

EFQM: European Foundation for Quality Management

EHTPA: European Herbal and Traditional Medicine Practitioners Association

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

EMA: European Medicines Agency

EP: European Pharmacopoeia

EPAR: European Public Assessment Report for medicines

EPID: Extended (also Expanded) Public Information Document

EQA: European Quality Award (see also EFQM)

ERA: European Regulatory Affairs

ETSI: European Telecommunications Standards Institute

EU: European Union

EUDRA: European Union Drug Regulatory Authorities

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

EudraGMP: The community database containing information on all pharmaceutical manufacturers.

EUDRALEX: Web server for the on-line dissemination of community guidelines, notice to applicants and pharmaceutical legislation.

EUDRALINK: As EudraNet II can only be accessed and used by the national competent authorities, the EudraLink secure communication service has been developed to allow secure information exchange between the pharmaceutical industry, research institutes and pharmaceutical experts via the public internet.

EUDRAMAIL: A dedicated secure e-mail system based on functional mailboxes, which allows working groups to exchange messages relevant to their specific group.

EUDRANET: A European human and veterinary pharmaceuticals telecommunication network allowing scientific experts, those working on pharmaceutical business processes and policy makers to have a secure and well structured electronic environment to ‘meet’, exchange information and work together on a pan-European scale.

EUDRANET II: A managed virtual private IP network (IP VPN) based on encrypted tunnels over the public internet.

EUDRAPHARM: The central European database providing core data on all centrally authorised medicinal products, including maximum residual limits for veterinary medicinal products and nationally authorised products from Member States ready to supply data as part of a pilot exercise.

EUDRAPORTAL: The central entry point for all the Eudra applications

EUDRATRACK: A tracking and communication system for mutual recognition and decentralised applications for Member States.

EudraVigilance: A data processing network and management system for reporting and evaluating suspected adverse reactions during development and following the marketing authorisation of medicinal products in the European Economic Area (EEA).

EURD list: The list of European Union reference dates and frequency of submission of PSURs

EVMPD: EudraVigilance Medicinal Product Dictionary

EWP: Efficacy Working Party

FARAW: Fairness & Respect at Work

FDA: Food and Drug Administration

FIN: Finance division of the MHRA

FOI: Freedom of Information

FTCM: Federation of Traditional Chinese Medicines

FVAR: Final Variation Assessment Report

GBS Guillain-Barre Syndrome

GCP: Good Clinical Practice

GDP: Good Distribution Practice

GHTF: Global Harmonisation Task Force

GLP: Good Laboratory Practice

GLPMA: Good Laboratory Practice Monitoring Authority

GMDN: Global Medical Device Nomenclature

GMO: Genetically Modified Organism

GMP: Good Manufacturing Practice

GMPLA: Good Manufacturing Practice Licensing Authority

GVP: Good pharmacovigilance Practices - *see also GPvP*

GP: General Practitioner

GPRD: General Practice Research Database

GPvP: Good Pharmacovigilance Practice

GRIDEAG: Gastroenterology, Rheumatology, Immunology & Dermatology Expert Advisory Group

GSI: Government Secure Intranet

GSL: General Sales List

GxP: General abbreviation for Good Practice standards.

HCPC: Health and Care Professions Council

Herbal highs: Products that mimic, or claim to mimic, the effects of controlled drugs

HFMA: Health Food Manufacturers' Association

HLGT: High Level Group Term - part of the Medical Dictionary for Drug Regulatory Affairs (MedDRA) terminology

HLT: High Level Term - part of the Medical Dictionary for Drug Regulatory Affairs (MedDRA) terminology

HMAC: Herbal Medicines Advisory Committee

HMPC: European committee on Herbal Medicinal Products

HMR: Human Medicines Regulations

HPV Human Papillomavirus

HRT: Hormone Replacement Therapy

HSE: Health & Safety Executive

HTA: Human Tissue Authority/Act

I&AC: Imaging and Acute Care

IB: Investigator's Brochure - compilation of clinical and non-clinical data on the investigational product

ICES: Integrating Community Equipment Services

ICH: International Conference on Harmonisation

ICNIRP: International Commission on Non-Ionising Radiation Protection

ICS: Inhaled Corticosteroids

ICSR: Individual Case Safety Report

ICT: Information and Communications Technology

IEC: International Electrotechnical Commission

IEPS: Inspections, Enforcement and Standards Division of the MHRA

IM: Intramuscular

IMD: Information Management Division of the MHRA

IMP: Investigational Medicinal Products

ImPACT: Imaging Performance Assessment of CT scanners

IMS: Information Management Strategy

INN: International Non-proprietary Name

INR: International Normalised Ratio

IP: International and Parliamentary function

IP: Intra-peritoneal or Intra-pleural

IPEM: Institute of Physics and Engineering in Medicine

IPU: Information Processing Unit

IRAS: Integrated Research Application System

IRC: Industrial Relations Council

IRG: Independent Review Group on silicone gel breast implants

IR (ME) R: Ionising Radiation (Medical Exposure) Regulations

IRR: Ionising Radiation Regulations

IVDMDD: In Vitro Diagnostic Medical Device Directive

ISAC: Independent Scientific Advisory Committee [for MHRA database Research]

ISBN: International Standard Book Number

ISO 9000: A series of international standards for quality systems.

ITT: Intention To Treat

ITU: Intensive Therapy (care) Unit

IU: International Unit (or UI)

IU (C) D: IntraUterine (Contraceptive) Device

IVD: In Vitro Diagnostic Medical Device

IT: Information Technology

IV: Intravenous

LA: Licensing Authority

LABA: Long Acting β2 Agonist

LFT: Liver Function Test

LGC: Laboratory at Teddington - formerly the Laboratory of the Government Chemist, now an independent chemical analysis laboratory.

LibCat: The MHRA library catalogue providing access to the holdings of the MHRA and the Department of Health.

LLT: Low Level Term - part of the Medical Dictionary for Drug Regulatory Affairs (MedDRA) terminology.

LOCF: Last Observation Carried Forward

MA: Marketing Authorisation

MAA: Marketing Authorisation Application

MAC: Microbiology Advisory Committee

MAH: Marketing Authorisation Holder

MDA: Medical Devices Agency - merged with the Medicines Control Agency in 2003 to become the MHRA

MDA: Medical Device Alert

MDD: Medical Devices Directive

MDR: Medical Device Reporting or Medical Device Regulations (SI 2002/618 and 2003/1697)

MDLO: Medical Device Liaison Officer

MEDDRA: Medical Dictionary for Drug Regulatory Affairs

MedDRA: Medical Dictionary for Regulatory Activities

MGPS: Multi-item Gamma Poisson Shrinker

MEDS: Management of Electronic Document Strategy

MHRA: Medicines and Healthcare products Regulatory Agency

MISG: Ministerial Industry Strategy Group

ML: Manufacturer’s Licence

MLWP: The Working Party on Community Monographs and Community List

MLX: Consultative letters sent out by the MHRA to interested parties when considering proposals to amend orders and regulations made under the Medicines Act

MORE: Manufacture's On-line Reporting Environment

MR: Mutual Recognition

MRA: Mutual Recognition Agreement

MRI: Magnetic Resonance Imaging

MS: Member State [of the European Union (EU)]

MTL: Medicines Testing Laboratory - formerly the Laboratory of the Government Chemist at Teddington, Middlesex.

MTS: Medicines Testing Scheme

Mutual Recognition: Part of the EU licensing system aimed at facilitating access to a single market using the principle of mutual recognition

MWHEAG: Medicines for Women's Health Expert Advisory Group

NAHS: National Association of Health Stores

NAO: National Audit Office

NAS: New Active Substance

NB: Notified Body

NBOG: Notified Body Operations Group

NCAS: National Clinical Assessment Service

NCE: New Chemical Entity

NEL: No Effect Level - now replaced by NOAEL or NOEL

NHS: National Health Service

NIBSC: National Institute for Biological Standards and Control

NICE: National Institute for Health and Care Excellence

NIGB: National Information Governance Board [for Health and Social

Care]

HIHR: National Institute for Health Research

NOAEL: No Observed Adverse Effect Level

NOEL: No Observed Effect Level

NOP: Non-Orthodox Practitioner

NOS: Not Otherwise Specified

NPPEAG: Neurology, Pain and Psychiatry Expert Advisory Group

NRLS: National Reporting and Learning System

NRPB: National Radiological Protection Board

NUI: Non-Urgent request for Information

OH: Occupational Health

OHEAG: Oncology and Haematology Expert Advisory Group

OG: Open Government

OGD: Other Government Department

OIS: The Department of Health's IT system.

Orange guide: Alternative title for the 'Rules and Guidance for Pharmaceutical Manufacturers and Distributors'

Orphan drug: A drug for a rare disease

OTC: Over-The-Counter [product]

P (Medicine): Pharmacy medicine

P-value: The probability (ranging from 0 to 1) that the result in a study could have occurred by chance.

P&CC: Patient and Client Council [for Assistive Technology (AT)]

PA: Persons Appointed

PACS: Picture Archiving and Communications Systems

PACSnet: Picture Archiving and Communications Systems National Evaluation Team

PAGB: Proprietary Association of Great Britain

PAR: Public Assessment Report

Parallel import: A pharmaceutical product therapeutically equivalent to an existing licensed UK product and licensed in the UK in accordance with the rules of the parallel import scheme

PCT: Primary Care Trust

PCS: Public and Commercial Services Union

PDA: Performance and Development Agreement

PDCO: European Paediatric Committee

PDP: Personal Development Plan

PEAG: Pharmacovigilance Expert Advisory Group

PEG: Paediatric Expert Group

PEM: Prescription Event Monitoring

PET: Positron Emission Tomography

PET/CT: Positron Emission Tomography (PET) and Computerised Tomography (CT)

PGD: Patient Group Directions

Pharmacopoeia: A compendium of standards for pharmaceutical or chemical substances.

Ph. Eur.: European Pharmacopoeia

PhVWP: Pharmacovigilance Working Party

PHE: Public Health England

PI: Principal Investigator

PIC: Pharmaceutical Inspection Convention

PICS: Pharmaceutical Inspection Co-operation Scheme

PIEAG: Patient Information Expert Advisory Group

PIL: Patient Information Leaflet

PIP: Paediatric Investigation Plan

PIQ: Patient Information Quality

PK: Pharmacokinetic(s)

PL: Product Licence

PLAT: Product Licensing Assessment Teams

PL(PI): Product Licence (Parallel Import)

PLR: Product Licence of Right

PMDD: Premenstrual Dysphoric Disorder

PMEAG: Paediatric Medicines Expert Advisory Group

PMH: Past medical history

PMS: Post-Marketing Surveillance

PO: Private Office

POM: Prescription Only Medicines

POM TO P: The means by which a Prescription Only Medicine can become a Pharmacy Medicine (i.e. available only from a pharmacist); also known as ‘de-pomming’.

PPEEAG: Patient and Public Engagement Expert Advisory Group

PPI: Patient Pack Initiative

PPI: Proton Pump Inhibitor

PQ: Parliamentary Question

PRAC: Pharmacovigilance Risk Assessment Committee [of the EMA]

PRR: Proportional Reporting Ratio

PRR: Proportioned Reporting Ratio

PSE WG: Pseudoephedrine Working Group

PSG: Professional Skills for Government

PSUR: Periodic Safety Update Report

PT: Preferred Term - part of the Medical Dictionary for Drug Regulatory Affairs (MedDRA) terminology

PUMA: Paediatric Use Marketing Authorisation

PUWER: Provision and Use of Work Equipment Regulations

PV: Pharmacovigilance

PVAR: Preliminary Variation Assessment Report

QA: Quality Assurance

QC: Quality Control

QOS: Quality Overall Summary

QP: Qualified Person

QWP: Quality Working Party

RamaXL: A subscription service that gives subscribers easy access to non-confidential information on all medicinal products authorised in the UK, together with the ability to track their own applications as they progress through the assessment process.

RCGP: Royal College of General Practitioners

RCHM: Register of Chinese Herbal Medicines

RCR: Royal College of Radiologists

RCT: Randomised (controlled) Clinical Trial

RFI: Request for Further Information

rINN: Recommended International Non-proprietary Name

RMP: Risk Management Plan

RMS: Reference Member State

ROR: Reporting Odds Ratio

RPPS: Regulatory Pharmacovigilance Prioritisation System

RP: Responsible Person

RPSGB: Royal Pharmaceutical Society of Great Britain

RMS: Records Management System

RSC: Royal Society of Chemistry

RSI: Request for Supplementary Information

RSM: Royal Society of Medicine

Rx: Abbreviation for a medical prescription

SABS: Safety Alert Broadcast System

SAE: Serious Adverse Effect

SAG: Scientific Advisory Group [of the EMA]

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

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

SD: Standard Deviation

SEAC: Spongiform Encephalopathy Advisory Committee

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

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

SI: Statutory Instrument

SLA: Service Level Agreement

SMF: Site Master File

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

SmPC: Summary of Product Characteristics - *see SPC*

SOC: System Organ Class - part of the Medical Dictionary for Drug

Regulatory Affairs (MedDRA) terminology

SOL: Department of Health Solicitor's Branch.

SOP: Standard Operating Procedure

SPC: (see also SmPC) Summary of Product Characteristics

SPC: Special Precautions and Contra-indications

SPECT: Single Photon Emission Computed Tomography

SSRI: Selective Serotonin Reuptake Inhibitor

SUSAR: Suspected Unexpected Serious Adverse Reaction

SWP: Safety Working Party

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

TAG: Technical Advisory Group

TCM: Traditional Chinese Medicine

TGA: Therapeutic Goods Administration (Australia)

THM: Traditional herbal medicine

THMPD: Traditional Herbal Medicinal Products Directive

THMRS: Traditional Herbal Medicines Registration Scheme

THR: Traditional Herbal Registration

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

TOPRA: The Organisation for Professionals in Regulatory Affairs

TOTO: Top Of The Office

TS: Tuberous Sclerosis

TSE: Transmissible Spongiform Encephalopathy

UKPAR: United Kingdom Public Assessment Report for Medicines

UKRC: United Kingdom Radiological Conference

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

USP: United States Pharmacopoeia

UTI: Urinary Tract Infection

vAIC: Virtual Adverse Incident Centre

vCJD Variant Creutzfeldt-Jakob Disease

VMD: Veterinary Medicines Directorate

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

VTE: Venous Thromboembolism

WHMP: Western Herbal Medicine Practitioner

WL: Wholesale dealer’s Licence

YCC: Yellow Card Centre

BRITISH PHARMACOPOEIA COMMISSION ANNUAL REPORT FOR 2016

INTRODUCTION

1. The British Pharmacopoeia Commission, appointed under Part 2 of the Human Medicines Regulations 2012, is responsible under regulation 317(1) 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(1) 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 2016, showing their terms of appointment, is shown in **Appendix I**. Following the review undertaken during 2015, eight new members were appointed with effect from 1st January 2016.

3. A list of members of the supporting Expert Advisory Groups, Panels of Experts and Working Parties for 2016 is given in **Appendix II**. The status of the Working Party on Identification Techniques was changed to that of a Panel of Experts in view of the expansion of the BP-NIBSC Herbal Project for a further three years and the extended remit of the group which now includes phytochemical analysis.

CODE OF PRACTICE

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

Pharmacopoeia (Veterinary).

MEETINGS

5. The British Pharmacopoeia Commission met three times during 2016. A meeting to introduce the newly appointed members to aspects of the work of the British Pharmacopoeia Commission was held in February, which enabled these members to gain an understanding of their role in advance of their first official meeting. Nineteen meetings of the Expert Advisory Groups, Panels of Experts and Working Parties were also held during the year. In addition, an *ad-hoc* meeting of the Expert Advisory Group on Biological and Biotechnological Products was held to discuss the BP's future direction for biological medicines. These meetings were held at the Medicines and Healthcare products Regulatory Agency (MHRA), 151, Buckingham Palace Road, London SW1W 9SZ.

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

TRIENNIAL REVIEW

7. With the exception of one item, the recommendations arising from the Triennial Review of the British Pharmacopoeia Commission were implemented during the year (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/417678/bpc-review-report.pdf).

BRITISH PHARMACOPOEIA BUSINESS REVIEW

8. A detailed review of all aspects of the BP business was undertaken during the year. The review took into account the recommendations of the Triennial Review, the feedback received in response to the 2015 Customer Insight Research Project and the current five year Strategy for the BP operation. Several recommendations were included in the review which was endorsed by the MHRA Corporate Executive Team. These recommendations aim to provide opportunities to deliver better value to customers, allow flexibility and innovation and to control costs while maintaining and enhancing the BP's role in protecting public health.

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 2016

12. Following publication of the British Pharmacopoeia 2016 three online updates were issued providing users with the text of Supplements 8.6, 8.7 and 8.8 of the 8th Edition of the European Pharmacopoeia.

British Pharmacopoeia 2017

13. The British Pharmacopoeia 2017 was published in August 2016. This new edition is now available as a package containing the five volumes of the British Pharmacopoeia 2017, the one volume of the British Pharmacopoeia (Veterinary) 2017 and access to the electronic versions of both publications (online BP and offline download format).

14. This new edition contains almost 4000 monographs for substances and articles used in the practice of medicine and over 400 infrared reference spectra, together with the necessary appendices and supporting material. The effective date of the British Pharmacopoeia 2017 is 1st January 2017.

15. All monographs published within the 8th Edition of the European Pharmacopoeia, as amended by Supplements 8.1 to 8.8, 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 2017 contains 29 new monographs of national origin which were not published in previous editions. These include two new monographs for biological products, developed in collaboration with the National Institute for Biological Standards and Control (NIBSC), one new monograph for a Traditional Herbal Medicine and two new monographs for unlicensed formulations. Four new infrared reference spectra have been added to this edition.

17. The new monograph for Vitex Negundo Leaf introduced the use of High Performance Thin-Layer Chromatography and the use of intensity markers into BP monographs for Herbal Drugs, allowing better characterisation of the critical TLC bands.

18. Following the implementation of the ICH guideline on Elemental Impurities (Q3D), and in line with the European Pharmacopoeia, the test for Heavy metals was removed from all national monographs for substances used in human medicine.

19. The titles of a number of monographs for medicinal substances were changed to remove the word “anhydrous” in line with changes to European Pharmacopoeia monographs introduced by means of the 9th Edition. This change was also made to similarly affected national monographs. In accordance with established practice the former titles were included as subsidiary titles, which have the same significance as the main titles. For a number of monographs the new Ph. Eur. title was the same as the BP 2016 title (approved synonym) of the monograph for the corresponding hydrated substance (for example, the Ephedrine and Ephedrine Hemihydrate monographs). In these cases the BP title of the hydrated form was changed to reflect the Ph. Eur. title; this was accompanied by the addition of a statement at the head of the monograph, indicating the former title, rather than using the subsidiary title approach. These changes were reflected in affected formulation monographs.

20. Monographs for products containing Heparin and low-molecular-weight heparins were revised to include a test for Related substances, incorporating a maximum limit for dermatan sulfate and chondroitin sulfate, and a Production statement intended to ensure products are free from contamination by over-sulfated chondroitin.

21. Two new Appendices were added to harmonise with the European Pharmacopoeia (VIII Y: Methyl, Ethyl and Isopropyl Benzenesulfonate in Active Substances and XIV J D2: Assay of Human C1-Esterase Inhibitor).

22. One new Supplementary Chapter was added to harmonise with the European Pharmacopoeia (IV R: Chemometric Methods Applied to Analytical Data).

23. A new Supplementary Chapter on Aseptic Preparation of Unlicensed Medicines (V F) was added. This Chapter provides general guiding

principles relating to aseptically prepared unlicensed medicines, together with information specifically relating to Parenteral Nutrition Solutions.

24. A further new Supplementary Chapter on DNA Barcoding as a tool for Botanical Identification of Herbal Drugs (VII D) was also added. This Chapter provides information on the use of DNA barcoding for the botanical identification of herbal drugs and its application in the BP.

British Pharmacopoeia (Veterinary) 2017

25. The British Pharmacopoeia (Veterinary) 2017 was published as a companion volume to the British Pharmacopoeia 2017 in August 2016. 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) 2017 is 1st January 2017.

26. A number of changes to national monographs for veterinary vaccines were made to align them with VICH Guidelines 41 (Target Animal Safety: Examination of Live Veterinary Vaccines in Target Animals for Absence of Reversion to Virulence) and 44 (Target Animal Safety for Veterinary Live and Inactivated Vaccines). This resulted in the deletion of *in-vivo* tests; in addition the non-mandatory Storage statements were also removed.

27. 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

28. British Approved Names 2017 was published in August 2016. This new edition is a consolidation of British Approved Names 2012 and its four Supplements. A further 30 new names, not previously published, were adopted as British Approved Names (BAN) and incorporated in the new edition. BAN 2017 also included updated action and use statements for anticancer drugs and radiopharmaceutical substances and a new Appendix listing drug substances that have different names in international markets. For the convenience of the user the list of Approved Synonyms included in the British Pharmacopoeia 2017 was also reproduced in BAN 2017.

BP Online

29. Access to the online version (www.pharmacopoeia.com) and the offline download edition of the publications is provided as a component of the British Pharmacopoeia 2017 package. The advantage of the offline download is that it allows the offline product to be updated to include the European Pharmacopoeia Supplement updates at the same time as the online BP.

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

Prices and Availability

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

Future Publications

32. By the end of 2016 work was progressing on the preparation of the next editions of the British Pharmacopoeia and British Pharmacopoeia (Veterinary). These will be published during 2017 and will have an effective date of 1st January 2018.

33. A digital update to the British Pharmacopoeia 2017 was issued in December 2016 providing users with the text of the 9th Edition of the European Pharmacopoeia which came into effect on 1st January 2017. Further updates will be issued to coincide with the implementation of Supplements 9.1 and 9.2 on 1st April and 1st July 2017 respectively. These updates will only be available via the online BP and the offline download. The texts will subsequently be included in the BP 2018 publications.

34. A tender was successfully completed for the future publication of the British Pharmacopoeia (BP 2018 onwards). The Secretariat will be liaising closely with the appointed publisher regarding improved ways of working and further improving the BP website.

OTHER PHARMACOPOEIAL MATTERS

BP Website

35. The new BP website (www.pharmacopoeia.com), which was launched in August 2015, 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.

36. The public consultation schedule for new and revised monographs was implemented on 1st January 2016 and four three-month consultation periods were held during the year. This initiative was developed in response to a recommendation arising from the Triennial Review of the BP Commission, as well as feedback from stakeholders, and has been very favourably received.

Biological Medicines

37. The BP Secretariat worked with MHRA colleagues during the year to prepare a draft MHRA Strategy relating to pharmacopoeial quality standards for biological medicines, together with a public consultation programme.

38. The public consultation, which included the draft strategy document, was launched on 9th January 2017 and will be open for three months. Stakeholders have been invited to provide feedback on the proposed strategy, on how pharmacopoeial standards are currently used and on how this can be improved.

39. The collaborative project between the BP and NIBSC to establish reference materials to support new monographs continued during the year. The first two materials were produced and a protocol has been developed to characterise the materials. Four laboratories, including two at NIBSC, are taking part in the project.

Unlicensed Medicines

40. Monographs that apply only to unlicensed medicines are identified as such in the British Pharmacopoeia by the inclusion of a statement indicating that the medicines are not currently licensed in the United Kingdom.

41. 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. The value of including such monographs was highlighted following reports of a lack of efficacy with Magnesium Glycerophosphate Oral Solution. Testing of the product against the BP monograph confirmed that the batch contained an insufficient amount of magnesium.

42. In addition to developing mongraphs 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.

Traditional Herbal Medicines

43. Information continues to be collected on a number of substances widely used in Traditional Chinese Medicine and in Ayurvedic Medicine in the UK for which there are currently no European standards. The BP has continued to seek national and international collaborations to identify validated analytical methods and suitable standards.

44. The BP-NIBSC Herbal team, supported by the Panel of Experts on Identification Techniques (DNA), produced an innovative British

Pharmacopoeia Nucleic Acid Reference Material (BPNARM). This is required to support the BP Appendix on DNA – Based Identification Techniques for Herbal Drugs, first published in the BP 2016.

45. The BP-NIBSC Herbal team expanded its capability during 2016. This involved commissioning new laboratory space and equipment to support the work in future years. In addition to working on DNA-Based Identification Techniques, phytochemical analysis of Herbal Drugs is now also carried out.

Nomenclature

46. The BP continued to provide advice and comments to the World Health Organization (WHO) Committee on International Nonproprietary Names (INN). Recommended INN (rINN) for products licensed in the UK are subsequently adopted as British Approved Names. UK Experts attended two meetings during the year and contributed to the evaluation of INN requests and the development of WHO policies on drug nomenclature. Two rINN Lists (75 and 76) were published by WHO during the year.

47. 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 550 proposed invented names were assessed on behalf of the EMA. BP staff organised a training programme on the assessment of invented names for the MHRA Licensing Division, which will enable relevant staff to examine the suitability of proposed invented names in licence applications. The BP provides advice to manufacturers on the acceptability of invented names on behalf of the MHRA and answered 148 questions on this matter during the year.

Analytical Quality by Design

48. Progress continues to be made on the MHRA/BP feasibility study investigating the application of the Quality by Design concept to analytical methods and the pharmacopoeia. Experts from the AQbD Working Party focussed on the development of the Analytical Target Profile during the year and additional experts were appointed to support the development of robust statistical approaches to the evaluation of analytical procedures. It is anticipated that the outcomes of the feasibility study will be available in late 2017.

Liaison with Other UK Organisations

49. The BP continues to develop and maintain strong links with academic institutions and is currently involved in projects with several universities. Lectures have been given to pharmacy and chemistry students on “Securing the Pharmaceutical Supply Chain” and “Pharmaceutical Analysis”. A new sponsored MSc project has been initiated on the use of Raman Spectroscopy to identify genuine and counterfeit medicines which

builds on the success of the previous MSc project on pharmacopoeial dissolution procedures.

50. 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. A new general monograph for Veterinary Vaccines for Emergency Use is currently in preparation.

Laboratory

51. The Laboratory has continued to support the work of the British Pharmacopoeia Commission and also the wider MHRA remit relating to public health, for example analysing a suspected low-quality batch of Magnesium Glycerophosphate Oral Solution. Using the published monograph method to determine the amount of magnesium, the Laboratory confirmed that the batch was sub-potent. The data were subsequently used to support corrective actions to ensure that future batches would be of the appropriate quality.

BP Reference Materials

52. 18 new BP Reference Materials were established to support the British Pharmacopoeia and British Pharmacopoeia (Veterinary) publications, 53 were replaced and 142 were re-tested to ascertain their continued stability.

53. The demand for these reference materials remained high throughout the year. 25780 vials were sold within the UK and to countries worldwide, representing a 14% increase in sales from the previous year.

European Pharmacopoeia

54. The 9th Edition of the European Pharmacopoeia and its first Supplement (Supplement 9.1) were published in July 2016 and October 2016 respectively. The 9th Edition came into effect on 1st January 2017 and Supplement 9.1 will come into effect on 1st April 2017. The second Supplement (9.2) was published in January 2017 and will come into effect on 1st July 2017.The text of these publications will be included in the next editions of the British Pharmacopoeia or British Pharmacopoeia (Veterinary), as appropriate.

55. The UK continued to play a highly active role in support of the work of the European Pharmacopoeia Commission and its expert groups, providing Chairs to three Groups of Experts and eight Working Parties and experts to all of the principal Expert Groups and Working Parties. 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.

56. The Laboratory provides technical support for the work of the European Pharmacopoeia Commission. It participates in the voluntary scheme to validate draft monographs published in Pharmeuropa and provides technical data in support of the elaboration of new monographs and revision of existing monographs.

57. 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.

58. 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 2016, is included in **Appendix V**.

International Liaison and Collaboration

59. 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. A number of bilateral meetings were held throughout the year to continue the interaction with other pharmacopoeias and to move collaborative partnerships forward.

60. Following the result of the EU Referendum, the MHRA is working closely with the Government to ensure the continued safe and effective regulation of medicines and medical devices in the UK. A statement was included on the BP website confirming that the BP would continue to focus on its public health role by continuing to work with and support customers, partners and stakeholders and by playing a full and active role with all our international stakeholders including the European Pharmacopoeia, part of the European Directorate for the Quality of Medicines and Healtcare under the Council of Europe. The BP also contacted all our international partners directly to inform them of the BP/MHRA position.

61. BP Staff attended the Seventh International Meeting of World Pharmacopoeias which was organised by the World Health Organization and was held in Tokyo, Japan, in September. The meeting focussed on the continuing development of the guidelines on “Good Pharmacopoeial Practices”. The text had been approved by the WHO Expert Committee on Pharmaceutical Preparations and the final version of the guidelines was issued in April. During the meeting in Tokyo, progress was made on additional guidelines relating to Herbal Medicines and to Compounded

Preparations which would be incorporated in future updates to the main document.

62. The WHO meeting was followed by the 130th Symposium of the Japanese Pharmacopoeia. This provided an opportunity for BP staff to hold meetings with representatives from the Japanese Pharmaceutical and Medical Devices Agency, the Indian Pharmacopoeia, the Brazilian Pharmacopoeia and the State Pharmacopoeia of Ukraine. The meetings focussed on current and potential future collaboration opportunities between the BP and these organisations and provided the opportunity to learn of developments in the various world pharmacopoeias.

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 participated in the WHO Consultation on Quality Control Laboratory Tools and Specifications for Medicines (May) and in the 51st Meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (October). These meetings covered a wide range of topics, including: monographs and policies for the International Pharmacopoeia; SSFFC (substandard / spurious / falsely-labelled / falsified / counterfeit) medicines; regulatory guidance; quality assurance initiatives.

65. BP staff attended the 62nd and 63rd WHO Consultations on International Nonproprietary Names (April and October) which were chaired by Dr Patience Holland, a member of the BP Secretariat. There has been a significant increase in the number of names requested for biological substances produced by emerging technologies, such as cell therapy and gene therapy products, which provided challenges for the experts.

66. Representatives from the BP attended a conference held in Tallinn, Estonia, to promote the 9th Edition of the European Pharmacopoeia. A number of workshops were held to discuss issues such as setting pharmacopoeial standards for biotherapeutic products, the control of elemental impurities, new technologies, excipients, other components and international harmonisation.

67. BP staff participated in discussions with senior representatives from the United States Pharmacopeia in January to expand the current successful joint working between the BP and the USP. Areas of discussion had included: the proposed development of a Memorandum of Understanding to facilitate future collaboration; cooperation on the development of strategies for quality standards for biological medicines; informal harmonisation of biological product monographs; ways to encourage additional companies and pharmacopoeias to become involved with

informal harmonisation projects; joint working to update BP and USP monographs.

68. Representatives from the BP attended the International Foundation Process Analytical Chemistry (IFPAC) conference held in Washington DC in January. The BP gave a presentation on the application of enhanced approaches to compendial methods which provided an overview of the MHRA/BP Analytical Quality by Design feasibility study. The BP has maintained a strong global presence on AQbD, presenting at leading conferences in the USA and Europe. In addition to these activities the strong collaborative relationships with our peers in the USP and the Japanese Pharmacopoeia on this topic have been maintained through information and knowledge sharing.

69. The BP continues to work with the USP on informal prospective harmonisation projects and a further harmonised monograph for Aprepitant Capsules was published in the BP 2017. The BP has also been collaborating with the USP to update a number of individual and family monographs and a number of manufacturers have expressed an interest in participating in future BP/USP harmonisation projects.

70. The BP participated in the Joint Compendial meeting organised in association with the US Consumer Healthcare Products Association. Updates on current and future BP activities, including the BP-NIBSC herbal project, were provided. Positive feedback had been received on the new website and on the ability of users to provide comments on new and revised monographs.

71. BP staff attended the 8th Annual “Develop Innovate Advance” Conference in Beijing, China, in May which had provided an opportunity to gain an understanding of the current and future pharmaceutical landscape of China. During the conference a number of meetings were held to discuss the BP and its potential use within China, including a meeting with representatives from the Chinese Pharmacopoeia (CP). A Memorandum of Understanding between the BP and the CP was signed which will allow the establishment of three working groups to jointly develop monographs for biologicals, traditional herbal medicines and medicinal substances and products. It was also agreed to develop a reciprocal information sharing programme between experts from China and the BP Herbal Laboratory for the testing of traditional herbal medicines.

72. The BP participated in an MHRA meeting with the China Chamber of Commerce for Import and Export of Medicines and Health Products and China industry in October. A number of issues had been discussed including the registration of traditional herbal medicines, Licensing and Inspection requirements and the development of BP monographs for traditional herbal medicines.

73. A teleconference was held with the Australian Therapeutic Goods Administration Office of Laboratories and Science Services in May to

discuss knowledge sharing and organisational updates. In addition to the existing arrangement whereby the TGA assisted in the development and revision of BP monographs by acting as a second laboratory to assess the robustness of proposed methods, it was agreed that the TGA would participate in the MHRA/BP Analytical Quality by Design feasibility study.

ACKNOWLEDGEMENTS

74. 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. The Commission wishes to place on record its heartfelt thanks to Dr Keith Helliwell who retired as Chair and member of the Panel of Experts on Identification Techniques during the year. Dr Helliwell made a significant contribution to the work of the BP-NIBSC Herbal Project during his time on the group and as a member of the Expert Advisory Group on Herbal and Complementary Medicines and a former member of the British Pharmacopoeia Commission.

75. The British Pharmacopoeia Commission also wishes to record its immense gratitude to the staff of the British Pharmacopoeia and Laboratory Services Group of the Medicines and Healthcare products Regulatory Agency concerned with the business of the Commission and its Expert Advisory Groups, Panels of Experts and Working Parties. Significant input to the work of the British Pharmacopoeia Commission continued to be received from members of staff from the Licensing Division, the Vigilance & Risk Management of Medicines Division, the Inspection, Enforcement & Standards Division, the Information Management Division and the Communications Division of the Agency. Significant input has also been received from the BP and MHRA Laboratories, from the Department of Health, from the National Institute for Biological Standards and Control and from the Veterinary Medicines Directorate.

76. The Commission wishes to acknowledge the advice of the publishing team at The Stationery Office in the production of the British Pharmacopoeia 2017, the British Pharmacopoeia (Veterinary) 2017 and British Approved Names 2017.

77. 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.

78. Mrs Maria Barrett retired at the end of 2016. The Commission wishes to place on record its gratitude to Mrs Barrett for her long service to the BP, including 14 years at the BP Laboratory and 13 years as a member of the Secretariat.

APPENDIX I

MEMBERSHIP OF THE BRITISH PHARMACOPOEIA COMMISSION DURING 2016

Chair

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

Members

Professor Matthew Almond BSc DPhil DSc CChem FRSC PFHEA NTF
Professor of Chemistry Education and Dean of the Faculty of Arts, Humanities & Social Services, 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

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

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

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

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

Dr Gerard Lee BPharm PhD FRPharmS MRSC CChem
Former Group Manager, British Pharmacopoeia and Laboratory Services, MHRA; former Secretary & Scientific Director, British Pharmacopoeia Commission

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

Dr Brian R Matthews BPharm PhD FRPharmS FTOPRA
Consultant on pharmaceutical and medical device regulatory affairs; former Senior Director, EC Registration, Alcon Laboratories

Professor John Miller MSc PhD MRSC CChem
Visiting Professor, Strathclyde Institute of Pharmacy and Biomedical Sciences; former Head of the EDQM Laboratory

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

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

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

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

Secretary and Scientific Director

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

APPENDIX II

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

EXPERT ADVISORY GROUPS

ABS: Antibiotics	R L Horder (**Chair**), G D Cook (**Vice-Chair**), G Blake, P Ellis, E Flahive, A Gibson[1], V Jaitely, W Mann, J Miller, B White, I R Williams
BIO: Biological and Biotechnological Products	P Varley (**Chair**), L Tsang (**Vice-Chair**), L Bissett*, A-M Brady,A F Bristow*,C Burns, D H Calam, K Chidwick*, A Cook*, J Cook*, L Findlay[1], S Gill, E Griffiths, C Jones*, A Kippen*, B Patel, A M Pickett*, T Pronce, L Randon, I Rees*, S Schepelmann*, D Sesardic, P Sheppard, P Stickings*, A H Thomas, R Thorpe, M Wadhwa*
HCM: Herbal and Complementary Medicines	E Williamson (**Chair**), L A Anderson (**Vice-Chair**), M Simmonds (**second Vice-Chair**), P Anderson, A Bligh, S Gibbons, K Helliwell, C Leon, R Middleton, B Moore, M Pires, E Reich, M Rowan, K Strohfeldt-Venables, J Sumal*, C Welham, K Zhao (*Corresponding members* SS Handa, A Krauss, Z-T Wang)
MC1: Medicinal Chemicals	A G Davidson (**Chair**), D Cairns (**Vice-Chair**), M Ahmed, J C Berridge, M Broughton, E Bush, A J Caws, P Fleming, A James, W J Lough, D J Malpas
MC2: Medicinal Chemicals	G Cook (**Chair**), C T Goddard (**Vice-Chair**), J Cowie, D Edwards, A Gibson[1], J Lim, J Miller, P Murray, A Ruggiero, M Turgoose, N Wynne (*Corresponding members* M Brits, W Sherwin)
MC3: Medicinal Chemicals	V Fenton-May (**Chair**), E Williamson (**Vice-Chair**)[2], M Almond, S Arkle[1], J Beach, J Beaman, C T Goddard, P Hampshire, W K L Pugh, B Rackstraw, R Torano, M Tubby,I R Williams
NOM: Nomenclature	J K Aronson (**Chair**), L Tsang (**Vice-Chair**), M Ahmed, B Granell-Villen[1], D Mehta, G P Moss, R Thorpe (*Corresponding members* R G Balocco Mattavelli, J S Robertson)

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

PANELS OF EXPERTS

BLP: Blood Products	K Chidwick, A R Hubbard, J More, P Varley
CX: Excipients	B R Matthews (**Chair**), C Mroz (**Vice-Chair**), C Cable, R Cawthorne, D Deutsch, N Hussain
DNA: Identification Techniques	K Helliwell[2] (**Chair**, *until June*), A Slater (**Chair**, *from July*), I Feavers, J Hawkins, E Mee, E Williamson
IGC: Inorganic and General Chemicals	C T Goddard (**Chair**), M Almond, S Atherton, S Boland, D Caulfield, P Henrys, G Lay
MIC: Microbiology	V Fenton-May (**Chair**), B Alexander, S Denyer, P Hargreaves, B R Matthews
RAD: Radioactive Materials	J Ballinger[1], J Brain, D Graham, G Inwards, R D Pickett, R Smith, S Waters[1]
VET: Veterinary Medicines	E Williamson (**Chair**), A Coulson **(Vice-Chair**), A Cairns, S Cockbill, D Evans, E Flahive, B Ward
VIP: Veterinary Immunological Products	A-M Brady (**Chair**), R Banks, R Cooney, K Redhead, J Salt, R Woodland

WORKING PARTIES

AQbD: Analytical Quality by Design	G Cook (**Chair**), S Brown, M Chatfield, S Ellison, M Hanna-Brown, S Jones, D Makohon[1], P Nethercote, E Razzano (*Corresponding members* K Barnett, W Sherwin)
MCS: Microscopy	E Williamson (**Chair**), R Arroo, R Fleck, K Helliwell, K Maclellan Gibson

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

MEMBERS OF THE BRITISH PHARMACOPOEIA COMMISSION STAFF DURING 2016

SECRETARY AND SCIENTIFIC DIRECTOR
Dr S Atkinson

SECRETARIAT
Mr J Pound (*Editor-in-Chief)*
Mr S Young (*Head of Analytical Science*)
Mrs M Barrett
Ms H Corns
Mr P Crowley
Mr A Evans
Ms J Francomb (*until February*)
Dr A Gardiner
Mr A Gibb
Ms S Gomersal
Dr P Holland
Dr G Kemp (*from July*)
Ms G Li-Ship
Dr R A Pask-Hughes
Ms C Pitt (*on secondment*)
Dr F J Swanson
Mr M Whaley

DH STAFF
Ms C Hill (*April to October*)
Mr J Ware (*from October*)

NIBSC BASED STAFF
Mr L Gibson
Ms C Gkouva (*from February*)
Dr C Howard
Ms M Kalantarzadeh (*from August*)
Ms C Lockie-Williams

LABORATORY MANAGEMENT BOARD
Dr S Atkinson (*Secretary and Scientific Director, BP)*
Mr J Pound (*Editor-in-Chief, BP)*
Mr S Young (*Head of Analytical Science, BP)*
Dr R Adams (*Service Delivery Manager, LGC, from May*)
Mr P Bedson (*Operations Director, LGC, from May*)
Dr D Griffiths (*Managing Director, Laboratory and Managed Services, LGC, until May*)
Mr P Stafford (*Key Account Manager, LGC, from May*)
Mr S Wood (*Head of Regulatory Services, LGC*)

ADMINISTRATIVE
Mr B Delahunty
Mr W Jeffries (*until February*)
Ms A Korzeniowska (*from July*)
Miss J Paine
Ms M-L Wall

APPENDIX IV

BRITISH PHARMACOPOEIA COMMISSION PUBLICATIONS DURING 2016

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

British Pharmacopoeia 2017 package

Consisting of:-

British Pharmacopoeia 2017

British Pharmacopoeia (Veterinary) 2017

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

(Price £150)

APPENDIX V

EUROPEAN PHARMACOPOEIA COMMISSION

MEMBERS OF THE UNITED KINDGOM DELEGATION DURING 2016

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

Alternates: R L Horder, J Pound

MEMBERS OF GROUPS OF EXPERTS FROM THE UNITED KINGDOM DURING 2016

Group 1	Biological Methods and Statistical Analysis	V Fenton-May (***Chair***), V Jaitely
Group 6	Biological Substances	C Burns
Group 6B	Human Blood and Blood Products	A R Hubbard
Group 7	Antibiotics	V Jaitely (*Specialist*)
Group 9	Inorganic and Organic Chemistry	C T Goddard
Group 9G	Medicinal Gases	M G Lee (***Chair***), P Henrys
Group 10A	Organic Chemistry (Synthetic Products)	D J Malpas (*Specialist*)
Group 10B	Organic Chemistry (Synthetic Products)	E Bush
Group 10C	Organic Chemistry (Synthetic Products)	J McKendrick
Group 10D	Organic Chemistry (Synthetic Products)	C T Goddard
Group 11	Organic Chemistry (Natural Products)	M Tubby
Group 12	Dosage Forms and Methods	R L Horder (***Chair***), S Wicks, G Nichols (*Specialist)*
Group 13B	Phytochemistry (B)	P Anderson
Group 13H	Fatty Oils and Derivatives	R Cawthorne, M Evans (*Specialist*)
Group 14	Radioactive Compounds	R D Pickett

Group 15	Sera and Vaccines	S Schepelmann (*Specialist*), D Sesardic (*Specialist*), P Stickings
Group 15V	Veterinary Sera and Vaccines	A-M Brady, R Cooney (*Specialist*)
Group 16	Plastic Containers for Pharmaceutical Use	C O'Neill
Group P4	Procedure 4	S Young

MEMBERS OF WORKING PARTIES FROM THE UNITED KINGDOM DURING 2016

Alkyl Mesilates	J Midgley (***Chair***) [*dormant group*]
Allergens	A Cook
Bacterial Endotoxins Test	L Findlay[1]
Carbohydrates	J Michaud (***Chair***)
Cell Therapy Products	G Stacey
Chromatographic Separation Techniques	S Young
Chairs of Chemical Groups	A G Davidson, M G Lee
Dialysis Solutions	M G Lee (***Chair***)
Extracts	K Helliwell (***Chair***), L Anderson, M Pires
Functionality-related Characteristics	C Mroz
Gene Therapy Products	E Pollitt
General Methods	A G Davidson (***Chair***), M Almond (*Specialist*), J Cowie (*Specialist*)
Glass Containers	L Yoest
Heavy Metals	A Evans
Homoeopathic Manufacturing Methods	R A Pask-Hughes, J Sumal
Homoeopathic Raw Materials and Stocks	R A Pask-Hughes, J Sumal
Host-cell Proteins	A Kippen

Inhalanda	K M G Taylor
Live Biotherapeutic Products	A Stevenson
Monoclonal Antibodies	R Thorpe (***Chair***), P Varley
Monocyte Activation Test	L Findlay[1]
Nuclear Magnetic Resonance Spectroscopy	C Jones
Paediatric Formulary	N Hussain, A Nunn
Pharmaceutical Preparations	V Fenton-May (***Chair***), M G Lee
Procedure 4 for Biologicals	K Chidwick[1], M Wadhwa
Process Analytical Technology	I Lynch
Propellants	T Purewal
Raw Materials for the Preparation of Cellular and Gene Therapy Products	L Bisset
Rules of Procedure	S Atkinson
Special Revision Programme	A Evans
Standard Terms	M Ahmed
Statistics	R Gaines Das
Sutures	L Ferris
Traditional Chinese Medicines	M Whaley
Vibrational Spectroscopy and Analytical Data Modelling	N Broad, I Lynch (*Specialist*)
Water for Pharmaceutical Use	M G Lee (***Chair***), A Hopkins

[1]*Resigned during the year*.

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

1. INTRODUCTION

Purpose of the Code

1.1 This Code of Practice sets out the rules to be followed by chairmen and members of advisory committees holding and declaring interests in the pharmaceutical industry. The Code of Practice also provides guidance on holding and declaring other relevant interests, and on how interests that have been declared will be managed. The Code applies to chairmen and members of all the statutory committees and Expert Advisory Groups (EAGs) established to contribute advice to the Licensing Authority on the regulation of medicines available on the UK market. Separate rules apply to the British Pharmacopoeia Commission (BPC) because of their different role and remit.

Importance of impartiality

1.2 Ministers expect the advice they receive on matters relating to the regulation of medicines to be impartial. Ministers also expect to be able to seek such advice from a wide range of highly skilled professionals who are senior and well regarded in their respective fields. Many experts in the field of medicines have, or have had, connections with the pharmaceutical industry and other commercial organisations whose business may be considered relevant to their work on the advisory bodies but may have an impact on their impartiality. For example, the University department for which an individual is responsible may have received a research grant from industry, or the individual may have shareholdings from previous industry employment.

1.3 To reassure Ministers and the public that the advice on which decisions about medicines is based is impartial, it is important to have in place a robust policy governing the declaration and management of relevant interests. In the interests of transparency and accountability, this Code of Practice, the declarations made by chairmen and members of the various committees, and the actions taken to manage potential conflicts of interest are made public. In addition, where an individual has declared in advance of a meeting an interest that would exclude him or her from the relevant discussions, this information will be used by the secretariat to ensure that, wherever possible, the relevant committee papers are not sent to that individual.

2. SCOPE

Committees and groups to which this Code applies

2.1 The Code of Practice applies to the chairmen and members of the following committees and groups:

- Commission on Human Medicines (CHM)
- The following committees ("the Committees"):

  Herbal Medicines Advisory Committee (HMAC);

  The Advisory Board on the Registration of Homeopathic Products (ABRHP)

- The Expert Advisory Groups (EAGs) established by the CHM and/or the Committees.

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

3. DEFINITIONS

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

Pharmaceutical Industry

3.2 "Pharmaceutical industry" means:

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

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

Immediate family

3.3 "Immediate family" means:

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

4. INTERESTS WHICH NEED TO BE DECLARED

Summary of interests that need to be declared

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

- Their own financial interests in the pharmaceutical industry; (financial interests are either personal or non-personal, and either specific to the product being discussed, or non-specific);

- Financial interests in the pharmaceutical industry held by members of their immediate family;

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

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

Personal interests

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

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

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

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

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

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

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

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

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

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

Non-personal interests

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

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

Support by the pharmaceutical industry or any other relevant industry: any payment, other support or sponsorship by the pharmaceutical or other

industry that does not convey any pecuniary or material benefit to the individual personally but that benefits his/her position or department;

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

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

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

Other relevant interests

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

- An individual, or his department, has done research work relating to a particular product, or class of products. Although the research has not been funded by any particular pharmaceutical company, the research has taken a particular line e.g. in relation to the safety of the products, or their efficacy;

- An individual has made public statements (either favourable or unfavourable) about a particular company, or product, or class of products or about a competitor's product or class of product;

- The relevant committee is considering whether a product should be reclassified e.g. from prescription only, to a pharmacy medicine, and the individual has a particular interest in the reclassification being made e.g. because he is a retail pharmacist and he will benefit financially;

- An individual participates in, or is connected with, a charity or pressure group that would have an interest in the outcome of the advice being given;

- An individual has a family member who suffers from an illness who would benefit from treatment if a product under discussion were to be authorised;

- An individual has a family member who has suffered a severe reaction or other problem as a result of treatment with a product under discussion;

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

- Interests in a company manufacturing the delivery system (e.g. syringes or other medical equipment) for a particular medicinal product;

Attendance at conferences, scientific meetings and similar

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

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

4.10 In order that the chairmen and members of CHM, HMAC, ABRHP and the three EAG chairmen specified in paragraph 4.8 above should be able to attend appropriate scientific events to keep their knowledge up to date, the MHRA has established a discretionary fund to meet the reasonable expenses (e.g. travel and accommodation costs) incurred in their attendance. The relevant MHRA committee secretariat will administer the fund, and chairmen and members wishing to claim the costs of attendance at such events must make an application in good time to enable appropriate travel and other arrangements to be made. The fund will cover educational events that are relevant to maintaining the expertise of individuals serving on the CHM, HMAC, ABRHP and the three specified EAGs, where acceptance of financial support from industry (for example a single pharmaceutical company) would not be appropriate. Separate guidance on the allocation of resources from the fund has been developed for use by the MHRA secretariat.

4.11 In some cases it will permissible for members of CHM, HMAC, ABRHP 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.

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

5.1 Experts who are invited to attend committees for the day, for example if a regular member cannot be available or cannot participate in discussions

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

6. DECLARATION OF INTERESTS

6.1 Chairmen and members are required to make a full declaration of interests on appointment and annually. They must also inform the MHRA secretariat promptly of any changes or updates to the terms of their declaration during the year. This includes reporting promptly attendance at events described in paragraphs 4.8 – 4.17. If an individual is uncertain as to whether or not an interest should be declared, he or she must seek guidance from the MHRA secretariat. Chairmen and members are also required to make further declarations of relevant interests at meetings when they will be advised as to the procedure that will apply.

Annual declaration

6.2 The annual declaration must include all the financial (personal and non-personal) interests in the pharmaceutical industry of the chairmen and members currently held or held in the last 12 months and financial interests in the pharmaceutical industry that they know of that are held by their immediate family. Members and chairmen are also required to include in the annual declaration details of any other matter which could reasonably be regarded as affecting their impartiality.

6.3 The declaration of certain interests will not be restricted to the last 12 months. For example, an individual’s significant involvement in the development of a particular product will need to be declared each year as well as at relevant meetings, and may restrict that individual’s participation in some discussions.

6.4 The chairmen and members’ declaration of their own interests will identify them with the interests declared, but the interests declared do not need to be quantified. For example, in declaring a grant received by a department for which the individual is responsible, only the company name is required, not the value of the grant.

6.5 When the annual declaration includes matters relating to other persons, names are not required, nor do the interests declared need to be quantified. For example, in declaring shareholdings only the company name is required, not the numbers or values of shares held. Family members should be referred to simply as: “immediate family member” and closely connected persons as “other person”. In nearly all circumstances this will protect the anonymity of those whose interests must be declared by the serving committee member, although we recognise that in very exceptional circumstances it may be possible for that individual to be identified.

6.6 The annual declaration made by all chairmen and members of all the CHM, the Committees and EAGs will be published each year in the Annual Report of the Advisory Bodies.

Declarations at meetings

6.7 Chairmen and members are required to declare relevant interests at meetings, whether or not those interests have previously been declared to MHRA. The type of interest must be declared, that is, whether it is personal or non-personal, specific or non-specific or other.

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

7. PARTICIPATION IN DISCUSSIONS WHEN AN INTEREST HAS BEEN DECLARED

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

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

Personal Interests

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

7.4 If an individual has declared a ***personal non-specific interest*** the individual must take no part in discussions on that agenda item, except at the Chairman's discretion to answer questions from other members. If the personal non-specific interest relates to shares that have been disposed of, the individual will generally be permitted to take part in discussions once three months have elapsed from the date of the disposal of them If the personal non-specific interest relates to other matters, such as a payment received from a pharmaceutical company, the individual will generally be permitted to take part in discussions once 12 months has elapsed from the

date of receipt of payment. However, in some cases it will not be appropriate for the individual to take part even though 12 months have elapsed – for example, where he has an ongoing consultancy or other financial relationship with the pharmaceutical company.

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

Non-Personal Interests

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

7.7 A ***non-personal, non-specific interest*** will not normally debar an individual from taking part in discussions, unless exceptional circumstances arise in which it is not appropriate for them to do so.

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

Other Interests

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

Rival Products

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

7.11 If a product is being discussed and an individual is aware that he or she has an interest in a company which markets a rival product, the business of

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

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

Consideration of Classes of Products

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

8. RECORD OF INTERESTS

8.1 A record is kept in the MHRA of:

- names of chairmen and members who have declared interests on appointment, when an interest first arises or through the annual declaration, and the nature of the interest;

- names of chairmen and members who have declared interests at meetings of the CHM, the Committees and EAGs, giving dates, names of relevant products and companies, details of the interest declared and whether the individual took part in the proceedings.

9. PUBLICATION

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

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

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Stuart Ralston (Chair)	None	None	Amgen	Romosozumab - Department is recruiting centre in clinical trial. I am local PI.	Yes	None
			Eli Lilly	Teriparatide - Research grant to institution. I am PI	Yes	
			Pfizer	Tanezumab - Department is recrutiing centre in clinical trial. Another consultant is local PI	Yes	
			Abbvie	Adalimumab - Department is recrutiing centre in clinical trial. I am local PI	Yes	
			Roche	Tocilixumab - Department is recruiting centre in clinical trial. Another consultant is local PI	Yes	
			Novartis	Secukinumab - Department is recrutiing centre in clinical trial. Another consultant is 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**
				Zoledronic acid - Consultancy fees to institution. I am chair of a DMC for a clinical trial	Yes	
			Bristol Myers Squibb	Abatacept - Department is recruiting centre in clinical trial. Another consultant is local PI.	Yes	
			Ultragenyx	KRN23 (antibody to FGF23) - Department is recruiting centre in clinical trial. I am local PI.	Yes	
Mrs Eileen J Barrett	None	None	Multiple companies, see additional information	The companies listed in the additional information section, will have been a client of Source Bioscience Plc at the time of a given CHM meeting but the product of interest on the CHM agenda will not have been relevant to the services or products Source Bioscience Plc was providing to the companies at the time.	No	Abbott Laboratories Limited, Actavis Group PTC EHF, Actavis UK Ltd, AMPAC Fine Chemicals (USA), AMRI Rensselaer, AMRI SSCI LLC, AstraZeneca, Bio Labs Ltd, Biogen Inc, Biooutsource Ltd, BioReliance, Boeringher Ingeleim, Catalent CTS Inc, Catalent Pharma Solutions Limited, Charles River Laboratories, Cipla (EU) Ltd, Colorcon Asia Pvt. Ltd (USA), Covance, Crescent Pharma Limited, CSL Behring, Custom Pharmaceuticals, Dr Reddy's Laboratories Ltd, Exova, GlaxoSmithKline, Great Ormond Street Hospital, Helsinn Birex, King's College

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						London, Lek Pharmaceuticals d.d., Life Technologies, MedImmune, Medreich Plc, Merck Serono Ltd, Mercury Pharmaceuticals Ltd, Morningside Healthcare Ltd, Mundipharma GmbH, Novartis Pharma AG, Pantheon Inc, Pfizer Ltd, Reckitt Benckiser Healthcare (UK) Limtied, Roche, Roche Products Ltd, SA, Sandoz GmbH, Schering Plough, Select Bio Laboratories Limited, SGS M-Scan Ltd, Sigma-Aldrich Corporation, Teva UK Limited, University College London, Warner Chilcott UK Ltd, WiXi AppTec Inc
Dr J Colin Forfar	None	None	None	None	No	None
Dr Jamie Fraser	Internis	The company paid my travel, accomodation and conference fees so I could attend the 2016 National Osteoporosis Conference Birmingham, UK	None	None	No	None
Professor Jonathan Friedland	None	None	None	None	No	None
Dr Richard Gilson	None	None	Viiv	Anitretroviral therapies - my department is a collaborating site in clinical trials.	Yes	None
			Pfizer	Maraviroc - UK chief investigator for one commercial trial, now	Yes	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
				complete. Chief investigator for one ivestigator-initiated study which is now complete and the publication is in press.		
			Gilead Sciences	Anitretroviral therapies - my department is a collaborating site in clinical trials. I am a site principal investigator for one clinical trial.	Yes	None
			Merck	Anitretroviral therapies - my department is a collaborating site in clinical trials.	Yes	None
			Janssen	Anitretroviral therapies - my department is a collaborating site in clinical trials.	Yes	None
Professor Martin Gore	None	None	None	None	No	None
Professor Malcolm R Macleod	None	None	Janssen Pharmaceutica NV	Planning to share 2 PhD students; Co-applicants for funding - see additional information	Yes	I am the coordinator of the EQIPD consortium, formed to bid for 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 to submit a revised bid. On 4th
			AbbVie Inc	Planning to share 2 PhD students; Co-applicants for funding - see additional information	Yes	
			Boehringer Ingelheim International GmbH	Planning to share 2 PhD students; Co-applicants for funding - 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**
			Novartis Pharma AG	Planning to share 2 PhD students; Co-applicants for funding - see additional information	Yes	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 funding decision expected 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 from Janssen. This is described in the application (attached) and will be further described in the consortium agreement. These non-specific non-personal potential conflicts of interest arise because my Department is advantaged in in our IMI stage 2 application through the involvement of the pharmaceutical companies listed to the left under Non-Personal Interests.
			Orion Corporation	Planning to share 2 PhD students; Co-applicants for funding - see additional information	Yes	
			Pfizer Limited	Planning to share 2 PhD students; Co-applicants for funding - see additional information	Yes	
			PhsychoGenics Inc.	Planning to share 2 PhD students; Co-applicants for funding - see additional information	Yes	
			F. Hoffmann-La Roche Ltd.	Planning to share 2 PhD students; Co-applicants for funding - see additional information	Yes	
			INSTITUT DE RECHERCHES SERVIER S.A.S	Planning to share 2 PhD students; Co-applicants for funding - see additional information	Yes	
			UCB Biopharma SPRL	Planning to share 2 PhD students; Co-applicants for funding - see additional information	Yes	
			Sanofi-Aventis Research and Development	Planning to share 2 PhD students; Co-applicants for funding - see additional information	Yes	
Dr Rebecca Mann	ABBVIE	Palivizumab - Fees, now disposed of	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Sarah Meredith	None	None	Abbott	Lopinavir, Ritonavir - grant & product donated for a trial	Yes	None
			Amgen	Neupogen/GM-CSF - product donated for a trial/grant	Yes	
			Astellas	Enzalutamide - grant & product donated for a trial	Yes	
			AstraZeneca	Cediranib/AZD 8931 - grant & product donated for a trial/product donated for a trial	Yes	
			Bayer	Sorafenib - grant & product donated for a trial. Aspirin - product donated for a trial	Yes	
			Boehringer Ingelhein, Bristol-Myers Squibb	Efavirenz, atripla - grant & product donated for a trial. Atazanavir - Product donated for a trial	Yes	
			Boehringer Ingelhein, Bristol-Myers Squibb	Anazanavir - product donated for a trial	Yes	
			Cipla	Albendazole, Azithromycin, Cotrimoxazole/Isoniazid/ Pyridoxine, Fluconazole, Efavirenz, Nevirapine, Lapimune minitabs, Zidovudine/lamivudine, Aabacavir/lamivudine, Stavudine/lamivudine -	Yes	

MEMBER	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS	WHETHER CURRENT	ADDITIONAL INFORMATION
				products donated for a trial		
			Gilead Sciences	Tenofovir, Emitricitabine, Atripla - grant & product donated for a trial. Truvada - product donated for 4 trials; grant for the Proud study. Efavirenz, Tenofovir - Product donated for a trial	Yes	
			Gilead, Tibotec, a division of Janssen-Cilag Ltd, Roche	Financial support for Resistance Database	Yes	
			GlaxoSmithKline	Lapatinib, Abacavir, Zidovudine, Lamivudine - grant & product donated for a trial	Yes	
			GlaxoSmithKline	Abacavir, Lamivudine; Zidovudine, Lamivudine; Abacavir; Lamivudine; Combivir; Kivexa; HIV Conserve Vaccine - product donated for a trial	Yes	
			Janssen	Bedaquiline - Grant & Product donated for a trial	Yes	
			Janssen-Cilag	Abiraterone - Grant & product donated for a trial	Yes	
			Lilly	Gemcitabine - product donated for a trial	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Merck	Topotecan, Pegylated Interferon, Doxoirubicin, Efavirenz - products donated for a trial. Temozolomide, Virinostat - Grant & Product donated for a trial	Yes	
			Pilatus	Amoxycillin - Product donated for a trial	Yes	
			Roche	Bevacizumab - grant & product donated for a trial	Yes	
			Sanofi-Aventis	Docetaxel - grant & product donated for a trial	Yes	
			Sanofi Pasteur	NYVAC C - product donated for a trial	Yes	
			Tibotec	Darunavir - product donated for a trial	Yes	
			Virco	Resistance-tests - product donated for a trial		
			WHO/GDF	Clofazimine - product donated for a trial	Yes	
			TB Alliance	Pretominid - Grant & product donated for a trial	Yes	
			Emergent Biosolutions	Hyperimmune IVIG - product donated for a trial	Yes	
Dr Siraj Misbah	None	None	CSL Behring	UK National Co-ordinator for multicenter,open-label extension study of	No	20% SCIg – IgPro20 Hizentra. Honorarium will be paid into departmental funds

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
				IgPro20 in maintenance treatment of chronic inflammatory demyleinating polyneuropathy (CIDP) in patients completing study IgPro20_3003.		
Professor David G C Owens	None	None	None	None	No	None
Professor Munir Pirmohamed	None	None	Pfizer	Research grant to look at mechanisms of TKI-induced diarrhoea	No	None
			Roche	Research grant to support clinical training fellowships jointly with MRC	Yes	
			Eli Lilly	Research grant to support clinical training fellowships jointly with MRC	Yes	
			UCB Pharma	Research grant to support clinical training fellowships jointly with MRC	Yes	
			Novartis	Research grant to support clinical training fellowships jointly with MRC	Yes	
Professor Shirley Price	None	None	None	None	No	None
Professor Kevin M G Taylor	None	None	AstraZeneca	Contribution to EPSRC Doctoral Training Centre in my department	Yes	None
			Boots	Contribution to EPSRC Doctoral Training Centre in my department	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Pfizer	Contribution to EPSRC Doctoral Training Centre in my department	Yes	
			GlaxoSmithKline	Contribution to EPSRC Doctoral Training Centre in my department	Yes	
			Quadrant	Contribution to EPSRC Doctoral Training Centre in my department	Yes	
Professor Angela E Thomas (Vice-Chair)	None	None	None	None	No	None
Professor Helen M Ward	None	None	None	None	No	None
Dr Christopher Weir	None	None	Reneuron Ltd	DSMB membership resulting in income to my department	Yes	None
			Celgene	DSMB membership resulting in income to my department	Yes	None
Dr Martin Wilson	None	None	None	None	No	I am involved in 4 pieces of research, none of which have drug company sponsors. However, these may be relevant: 1. PD MED Trial - A large randomised assessment of the relative cost-effectivesness of different classes of drugs for Parkinson's disease. Funded by NHS Health Technology Assessment programme and is supported by the European Parkinson's Disease Association, the Parkinson's

MEMBER	PERSONAL INTERESTS		NON-PERSONAL INTERESTS		WHETHER CURRENT	ADDITIONAL INFORMATION
	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS		
						Disease Society and the Parkinson's Disease Nurse Specialist Association. Hosted by Birmingham Clinical Trials Unit. Running since 1999, I am the local prinicple invesitgator (taking over from my predecessor in 2005) this involves follow-up of a single patient. 2. PROBAND - Parkinson's Respiratory of Biosamples and Network Datasets: Prospective Observational Dtudy of Parkinson's Disease with Repeat Clinical Assessment and Biobanking of Blood Samples Funding. Sponsored and based in NHS Glasfow and Clyde. Funded by PD Society, I am the local principle investigator with assessments carried out by PD Nurse and Research Nurse. 3. SIMPATHY - Stimulating Innovation in Management of Polypharmacy and Adherence in the Elderly. Funded by European Union Health Programme. Research looking at the developments o Polypharmacy programmes in different European regions. I am part o the Scottish Government team on this. Funding for travel

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						and accomodation for meetings. 4. Prescribing Outcomes from implementing Enhanced Medication Summaries (POEMS) - Funded by CSO grant. I am on advisory board for this study. Other **-** I am a regular speaker at Royal Colleges, Regional Speciality meetings on a range of subjects including management of Polypharmacy. I receive travel and accomodation reimbursement. None of the meetings have been solely drug sponsored.

N.B - Concerning Dr. Jamie Fraser's Personal Interest
Travel, accomodation and conference fees were repaid in full in February 2017. Dr Fraser took no part in any relevant discussions from 26th January (when MHRA was made aware of the interest) to 26th April 2017.

N.B - Concerning Dr. Rebecca Mann's Personal Interest
The fee was repaid in full in March 2017. Dr Mann took no part in any relevant discussions from 15th March 2017 (when MHRA was made aware of the interest) to 15th June 2017).

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr J Colin Forfar (Chair)	None	None	None	None	No	None
Dr Amanda Adler	None	None	None	None	No	None
Dr Iolo Doull	AstraZeneca	Symbicort - Educational lectures	None	None	No	None
	Boehringer Ingelheim	Tiotropium - advisory board				
	GlaxoSmithKline	Seretide - Attended educational meeting, dinner provided afterwards				
Dr John Firth	None	None	Amgen	Aranesp, Mimpara - Support of renal anaemia service / research and renal mineral and bone disease studies and of renal educational meetings	No	None
			Astellas	Advagraf, Prograf - Support of renal transplantation service / research and of renal educational meetings	No	
			Genzyme	MabCampath, Renagel, Renvela, Thymoglobuline -	No	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
				Support of renal mineral and bone disease studies and of renal educational meetings		
			Novartis	Sandimmun, Simulect - Support of renal transplantation service / research and of renal educational meetings	No	
			Roche	Cellcept, NeoRecormin, Rocaltrol, Valcyte - Support of renal transplantation and renal anaemia service / research and renal mineral and bone disease studies and of renal educational meetings	No	
			Shire	Calcichew, Fosrenol - Support of renal mineral and bone disease studies and of renal educational meetings	No	
			Wyeth	Rapamune - Support of renal transplantation service / research and of renal educational meetings	No	
Dr Andrew Grace	None	None	None	None	No	None
Professor Wasim Hanif	Novo Nordisk	Degludec & Liraglutide - Grants, Consultancy	None	None	No	
	AstraZeneca	Dapagliflozin & Bydueron - Grants, Consultancy	None	None	No	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	BI	Empagliflozin & Linagliptin - Grants, Consultancy	None	None	No	
	Jannsen	Cannagliflozin - Grants, Consultancy	None	None	No	
	MSD	Sitagliptin - Grants, Consultancy	None	None	No	
Dr Philip Ind	Teva	I was paid £600 for lecturing on treatment of Airways disease (with no mention of TEVA products) and for chairing sessions and leading a Debate at a weekend Educational meeting aimed at SpRs and new Consultants. I was paid by the Organisers but the meeting received an unrestricted Educational grant from TEVA.	None	None	No	None
	Trinity Chiesi	Received refreshments at a sponsored departmental breakfast meeting				
	Bristol Myers Squibb	Received refreshments at a sponsored departmental breakfast meeting				
Professor Alan Jardine						
Dr Patrick Mark	Eli-Lilly	Lecture fee	Pharmacosmos	Lecture fee paid to hospital research fund	No	Monofer

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Astellas	Consultancy fee - Un-named anaemia drug in development	Abbvie	Research fund paid to University of Glasgow (via subcontract with University of Innsbruck)	No	
Professor Ann Millar	None	None	None	None	No	None
Dr Hilary Pinnock	Circle Partnerships	Private healthcare - 1,500 'restricted' shares in Circle in recognition of the contribution the practice has made to developing care pathways				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 education sub-committee - some of the projects are supported by unrestricted educational grants from respiratory interested Pharmaceutical Companies. International Primary Care Respiratory Group, (A registered charity that receives financial support from a number of pharmaceutical and respiratory device companies.) I am education lead - some of the projects are supported by unrestricted educational grants from respiratory interested pharmaceutical companies. Scottish Allergy and Respiratory Academy. (A national training programme and resource in allergice and respiratory disorders for healthcare professionals in primary, secondary and tertiary
	Napp Pharmaceuticals	Non-promotional presentation on self-management				
	Novartis	Non-promotional presentation on psychosocial aspects of chronic airways disease	None	None	No	
	Boehringer Ingelheim	Accomodation in London for ERS 2016				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						care and other interested individuals.) I am course co-ordinator for this initiative which is suppoorted by unrestricted educational grants from respiratory interested Pharmaceutical companies.
Dr Pallav Shah	Olympus	Consultancy	PneumRX	RePneu Coil - RCT with RenPneu coils Royal Brompton Hospital and Chelsea & Westminster Hospital reimbursed for clinical trial expenses	Yes	None
	PneumRX	RePneu lung volume reduction coils - Lecture/workshop, consultancy	ERBE, Cook Medical, Immotech, Medtronic, Olympus,	Sponsor Imperial college for bronchoscopy course	Yes	None
	Boston Scientific	Lecture - Thermoplasty	PneumRX, Pulmonx			
	Pulmonx	Endobronchial valves for emphysema - Consultancy/lecture	Pulmonx	Zephyr valves - RCT with endobronchial valves Royal Brompton Hospital eimbursed for clinical trial expenses		
	CSA Medical	Lecture - Cryospray	CSA medical	ReJuvinair (cryopspray) - RCT with cryospray Royal Brompton Hospital eimbursed for clinical trial expenses		
Dr Caroline Vaughan	None	None	None	None	No	None
Mr Phil Willan	None	None	None	None	No	None
Professor Sarah Wild	None	None	None	None	No	None

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Kevin M G Taylor (Chair)	None	None	AstraZeneca	Contribution to EPSRC Doctoral Training Centre in my department	Yes	None
			Boots	Contribution to EPSRC Doctoral Training Centre in my department	Yes	
			Pfizer	Contribution to EPSRC Doctoral Training Centre in my department	Yes	
			GlaxoSmithKline	Contribution to EPSRC Doctoral Training Centre in my department	Yes	
			Quadrant	Contribution to EPSRC Doctoral Training Centre in my department	Yes	
Professor Michael E Aulton	Actelion	Fees – patent advice	None	None	No	None
Professor Graham Buckton	Accord	Aripiprazole - Consultancy	None	None	No	Apotex, Zydusm, Lupin, Accord, Torrent and Hetero interests surrounding Aripiprazole Consultancy work linked under an associated patent case
	Actavis	Tadalafil - Consultancy				
	Apotex	Aripiprazole - Consultancy				
	Hetero	Aripiprazole - Consultancy				
	Impax	Consultancy				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Lupin	Rufinamide - Consultancy, Aripiprazole - Consultancy				
	Mylan	Buprenorfen - Consultancy				
	Plant Impact	Consultancy				
	Roxane	Rufinamide - Consultancy				
	Teva	Tiotropium - Consultancy				
	Torrent Pharmaceuticals Ltd	Aripiprazole - Consultancy				
	Zydus Pharmaceuticals	Aripiprazole - Consultancy				
Professor Derek H Calam	None	None	None	None	No	None
Professor Brian J Clark	None	None	None	None	No	None
Professor Ruth Duncan	None	None	None	None	No	None
Mr V'lain G Fenton-May	None	None	None	None	No	None
Professor Geoffrey W Hanlon	None	None	None	None	No	None
Dr Gillian M Hawksworth	None	None	None	None	No	None
Miss Carol Knott	Windcliff Management Ltd	Management consultancy for the NHS and healthcare industry	None	None	No	None
	Baxter	Company Shares				
	Baxalta	Company Shares				
Dr Majella Lane	None	None	None	None	No	I have established a consultancy company called Melderm Ltd. The company provides expert witness services for patent litigation cases in the United States.
Mr Robert A Lowe	None	None	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Christopher Marriott	Vectura Ltd	Shares	None	None	No	An immediate family member has shares in Vectura Ltd, Halation Ltd and MedPharm Ltd
	MedPharm Limited	Shares				
	Remedica Limited	Directorship, Fees				
	Halation Limited	Directorship, Fees, Shares				
Professor Yvonne Perrie	None	None	GlaxoSmithKline	Grant	Yes	None
			Colorcon	Grant	No	
			APSGB	Board Member - Non-salary, volunary)	Yes	
Ms Hilary A Shenton	None	None	None	None	No	None
Professor Michael D Threadgill	None	None	None	None	No	In respect of my membership of HPTWG, I made the following declaration when I joined. This declaration stands unaltered. "I have no current coflicts of interest for any of the companies and other bodies concerned and I have not been involved in any campaigning or strong opinions in this area. For the sake of completeness, I declare that my research group collaborated with and received a small (approx £2000) amount of research funding from Sterling Winthrop 1992-1995 on a project to assay theophylline in biosamples for patients being treated with asthma and related disorders (nothing to do with pregnancy testing); part of Sterling Winthrop went on to

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						become part of Sanofi a few years alter. This relationship ceased over twenty years ago when the project ended". I have nil additional information to declare in respect of CPSEAG.
Professor Peter York	Nektar Therapeutics Inc	Shares	Torrent, India	Funded project at CrystecPharma	No	None
	CrystecPharma	Director, Shares	AstraZeneca	Funded project at CrystecPharma	No	
	Lena Nanoceutics	Director				
	Cosmo Technologies	Consultancy (via Paul Hastings LLP, Lawyers, New York)				

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Angela E Thomas (Chair)	None	None	None	None	No	None
Professor Farzin Farzaneh	Cellectis, France	Consultancy	None	None	No	None
	Autolus, UK	Consultancy payments and shares in the company				
	AvrioBio - USA	Consultancy as member of the Scientific Advisory Board				
Professor Andrew J T George	Smart Targeting	Shares	None	None	No	There will be pharmaceutical companies that pay grants to my university, but not to any person or department that I have line management responsibilities for. I am unaware of details, though could find out if necessary.
Dr Elwyn Griffiths	None	None	Noe	None	No	Member of the Special Advisory Board of the Korean Ministry of Food and Drug Safety. Member of the Board of the International Alliance for Biologicals (IABS) which has membership drawn from regulatory agencies,

MEMBER	PERSONAL INTERESTS		NON-PERSONAL INTERESTS		WHETHER CURRENT	ADDITIONAL INFORMATION
	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS		
						acadaemia and indsutry (unpaid). Member, WHO Expert Committee on Biological Standardization (2010-15 Chairman, 2016 Rapporteur). I received an honorarium (£2200) for preparation and chairing the third "Alternative Potency Assay Workshop for Inactivated Influenza Vaccine", London (Jan 2016) organised by the US department of Health and Human Services/BARDA, the NIBSC UK and IFPMA. I received an honorarium and local expenses (£1606.80) for preparation and participation in the First Turkish Interactive Workshop on Regulation and Approval of Similar Biotherapeutic Products/Biosimilars, Ankara, Turkey (March 2016). Organised by the Generics and Biosimilars Initiative, Hacettpe university and the Turkish Ministry of Health. My daughter, Nia Wyn Voase, is Manager, Respiratory Clinical Research Facility, Imperial College and Royal Brompton Hospital, London. She has no personal interest in the pharmaceutical industry.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Helen J Lachmann	Novartis	Canakinumab - Consultancy, PI on studies	None	None	No	None
	SOBI	Anakinra - Travel expenses to meetings, consultancy				
	Ionis	IONIS-TTRX - DSMB				
Professor Elizabeth Miller	None	None	None	None	No	None
Dr Siraj Misbah	None	None	CSL Behring	UK National Co-ordinator for multicenter,open-label extension study of IgPro20 in maintenance treatment of chronic inflammatory demyleinating polyneuropathy (CIDP) in patients completing study IgPro20_3003.	No	20% SCIg – IgPro20 Hizentra. Honorarium will be paid into departmental funds
Professor B Kevin Park	None	None	Merck & Co. (USA)	Donation for the support of the Centre for Drug Safety (PI Grant)	No	None
			Astra Zeneca Ltd (UK)	North West England MRC Fellowships in Clinical Pharmacology and Therapeutics (CO-I Grant)	Yes	
			GlaxoSmithKline Research & Development Ltd (UK)	North West England MRC Fellowships in Clinical Pharmacology and Therapeutics (CO-I Grant)	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Icon Clinical Research Ltd (UK)	North West England MRC Fellowships in Clinical Pharmacology and Therapeutics (CO-I Grant)	Yes	
			Janssen Pharmaceuticals (Belgium)	Mechanism-based integrated systems for the predication of drug-induced liver injury (MIP-DILI) (PI Grant)	Yes	
			Wellcome Trust (UK)	YEAR 1 Wellcome Trust ISSF Non-Clinical Fellowships (PI Grant)	Yes	
			GlaxoSmithKline Research & Development Ltd (UK)	Quantitative assessment of drug-protein adduct formation and function (PI Grant)	Yes	
			Amgen Ltd (UK)	Generation and Validation of Models to Probe Keap1 Adducation as a Marker of the Hepatotoxic Liability of Drug Candidates (PI Grant)	Yes	
			Medicines Evaluation Unit Ltd (UK)	North West England MRC Fellowships in Clinical Pharmacology and Therapeutics (CO-I Grant)	Yes	
Professor Andrew Pollard	None	None	Okairos	Grant to Oxford University (vaccine trial)	Yes	RSV Vaccine
			Pfizer	Grant to Oxford University	No	Unrestricted educational funding for a three day course
			GlaxoSmithKline	Grant to Oxford University	No	Unrestricted educational funding for a three day course

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Astra Zeneca	Grant to Oxford University	No	Unrestricted educational funding for a three day course
			GlaxoSmithKline, Novartis, Astra Zeneca	Grant to Oxford University	No	I lead where the research is not funded by pharmaceutical companies: 1. European Commission grant (EBOVAC) to study an Ebola vaccine which has been developed by Janssen (2015-current). 2. European Commission grant (EUCLIDS; funding 2011-2016) to study the cause of fever with Bexsero (vaccine provided for the study under a supply agreement with University by Novartis/GSK). 3. Grant from the Bill and Melinda Gates Foundation to study the efficacy of a typhoid vaccine (Tybar-CV) procduced by Bharat Biotech, India (2013-2016). 4. European Commission grant (ADITEC, 2011-2016) to study the genes expressed in children when they receive an adjuvanted influenza vaccine (FluAd, Novartis). 5. Grant from the National Institute for Health Research (2015-2020) to study treatment of encephalitis in children with intravenous immunoglobulin (supply agreemen with CSL Behring). 6. Grant from the Global Alliance for Vaccines and Immunisation

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						to study the infant pneumococcal vaccine schedule in Nepal (2013-2017). Other investigators in the same academic department as me undertake research funded by vaccine manufacturers and this research is listed under non-personal interests above for transparency although I am not involved in those projects.
Dr Stephen Poole	Janssen Research & Development LLC	Consultancy - Limited to validation of the monocyte activation test	None	None	No	None
Dr Peter F Searle	None	None	None	None	No	I have worked, and have a continuing interest, in the field of cancer gene therapy. My group has conducted gene therapy clinical trials in collaboration with biotech/pharmaceutical companies, and we have an ongoing clinical trial in prostate cancer. I have on occasion undertaken paid consultancy work for biotech/pharmaceutical companies and may do so again in future. I also advise the University Hospitals Birmingham NHSFT on matters relating to biological safety of genetically modified organisms (GMOs), a role which sometimes involves communication with the

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						companies running the clinical trials involving GMOs. Since February 2010, my research group has held a license agreement with Crucell Holland BV, relating to the use of PER.C6 technology for manufacture of our genetically modified adenovirus, AdNRGM, and its subsequent use in clinical trials. This arrangement has involved both the payment of fees to Crucell, and granting Crucell certain rights over the AdNRGM virus. Crucell is now part of the Janssen Pharmaceutical Companies of Johnson & Johnson. I have now been involved with others in discussions with Oncos Therapeutics (Finland), about a possible collaboration leading to clinical trials, and we have MTA with them providing access to some of their viruses for laboratory research.
Mrs Madeleine Wang	None	None	None	None	No	None
Dr Christopher Weir	None	None	Reneuron Ltd	DSMB membership resulting in income to my department	Yes	None
			Celgene	DSMB membership resulting in income to my department	Yes	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)	Novartis	Support to attend EULAR AGM, London	None	None	No	None
Dr Michael Arden-Jones	GW Pharma	Epidiolex - Consultancy	GlaxoSmithKline	Consultancy	Yes	I have recently started a programme of research with Sanofi (as declared) and in declaring this interest, I realise that I have previously been an investigator for an industry sponsored research study (within University Hospitals Southampton NHS Trust) of dupilumab in atopic dermatitis. The clinical trials were a non-personal interest. I apologize if I should have declared this previously.
			Unilever	Consultancy	Yes	
			Novartis	Omalizumab - Novartis provide a nurse to assist with delivert of the Chronic spontaneous urticaria service	Yes	
			Sanofi/Regeneron	Dupilumab - Undertaking clinical trials. Researching atopic eczema. Publishing outcomes of research: epidemiology of atopic eczema	Yes	
Dr Ian Barrison	None	None	None	None	No	None
Mr David Chandler	None	None	None	None	No	I'm employed by a patient charity, but the charity has a policy not to receive any funding or financial support whether monetary, in kind of via third parties from pharmaceutical companies or other commercial

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						organisations. Any events of meetings I attend in relatino to my work for the charity are funded by the charity, this includes: registration fees, travel, subsistence and accomodation. My wife also works for the same charity, and the above also applies to her. No other members of my immediate household have any connections or financial interests in the pharmaceutical industry or associated organisation.
Dr Richard Groves	Karus Therapeutics	Experimental HDAC and PI3 kinase inhibitors - Scientific advisory board	None	None	No	None
Professor Kevin Moore	Servier	Consultancy Work	None	None	No	None
	Cumberland Pharmaceuticals	Consultancy Work	None	None	No	None
Dr Frances Williams	None	None	None	None	No	None

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Jonathan Friedland (Chair)	None	None	None	None	No	None
Professor David Dockrell	None	None	GlaxoSmithKline	Grant - Investigation of NRf2 pahway in macrophage innate responses in COPD	Yes	None
			GlaxoSmithKline	PhD Studentship - No specific product. Studentship jointly funded by University of Sheffield and by GSK.	Yes	
Dr Andrew Freedman	Gilead	Sponsorship to attend the conference on retroviruses and opportunistic infections, Boston, USA	Gilead	Participation in Phase 3 clinical trials - Tenofovir Alafenamide	No	None
	Janssen	Payment to chair a scientific meeting				
Dr Richard Gilson	None	None	Viiv	Anitretroviral therapies - my department is a collaborating site in clinical trials.	Yes	None
			Pfizer	Maraviroc - UK chief investigator for one commercial trial, now complete. Chief investigator for one	Yes	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
				investigator-initiated study which is now complete and the publication is in press.		
			Gilead Sciences	Anitretroviral therapies - my department is a collaborating site in clinical trials. I am a site principal investigator for one clinical trial.	Yes	None
			Merck	Anitretroviral therapies - my department is a collaborating site in clinical trials.	Yes	None
			Janssen	Anitretroviral therapies - my department is a collaborating site in clinical trials.	Yes	None
Dr Richard Hobson	None	None	None	None	No	None
Dr Susan M Hopkins	None	None	None	None	No	None
Dr Katie Jeffery	None	None	None	None	No	None
Professor Martin Lombard	None	None	None	None	No	None
Dr Hermione Lyall	None	None	None	None	No	None
Professor Kevin Moore	Servier	Consultancy Work	None	None	No	None
	Cumberland Pharmaceuticals	Consultancy Work	None	None	No	None
Professor Robert C Read	None	None	None	None	No	None
Dr Matthias Schmid	None	None	None	None	No	I am head of department of Infection & Tropical medicine. We have regular weekly meetings which receive support for food from some companies

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						including Gilead, Abbvie, Viiv. This is not linked to any personal funding and does not influence the content of meeting. None of my family members have any personal interests in the pharmaceutical industry.
Ms Hilary A Shenton	None	None	None	None	No	None

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Ailsa Gebbie (Chair)	None	None	None	None	No	None
Dr E Jane Dickson	None	None	None	None	No	None
Professor Philip Hannaford	None	None	None	None	No	None
Professor Mary Lumsden (Vice-Chair)	None	None	NeRRe Biotechnology Company	Consultant	No	September 2016 - Nove Nordisk Symposium. Presentation given on NICE guidline 'Menopause: Diagnosis and Management' but no money received by myself or University of Glasgow (NICE stipulation)
Ms Linda Pepper	None	None	None	None	No	None
Professor Siobhan Quenby	Ferring	Speaker fee for conferences not about a drug, but about recurrent miscarriage x2	None	None	No	None
	Clear Blue Advisory Board	Fee for advising company for one day - HCG-based Pregnancy Tests & Ovulation Kits				
Carolyn, Lady Roberts	None	None	None	None	No	Member of Council, University of Hull
Dr Claire Spencer	None	None	None	None	No	None
Professor Jonathan Tobias	UCB Pharma	Honorarium and expense payment (ran workshop on osteoporosis at symposium)	None	None	No	None

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor David G C Owens (Chair)	None	None	None	None	No	None
Professor Thomas R. E. Barnes	Otsuka/Lundbeck	Aripiprazole - Advisory board	None	None	No	None
	Sunovion	Antipsychotic medication/lurasidone - Chair and introduction for Sunovion Satellite session at British Association for Psychopharmacology meeting				
Professor Naomi Fineberg	British Association for Psycho-pharmacology (BAP)	A range of psychotropic medications for OCD and related psychiatric disorders - Honorarium and travel expenses for delivering a masterclass, twice a year, on this subject	European College of Neuropsycho-pharmacology	Research Network Coordination - Network Administrator's salary	No	I work as a medical leaf of an NHS England NHS service for treatment of resistant obsessive compulsive disorders. I act as an unpaid medical adviser to national consumer charities for OCD and related disorders. I chair the ECNP research Network on OCD and related disorders. I have contributed to the British Association for Psychopharmacology (BAP) treatment guidelines for
	Shire	Lisdexamfetamine in eating disorders - Travel expenses to attend and deliver a lecture touching on this subject	Medical Research Council	Research into deep brain stimulation in OCD - Research grant	No	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	International College of Obsessive Compulsive Spectrum Disorders	Research meetings and symposia touching upon medication related to OCD and related psychiatric disorders - Travel and subsistence expenses to attend the meetings.	NIHR	RFPB and HTA Research touching upon drug treatment of OCD - Research grant	No	anxiety disorders (2014) and the NICE treatment guidelines and the most recent update (2013). I am a member of the Royal College of Psychiatrists Psychopharmacology Special Committee. I do not hold any personal interests in the pharmaceutical industry, nor does my husband or do any adult members of my immediate household.
	European College of Neuropsycho-pharmacology (ECNP)	Research meetings and symposia touching upon medication related to OCD and related psychiatric disorders - Travel and subsistence expenses to attend the meetings.	Wellcome Foundation	Research into translational mechanisms in OCD - Research grant	No	
	Royal College of Psychiatrists	Psychopharmacology special committee work - travel expenses to attend committee meetings	University of Hertfordshire	Research dissemination activities - Research grant	No	
	Oxford University Press	Pocketbook obsessive compulsive and related disorders - Royalties	EU (FP7)	Marie Curie IRSE - Research grant	No	
	Taylor and Francis	Associated editor work, international journal of psychiatry in clinical practice - Fees for editorial work	Shire	Lisdexamfetamine in binge eating disorders - Financial support to run a research meeting	No	
	Otsuka	Lecture series on drug treatment of OCD and Schizophrenia - Travel expenses	Otsuka	Lecture series on drug treatment of OCD and Schizophrenia - Fees to deliver lecture series	No	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Royal Australia and New Zealand College of Psychiatrists	Plenary Lecture on OCD - Travel and subsistence costs	Janssen	Refreshments provided for research showcase event	No	
	International College of Neuropsycho-pathology (CINP)	Plenary Lecture on OCD - Travel and subsistence costs				
Dr Anthony L Johnson	None	None	None	None	No	None
Professor Malcolm R Macleod	None	None	Janssen Pharmaceutica NV	Planning to share 2 PhD students; Co-applicants for funding - see additional information	Yes	I am the coordinator of the EQIPD consortium, formed to bid for 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 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 funding decision expected 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
			AbbVie Inc	Planning to share 2 PhD students; Co-applicants for funding - see additional information	Yes	
			Boehringer Ingelheim International GmbH	Planning to share 2 PhD students; Co-applicants for funding - see additional information	Yes	
			Novartis Pharma AG	Planning to share 2 PhD students; Co-applicants for funding - see additional information	Yes	
			Orion Corporation	Planning to share 2 PhD students; Co-applicants for funding - see additional information	Yes	
			Pfizer Limited	Planning to share 2 PhD students; Co-applicants for funding - see additional information	Yes	
			PhsychoGenics Inc.	Planning to share 2 PhD students; Co-applicants for funding - 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**
			F. Hoffmann-La Roche Ltd.	Planning to share 2 PhD students; Co-applicants for funding - see additional information	Yes	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 (attached) and will be further described in the consortium agreement. These non-specific non-personal potential conflicts of interest arise because my Department is advantaged in our IMI stage 2 application through the involvement of the pharmaceutical companies listed to the left under Non-Personal Interests.
			INSTITUT DE RECHERCHES SERVIER S.A.S	Planning to share 2 PhD students; Co-applicants for funding - see additional information	Yes	
			UCB Biopharma SPRL	Planning to share 2 PhD students; Co-applicants for funding - see additional information	Yes	
			Sanofi-Aventis Research and Development	Planning to share 2 PhD students; Co-applicants for funding - see additional information	Yes	
Professor John T O'Brien	TauRx	Personal fees for consultancy	Lilly	Grant	No	None
	Axon	Personal fees for consultancy				
	Lilly	Grant, speaker fees and personal fees for consultancy				
Dr Waqar Rashid	Novartis	Ad hoc consultancy work on multiple sclerosis service provision and treatment landscape, and travel fees for a conference in Sept 2016	Sanofi Genzyme	Grant for a doctorate student at Brighton Sussex Medical School.	No	None
	Roche	Ad hoc consultancy work on multiple sclerosis service provision and treatment landscape				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Merck	Ad hoc consultancy work on multiple sclerosis service provision and treatment landscape				
	Sanofi Genzye	Ad hoc consultancy work on multiple sclerosis service provision and treatment landscape				
	Teva	Ad hoc consultancy work on multiple sclerosis service provision and treatment landscape				
	Biogen-Idec	Ad hoc consultancy work on multiple sclerosis service provision and treatment landscape				
Dr Fergus Rugg-Gunn	None	None	None	None	No	None
Professor Peter A G Sandercock	None	None	None	None	No	None
Dr Catherine F Stannard	None	None	None	None	No	None
Professor Eric A Taylor	None	None	None	None	No	I have published books, articles and website pages on ADHD and related topics; some of these contain opinions and some pay royalties (Blackwell Wiley, Oxford University press, MacKeith press). I am, or have recently been, a trustee (unpaid) for: Autistica, National Academy of Parenting Research, Eunethydis International Conferences, Place2Be, Child Psychiatry Research Society. I chair the Professional Advisory Board,

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						Attention Deficit Disorder Advisory Services
Dr Christopher Weir	None	None	Reneuron Ltd	DSMB membership resulting in income to my department	Yes	None
			Celgene	DSMB membership resulting in income to my department	Yes	None

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Martin Gore (Chair)	None	None	None	None	No	None
Mrs Eileen J Barrett	None	None	Multiple companies, see additional information	The companies listed in the additional information section, will have been a client of Source Bioscience Plc at the time of a given CHM meeting but the product of interest on the CHM agenda will not have been relevant to the services or products Source Bioscience Plc was providing to the companies at the time.	No	Abbott Laboratories Limited, Actavis Group PTC EHF, Actavis UK Ltd, AMPAC Fine Chemicals (USA), AMRI Rensselaer, AMRI SSCI LLC, AstraZeneca, Bio Labs Ltd, Biogen Inc, Biooutsource Ltd, BioReliance, Boeringher Ingeleim, Catalent CTS Inc, Catalent Pharma Solutions Limited, Charles River Laboratories, Cipla (EU) Ltd, Colorcon Asia Pvt. Ltd (USA), Covance, Crescent Pharma Limited, CSL Behring, Custom Pharmaceuticals, Dr Reddy's Laboratories Ltd, Exova, GlaxoSmithKline, Great Ormond Street Hospital, Helsinn Birex, King's College London, Lek Pharmaceuticals d.d., Life Technologies, MedImmune, Medreich Plc, Merck Serono Ltd,

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						London, Lek Pharmaceuticals d.d., Life Technologies, MedImmune, Medreich Plc, Merck Serono Ltd, Mercury Pharmaceuticals Ltd, Morningside Healthcare Ltd, Mundipharma GmbH, Novartis Pharma AG, Pantheon Inc, Pfizer Ltd, Reckitt Benckiser Healthcare (UK) Limtied, Roche, Roche Products Ltd, SA, Sandoz GmbH, Schering Plough, Select Bio Laboratories Limited, Select Pharma Ltd, SGS M-Scan Ltd, Sigma-Aldrich Corporation, Source Bioscience PLC, Teva UK Limited, University College London, Warner Chilcott UK Ltd, WiXi AppTec Inc
Professor Mark D Bower	ViiV	Speaker fees	None	None	No	None
	Gilead	Speaker fees				
	MSD	Speaker fees				
	Janssen	Speaker fees				
Professor Stephen Devereux	Janssen	Ibrutinib - Speaker fee and accomodation funding Ibrutinib - Consultancy	None	None	No	None
	Gilead	Idelalisib - Consultancy Idelalisib - Speaker fees Idelalisib - Conference registration, travel and accomodation funding				
	BMS	Nivolumab - Consultancy				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF**	**NATURE OF**	**NAME OF**	**NATURE OF**	**WHETHER**	**ADDITIONAL INFORMATION**
	Servier	UCART19 Chimeric antigen receptor T-cells - Consultancy				
Dr Hugo Ford	None	None	None	None	No	None
Dr Chris Gallagher	None	None	None	None	No	None
Professor Angela E Thomas	None	None	None	None	No	None
Professor Hilary Calvert (Invited Expert)						

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Rebecca Mann (Chair)	None	None	None	None	No	None
Dr Eileen M Baildam						
Dr Helen Burdett	None	None	None	None	No	None
Professor J Helen Cross	None	None	Vitaflo	Betashot - research grant to department	Yes	None
			GlaxoSmithKline	Advisory Board - honorarium to department	No	None
			Shire	Buccalam - lecture and advisory board - honorarium to department	No	None
			Eisai	Eslicarbazepine - Advisory Board - honorarium to department	No	None
			Takeda	Advisory Boards - honorarium to department	Yes	None
			Zogenix	Fenfluramine - Advisory Board - honorarium to department	No	None
Dr Steven Cunningham						

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Peter C Hindmarsh	Medtronic Diabetes	Medtronic Insulin Pump - ad hoc consultancy	Diurnal	Chronocort - External Safety monitor for Chronocort clinical trials	Yes	None
Dr Meriel Jenney	None	None	None	None	No	None
Professor Nigel Klein	None	None	None	None	No	None
Dr Rubin Minhas	None	None	None	None	No	None
Professor Marie-Louise Newell	Crucell BVm a Janssen pharmaceutical company of Johnson & Johnson	A new Ebola vaccine - Member of the DSMB of the phase 2 trial	None	None	No	None
Professor Anthony Nunn	None	None	None	None	No	I am a registered scientific expert with EMA and a member of the EMA PDCO Formulation Working Group. I am a PDCO nominee to the EMA excipients working group and the 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 reformulation of a medicine for children with cancer. Nova Laboratories is an industry partner in the project and administers the grant. Through my company 'Tony industry partner in the project and administers the grant.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						Through my company 'Tony Nunn Conulting Ltd' I work with the University of Liverpool (for coordination of research and advice to academic researchers about paediatric formulations) and Alder Hey Children's NHS Foundation Trust, Liverpool (research in paediatric pharmacy and pharmacology - not product specific).
Ms Sara Payne	None	None	None	None	No	My husband (Richard Meade QC) is a barrister who often represents pharmaceutical and other health technology companies in relatinon to their patents, both in UK and EU
Dr Jane Tizard	GlaxoSmithKline	Shares	None	None	No	None
Dr Beverly Tsai-Goodman	None	None	None	None	No	None
Dr Catherine L C Tuleu	Wellcome Trust	Consultancy (advisor for the project mentioned here until 2019) - 13-cis-tetinoic acid (developed by Nova Labs)	Novartis	LMI070 & TMT212 - Consultancy work (palatability assessments in vitro and in vivo)	No	I chair the European Paediatric Formulation Initiative, which is a consortium working in a pre-competitive way on paediatric drug formulations. Members are from academia, hospital pharmacies, pharmaceutical industry (Innovators, Generics, Contract Research Organizations (CRO), Specials and Excipient Manufacturers) with European Medicine Agency (EMA) as an observer. The companies are Novartis, Roche, Sanofi Aventis, Abbvie,
			MercK ag	Praziquantel - Consultancy work (in vitro palatability assessments)	No	
			MSD	Consultancy work (in vitro palatability assessments)	No	

MEMBER	PERSONAL INTERESTS		NON-PERSONAL INTERESTS		WHETHER CURRENT	ADDITIONAL INFORMATION
	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS		
						GlaxoSmithKline, Merch Sharp & Dohme, JenssenR&D, EliLilly, Pfizer. Its main aim and ibjective is to identify/scope issues and challenges in paediatric formulation development in order to raise awareness and facilitate preparation of better/safe medicines for children. No specific products are discussed. I am a recipient of a Bill & Melinda Gates Foundation grant to work on amoxicillin. I am part of the CloSed project. It is a 5-year project funded under the Seventh Framework Programme (FP7) with an international Consortium comprising 10 European partners. The project aims to conduct a multicentre clinical trial of clonidine for Sedation of Paediatric Patients in the Intensive Care Unit. UCL-SoP coordinates the paediatric formulation development, assures IMP is manufactured according to GMP and in a timely manner and makes sure that quality data are completely available for the PUMA application. The trial has barely started and no

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						commercial partner has been identified yet. I am co-supervising 2 EPSRC CDT PhD with GSK as well as one EPSRC CDT PhD
Professor Heather M Wallace	Novabiotics (University spin out company)	Shares less than 0.1% of company shares	None	None	No	None
	Antoxis (University spin out company)	Shares less than 0.1% of company shares				
	Precious Cells (University spin out company)	Shares less than 1% of company shares				
	Cell ProTx (University spin out company)	Director				
Mrs Madeleine Wang	None	None	None	None	No	None
Dr Mark Whiting	None	None	None	None	No	None
Dr Morris Zwi	None	None	None	None	No	None

N.B - Concerning Dr. Rebecca Mann's Personal Interest
The fee was repaid in full in March 2017. Dr Mann took no part in any relevant discussions from 15th March 2017 (when MHRA was made aware of the interest) to 15th June 2017).

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Mr Phil Willan (Chair Pro Tem)	None	None	None	None	No	None
Ms Hellen Adom	None	None	None	None	No	None
Mr David Chandler	None	None	None	None	No	I'm employed by a patient charity, but the charity has a policy not to receive any funding or financial support whether monetary, in kind or via a third parties from pharmaceutical companies or other commercial organisations. Any events of meetings I attend in relatino to my work for the charity are funded by the charity, this includes: registration fees, travel, subsistence and accomodation. My wife also works for the same charity, and the above also applies to her. No other members of my immediate household have any connections or financial interests in the pharmaceutical industry or associated organisation.

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						No other members of my immediate household have any connections or financial interests in the pharmaceutical industry or associated organisation.
Mr John Chapman	None	None	None	None	No	None
Mrs Joyce Epstein	None	None	None	None	No	None
Dr Nicola Jane Gray	None	None	Pfizer Inc USA	Corporate sponsor of annual meeting of an organisation where I am on the board (US Society for Adolescent Health and Medicine), And development of an App for the Organisation	Yes	None
Ms Amanda Hoey	None	None	None	None	No	None
Mrs Farrah Pradhan	None	None	None	None	No	None
Mrs June Rogers	None	None	Ferring	Unrestricted grant towards running of Employiong Charity Disabled Living	No	None
Dr Bella Starling	None	None	Innovative Medicines Joint Undertaking (European Commission and European Federation of Pharmaceutical Industries and Associations)	European Patient Academy on Therapeutic Innovations EUPATI - Grant Beneficiary is University of Manchester. Dr Starling is Workpackage leader/principal investigator for University of Manchester	Yes	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Mrs Anne Joshua (External Expert)	None	None	None	None	No	Husband is Director of a market research company that provides services to the biopharmaceutical global industry
Professor Angus Mackay (External Expert)	None	None	None	None	No	None
Professor Theo Raynor (External Expert)	None	None	AbbVie	Humira, Venetoclax, Kaletra - Advice on wording and layout of patient leaflet	No	
			AstraZeneca	Cediranib, Brilique, Lokelma, Durvalumab - Advice on wording and layout of patient leaflet	No	
			Basilea	Cresemba - Advice on wording and layout of patient leaflet	No	
			Boehringer Ingelheim	Neupro - Advice on wording and layout of patient leaflet	No	
			Catalent Pharma Solutions	Ibuprofen - Advice on wording and layout of patient leaflet	No	
			Clovis Oncology	Roceletinib, Rucaparib - Advice on wording and layout of PIL/patient alert card	No	
			Celgene	Revlimid - Advice on wording and layout of patient leaflet	No	
			Eisai	Fycompa - Advice on wording and layout of patient leaflet		

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Endoceutics	Prasterone - Advice on wording and layout of patient leaflet/IFU		
			Genpact	Mirvaso - Advice on wording and layout of patient leaflet		
			GSK Biologicals	Rotarix, Infantrix, Polio Sabin, Twinrix - Advice on wording and layout of materials for professionals/informed consent forms		
			Ipsen	Xermelo, Lanreotide - Advice on wording and layout of patient leaflet/lay summary		
			Janssen-Cilag	Durogesic, Guselkumab - Advice on wording and layout of patient leaflet		
			Johnson & Johnson	Naproxen Natrium - Advice on wording and layout of patient leaflet		
			MSD	Isentress, Nuvaring - Advice on wording and layout of patient leaflet/IFU/clinical trial lay summary		
			Mylan	Supralip - Advice on wording and layout of patient leaflet		
			Novartis	Midostaurin, Lucentis, Ilaris, Ribociclib - Advice on wording and layout of patient leaflet/IFU		

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Novo Nordisk	Ozempic - Advice on wording and layout of patient leaflet/pack/informed consent forms		
			Oystershell	Pixie - Advice on wording and layout of IFU		
			Oxon	Dronedarone - Advice on wording and layout of educational materials for health professionals		
			Roche	Atezolizumab, Ocrevus - Advice on wording and layout of patient leaflet		
			Portsmouth NHS Trust	NOACs - Expert review of booklet		
			Puma Biotech	Neratinib - Advice on wording and layout of patient leaflet		
			Sanofi Aventis	Tadalafil, Soliqua, Kevzara, Valproate, Dupilumab, Lovenox - Advice on wording and layout of patient leaflet/pack/IFU		
			Shire	Revestive - Advice on wording and layout of patient leaflet/IFU		
			Santhera	Raxone - Advice on wording and layout of patient leaflet		
			UCB Pharma	Cimzia, Keppra, Vimpat - Advice on wording and layout of patient leaflet/IFU		

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Ultragenyx	Acenueramic acid - Advice on wording and layout of patient leaflet		
Carolyn, Lady Roberts (External Expert)	None	None	None	None	No	Member of Council, University of Hull

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Munir Pirmohamed (Chair)	None	None	Pfizer	Research grant to look at mechanisms of TKI-induced diarrhoea	No	None
			Roche	Research grant to support clinical training fellowships jointly with MRC	Yes	
			Eli Lilly	Research grant to support clinical training fellowships jointly with MRC	Yes	
			UCB Pharma	Research grant to support clinical training fellowships jointly with MRC	Yes	
			Novartis	Research grant to support clinical training fellowships jointly with MRC	Yes	
Dr Robert C G Bracchi	None	None	None	None	No	Presentations given to meetings sponsored by companies but no renumeration of any kind received. 19/10/2016 - National Prescribing Society meeting - Talk given on Adverse Drug

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						Reaction Reporting - meeting sponsored by NAPP. 17/11/2016 - Genetic Alliance Meeting - Talk given on the All Wales Medicines Strategy Group Appraisal Process - meeting sponsored by Pfizer, Genzyme, Novartis
Professor Jamie Coleman	None	None	None	None	No	None
Dr William Dixon	None	None	None	None	No	None
Dr Ian J Douglas	GlaxoSmithKline	Shares	None	None	No	None
	GlaxoSmithKline	Grant to LSHTM that pays my salary				
	Gilead	Consultancy on various topics - Ledipasvir, Sofosbuvir, Tenofovir, Emtricitabine				
Professor Alison B Ewing	None	None	None	None	No	None
Ms Amanda Lee	None	None	None	None	No	None
Professor Glyn Lewis	GlaxoSmithKline	Paroxetine - I am involved as an expert witness and have received payment from solicitors acting in a group litigation against GSK in relation to withdrawal effects from Paroxetine.	None	None	No	None
Professor Simon R J Maxwell	None	None	None	None	No	None
Dr Karen Miller	None	None	None	None	No	None
Dr Nicholas J Plant	None	None	AstraZeneca	BBSRC-CASE funded PhD student	Yes	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			GlaxoSmithKline	BBSRC-CASE funded PhD student	Yes	
			Breast Cancer Now	PhD Student	Yes	
Ms Christine Randall	None	None	Sanofi	Funding of training courses for NHS Deputy Chief Pharmacists (3 one day sessions held in 2016)	No	None
			Astellas	Sponsorship of North West Chief Pharmacists meeting (lunch and room hire)	No	None
Dr Ruben Thanacoody	None	None	None	None	No	None
Dr Caroline Vaughan	None	None	None	None	No	None
Mr Phil Willan	None	None	None	None	No	None

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Kevin M G Taylor (Chair)	None	None	AstraZeneca	Contribution to EPSRC Doctoral Training Centre in my department	Yes	None
			Boots	Contribution to EPSRC Doctoral Training Centre in my department	Yes	
			Pfizer	Contribution to EPSRC Doctoral Training Centre in my department	Yes	
			GlaxoSmithKline	Contribution to EPSRC Doctoral Training Centre in my department	Yes	
			Quadrant	Contribution to EPSRC Doctoral Training Centre in my department	Yes	
Dr Martin Duerden	Reckitt Beckinser	Paid consultancy fee to complete online questionnaires regarding future development of E45 range	None	None	No	None
	Lilly	Paid consultancy fee and travelling expenses to attend advisory meeting on a new rheumatology drug 'in the pipleline'				
Ruth Wakeman	None	None	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Mrs Anne Cawdron (Invited Expert)	None	None	None	None	No	None
Ms Lillian Ethapemi (Invited Expert)	Astellas Pharma Ltd	Lecture	None	None	No	None
Ms Elaine Hazell (Invited Expert)	Astellas	Conference fees and travel expenses	None	None	No	None
Dr Karen Miller (Invited Expert)	None	None	None	None	No	None

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Ailsa Gebbie (Chair)	None	None	None	None	No	None
Professor Pat Doyle	None	None	None	None	No	None
Mrs Joyce Epstein	None	None	None	None	No	None
Professor Joyce Harper	None	None	None	None	No	None
Professor Axel Heep	None	None	None	None	No	None
Professor Stephen Hillier	None	None	None	None	No	None
Professor Alison Macfarlane	None	None	None	None	No	I have a portfolio of shares maintained by Natwest Bank, which sometimes includes shares in pharmaceutical companies.
Ms Sara Payne	None	None	None	None	No	My husband (Richard Meade QC) is a barrister who often represents pharmaceutical and other health technology companies in relatinon to their patents, both in UK and EU
Mrs Farrah Pradhan	None	None	None	None	No	None
Professor Siobhan Quenby	Ferring	Speaker fee for conferences not about a drug, but about recurrent miscarriage x2	None	None	No	None
	Clear Blue Advisory Board	Fee for advising company for one day - HCG-based Pregnancy Tests & Ovulation Kits				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Richard Quinton	None	None	None	None	No	Eli Lilli (UK) funded his attendance at their annual UKCDF symposium in 2016
Dr Connie Smith	None	None	None	None	No	None
Professor Michael D Threadgill	None	None	None	None	No	In respect of my membership of HPTWG, I made the following declaration when I joined. This declaration stands unaltered. "I have no current coflicts of interest for any of the companies and other bodies concerned and I have not been involved in any campaigning or strong opinions in this area. For the sake of completeness, I declare that my research group collaborated with and received a small (approx £2000) amount of research funding from Sterling Winthrop 1992-1995 on a project to assay theophylline in biosamples for patients being treated with asthma and related disorders (nothing to do with pregnancy testing); part of Sterling Winthrop went on to become part of Sanofi a few years alter. This relationship ceased over twenty years ago when the project ended". I have nil additional information to declare in respect of CPSEAG.
Dr Diana Wellesley	None	None	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Anne Connolly (Invited Expert)	Bayer	Payments for lecturing on seven occasions - Mirena	None	None	No	None
	Bayer	Educationalgrant to attend European Contracteption Soceity conference - Mirena				
	MSD	Payments for lecturing on two occasions - Naxplanon				
	Pfizer	Payment for consultancy - Sayana Press				
	Pfizer	Payment for lecture - Sayana Press				
	MSD	Payment for consultancy - Nexplanon				
Mr Nick Dobrik (Invited Expert)	None	None	None	None	No	None
Professor Helen Dolk (Invited Expert)	None	None	GlaxoSmithKline	Research grant to invesigate whether lamotrigine is associated with an increased risk of orofacial clefts.	No	None
Professor Stephen Evans (Invited Expert)	None	None	None	None	No	LSHTM receives grants from a number of companies but I have no knowledge of them; my salary and research are not funded by any of them.
Professor Kay Marshall (Invited Expert)	None	None	None	None	No	None
Dr Irene Petersen (Invited Expert)	None	None	Pfizer	The Department of Clinical Epidemiology, Aarhus University Denmark holds a	Yes	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
				contract with Pfizer. I am not involved in any work related to this contract.		
Professor Shirley Price (Invited Expert)	None	None	None	None	No	None
Professor Dr med Christof Schaefer (Invited Expert)	None	None	None	None	No	None
Professor Faith Williams (Invited Expert)	GlaxoSmithKline	Shares, which are held through a nominee company of HSBC bank plc.	None	None	No	None
Dr Laura M Yates (Invited Expert)	None	None	None	None	No	None

INDEPENDENT PRESCRIBING AD HOC GROUP: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr J Colin Forfar (Chair) Dr John Black	None	None	None	None	No	None
Professor Jamie Coleman	None	None	None	None	No	None
Mr Sultan (Sid) Dajani	Ceuta	Vamousse - Consultancy	None	None	No	None
Dr Gillian M Hawksworth	None	None	None	None	No	None
Dr Jamie Fraser	Internis	The company paid my travel, accomodation and conference fees so I could attend the 2016 National Osteoporosis Conference Birmingham, UK	None	None	No	None
Dr Clifford Mann	None	None	None	None	No	None
Dr Rebecca Mann	None	None	None	None	No	None
Dr Karen Miller	None	None	None	None	No	None
Dr John Reynolds	Quintiles-IMS	Fees - Chairman of Independent Scientific and Ethics Advisory Committee	None	None	No	None
	Evidera Consultancy	Fees - Ad hoc consultancy work related to NHS commissioning				
Dr Raman Uberoi	Bolton Medical	Aortic stentfrafts - support to attend the BSIR annual conference	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Helen M Ward	None	None	None	None	No	None
Professor Anthony G Wilson	Novartis	Support to attend EULAR AGM, London	None	None	No	None

N.B - Concerning Dr. Jamie Fraser's Personal Interest
Travel, accomodation and conference fees were repaid in full in February 2017. Dr Fraser took no part in any relevant discussions from 26th January (when MHRA was made aware of the interest) to 26th April 2017.

N.B - Concerning Dr. Rebecca Mann's Personal Interest
The fee was repaid in full in March 2017. Dr Mann took no part in any relevant discussions from 15th March 2017 (when MHRA was made aware of the interest) to 15th June 2017).

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Sir Ian V D Weller (Chair)	None	None	None	None	No	None
Mr Simon Denegri	None	None	None	None	No	My role as NIHR National Director for Patients and the Public in Research and Chair of INVOLVE bring me into frequent contact with the pharmaceutical industry and other elements of the private sector. This includes attendence at meetings and events and some collaborative activity to promote patient and carer interests.
Professor Stephen Evans	None	None	None	None	No	LSHTM receives grants from a number of companies but I have no knowledge of them; my salary and research are not funded by any of them.
Dr Jamie Fraser	Internis	The company paid my travel, accomodation and conference fees so I could attend the 2016 National Osteoporosis Conference Birmingham, UK	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Marianne Gillings	None	None	None	None	No	None
Professor Keith Hawton	None	None	None	None	No	None
Dr Corinne Hayes	None	None	None	None	No	None
Dr Clifford Mann	None	None	None	None	No	None
Dr Rebecca Maxwell	None	None	None	None	No	None
Professor Kevin Moore	Servier	Consultancy Work	None	None	No	None
	Cumberland Pharmaceuticals	Consultancy Work	None	None	No	None
Mr Jerry Nolan						
Professor David G C Owens	None	None	None	None	No	None
Professor B Kevin Park	None	None	Merck & Co. (USA)	Donation for the support of the Centre for Drug Safety (PI Grant)	No	None
			Astra Zeneca Ltd (UK)	North West England MRC Fellowships in Clinical Pharmacology and Therapeutics (CO-I Grant)	Yes	
			GlaxoSmithKline Research & Development Ltd (UK)	North West England MRC Fellowships in Clinical Pharmacology and Therapeutics (CO-I Grant)	Yes	
			Icon Clinical Research Ltd (UK)	North West England MRC Fellowships in Clinical Pharmacology and Therapeutics (CO-I Grant)	Yes	
			Janssen Pharmaceuticals (Belgium)	Mechanism-based integrated systems for the predication of drug-induced liver injury (MIP-DILI) (PI Grant)	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Wellcome Trust (UK)	YEAR 1 Wellcome Trust ISSF Non-Clinical Fellowships (PI Grant)	Yes	
			GlaxoSmithKline Research & Development Ltd (UK)	Quantitative assessment of drug-protein adduct formation and function (PI Grant)	Yes	
			Amgen Ltd (UK)	Generation and Validation of Models to Probe Keap1 Adducation as a Marker of the Hepatotoxic Liability of Drug Candidates (PI Grant)	Yes	
			Medicines Evaluation Unit Ltd (UK)	North West England MRC Fellowships in Clinical Pharmacology and Therapeutics (CO-I Grant)	Yes	
Professor Munir Pirmohamed	None	None	Pfizer	Research grant to look at mechanisms of TKI-induced diarrhoea	No	None
			Roche	Research grant to support clinical training fellowships jointly with MRC	Yes	
			Eli Lilly	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**
			Novartis	Research grant to support clinical training fellowships jointly with MRC	Yes	
Carolyn, Lady Roberts	None	None	None	None	No	Member of Council, University of Hull
Dr J P Thompson	None	None	None	None	No	None
Dr Christopher Weir	None	None	Reneuron Ltd	DSMB membership resulting in income to my department	Yes	None
			Celgene	DSMB membership resulting in income to my department	Yes	None
Professor Nicholas (Nick) Bateman (Invited Expert)	None	None	None	None	No	Lead Author of Scottish and Newcastle Anti-emetic Pre-treatment for paracetamol poisoning (SNAP) study, published in 2014 in the Lancet 383, 697-704
Professor Kim Dalhoff (Invited Expert)	None	None	None	None	No	None
Professor Paul Dargan (Invited Expert)	None	None	None	None	No	None
Professor David Gunnell (Invited Expert)	None	None	None	None	No	I have carried out research work on paracetamol and self-harm (see list of papers below). The research relates to: the burden of paracetamol suicide; investigating associations between ease of availability of paracetamol and its use for suicide/self-harm; speculating about possible impacts of restricting the amount of paracetamol available in retail

MEMBER	PERSONAL INTERESTS		NON-PERSONAL INTERESTS		WHETHER CURRENT	ADDITIONAL INFORMATION
	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS		
						outlets as a suicide prevention strategy; looking at the impact of sales restrictions on paracetamol related harm in the UK (suicide/self-harm/liver transplant). In one paper we described ADRs associated with NAC administration in Bristol and specialated about the likely impact of revised NAC treatment guidelines. I;ve not been involved in any trials of different doses/administration schedules for NAC. Gunnell D, Frankel S. Prevention of suicide: aspirations and evidence. BMJ 1994; 308: 1227-1233. PMID: 8080520 Gunnell D, Hawton K, Murray V, Garnier R, Bismuth C, Fagg J, Simkin S. Use of paracetamol for suicide and non-fatal self poisining in te UK and France: are restrictions on availability justified? J Epidemiol Comm Health 1997; 51: 175-179. Gunnel D, Murray V, Kawton K. Use of paracetamol for suicide and non-fatal poisoning: world-wide patterns of use and misuse. Suicide and Life threatening Behaviour 2000; 30(4): 313-326.

MEMBER	PERSONAL INTERESTS		NON-PERSONAL INTERESTS		WHETHER CURRENT	ADDITIONAL INFORMATION
	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS		
						Hawton K, Twonsend E, Deeks J, Appleby L, Gunnell D, Bennewith O, Cooper J. Effects of change in legislation on pack size of paracetamol and salicylate on self-poisoning in the United Kingdom: before and after study. BMJ 2001; 322: 1203-7. Simkin S, Hawton K, Kapur N, Gunnell D. What can be done to reduce mortality from paracetamol overdoses? A patient interview study. Q J Med 2012; 105: 41-51. DOI: 10.1093/qjmed/hcr135. PMID: 21826743 Hawton K, Bergen H, Simkin S, Arensman E, Corcoran P, Cooper J, Waters K, Gunnell D, Kapur N. Impact on different pack sizes of paracetamol in the United Kingdom and Ireland on intentional overdoses: a comparative study. BMC Public Health 2011; 11: 460. DOI: 10.1186/1471-2458-11-460. PMID: 21663604 Hawton K, Bergen H, Simkin S, Dodd S, Pocock P, Bernal W, Gunnell D, Kapur N. Reduced pack sizes of paracetamol: time-series analysis of long-term impacts on poisoning deaths and liver transplant

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						activity in England and Wales: interrupted time series analysis. BMJ 2013; 346: f403. DOI: 10.1136/bmj.f403. PMID: 23393081 Carrol R, Benger J, Gibbard K, Williams S, Griffin L, Potokar J, Gunnell D. Epidemiology, management and outcome of paracetamol poisoning in an inner city emergency department. Emerency Medical Journal 2015: 32: 1550-60. DOI 10.1136/emermed-2013/2020518. Epub 2013 Oct 7. PMID: 24099830 Buckley N, Gunnel D. Does restricting pack size of paracetamol (acetaminophen) reduce suicidies? PloS Medicine 2007;4:152/3 Gunnel D. Paracetamol recall: a natural experiment inflencing analgesic poisoning. Med J Aust 2002;561-2 (letter)
Professor Laurie Prescott (Invited Expert)	None	None	None	None	No	None
Professor Simon H L Thomas (Invited Expert)	None	None	None	None	No	None

N.B - Concerning Dr. Jamie Fraser's Personal Interest
Travel, accomodation and conference fees were repaid in full in February 2017. Dr Fraser took no part in any relevant discussions from 26th January (when MHRA was made aware of the interest) to 26th April 2017.

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Kevin M G Taylor (Chair)	None	None	AstraZeneca	Contribution to EPSRC Doctoral Training Centre in my department	Yes	None
			Boots	Contribution to EPSRC Doctoral Training Centre in my department	Yes	
			Pfizer	Contribution to EPSRC Doctoral Training Centre in my department	Yes	
			GlaxoSmithKline	Contribution to EPSRC Doctoral Training Centre in my department	Yes	
			Quadrant	Contribution to EPSRC Doctoral Training Centre in my department	Yes	
Dr Martin Duerden	Reckitt Beckinser	Paid consultancy fee to complete online questionnaires regarding future development of E45 range	None	None	No	None
	Lilly	Paid consultancy fee and travelling expenses to attend advisory meeting on a new rheumatology drug 'in the pipleline'				
Ruth Wakeman	None	None	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr Robert Bracchi (Invited Expert)	None	None	None	None	No	Presentations given to meetings sponsored by companies but no renumeration of any kind received. 19/10/2016 - National Prescribing Society meeting - Talk given on Adverse Drug Reaction Reporting - meeting sponsored by NAPP. 17/11/2016 - Genetic Alliance Meeting - Talk given on the All Wales Medicines Strategy Group Appraisal Process - meeting sponsored by Pfizer, Genzyme, Novartis
Ms Karen Briggs (Invited Expert)	None	None	None	None	No	None
Mrs Anne Cawdron (Invited Expert)	None	None	None	None	No	None
Dr David Edwards (Invited Experts)	Bayer	Lecturing, travel & accomodation				I am a member of the British Society for Sexual Medicine. We have received funds from a number of Pharmaceutical companies. This sponsorship is used to help finance conferences in particular to partially fund attendance of such educational congresses connected with the BSSM for junior doctors in training. In addition, I am chair of the primary care testosterone advisory group which is funded predominantly be Besins. In the past I have been a member of
	Besins	Lecturing, travel & accomodation				
	Eli Lilly	Lecturing, travel & accomodation				
	Pfizer	Lecturing, travel & accomodation				
	Menarini	Lecturing, travel & accomodation				
	Yes	Lecturing, travel & accomodation				
	Takeda	Lecturing, travel & accomodation				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Owen Mumford	Lecturing, travel & accomodation				the men's health expert policy group and committee member on various NICE guidelines.
Ms Sue Thompson (Invited Expert)	None	None	None	None	No	None
Mr Hadar Zaman (Invited Experts)	None	None	None	None	No	None

EXTERNAL EXPERTS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Leon Aarons	Eli Lilly	Consultancy	AstraZeneca	Research Funding	Yes	None
			AstraZeneca	Case Studentship	Yes	
			Eli Lilly	Research Funding	Yes	
			Pfizer	Research Funding	Yes	
Professor D John Betteridge						
Prof Chris Chapple	Allergan	Meeting participant/Lecturer, Consultant/Advisor	Allergan	Scientific study/Trial (Researcher/Author)	Yes	None
	Astellas	Meeting participant/Lecturer, Consultant/Advisor	Astellas	Scientific study/Trial (Researcher/Author)	Yes	
	Boston Scientific	Meeting participant/Lecturer	Recordati	Scientific study/Trial (Researcher/Author)	Yes	
	Medtronic Inc	Consultant/Advisor				
	Recordati	Consultant/Advisor				
Professor Peter Clayton	Pfizer	Growth Hormone - Travel to meeting (EndoConnect) and Honorarium for lecture Growth Hormone - Travel to meeting (Best Practice and Controversies in Paediatric Endocrinology) and Honorarium for lecture	Ammonnett Pharma (LLC)	MK677 (Growth hormone secretagogue) - Consultancy, advising on design of clinical trial	Yes	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	NovoNordisk	Growth Hormone - Travel to meeting (Asia-Pacific Paediatric Endocrine Society Annual meeting) and Honorarium for Lecure				
Dr Thomas Clutton-Brock	EMAS Pharma	Unpaid consultancy, expenses only	None	None	No	Clinical director, NIHR Trauma Management Healthcare Technology Cooperative (mainly devices, some IVD, occasional drug-device combinations) - Director, ERDF Medical Devices Testing and Evaluation Centre, Birmingham (Mainly devices, some IVD, may include druf-device combinations)
	NAMSA (CRO)	Traval to Advamed Conference, USA				Deputy Director, Institute of Translational Medicine, Birmingham (Mainly devices, some IVD, may include drug-device combinations) - Chaire, NICE Interventional Procedures Advisory Committee (Mainly devices, some IVD, may include drug-device combinations)
Professor Peter Crome	None	None	None	None	No	None
Professor Karen Forbes	None	None	None	None	No	None
Dr Robin Grant	None	None	UCB	Lacosamide - UK Lead on a Planned RCT of Lacosamide vs Placebo as Prophylaxis in Patients with Glioblastoma who do not have epilepsy	Yes	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			UCB	Lacosamide - European Lead on a Non-Intervention Study of Efficacy and Side Effects in Low Grade Glioma patients with Epilepsy	Yes	
Dr Clive Grattan	Novartis	Omalizumab - Meeting Chair and Advisory Panel	None	None	No	None
	CSL Behring	CSL830 trial - Chair Data Safety Monitoring Board				
Professor Paul Griffiths	None	None	None	None	No	None
Professor Nedim Hadzic	Alnylam Pharma, Cambridge, MA, USA	Ad hoc consultant	None	None	No	None
	Alexion Pharmaceuticals, UK	Lecture fee				
Professor Freddie Hamdy	Ferring Pharmaceuticals	Attendance at Scientific Advisory Board	None	None	No	None
	MDxHealth S.A,	Attendance at Scientific Advisory Board				
Dr Nigel Hoggard	None	None	None	None	No	None
Professor David Isenberg	Merck-Serono	Atacicept - I ask for my fees to be paid to a local arthritis charity	None	None	No	None
	Immupharma	Genetech (re development of Bruton's kinase inhibitor antagonist) - I ask for my fees to be paid to a local arthritis charity				
	Astra Zeneca	Anifrolumab - I ask for my fees to be paid to a local arthritis charity				
Professor Colin Kennedy	None	None	None	None	None	None
Professor Karen Luker	None	None	None	None	No	None
Professor Robert	None	None	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Professor Stephen Powis	None	None	None	None	No	None
Professor Shakeel Qureshi	NuMED Inc, Hopkinton, New York, USA	Consultancy - Paediatric cardiology related balloons and stents	None	None	No	None
	Medtronic Inc	Proctor on an ad hoc basis - melody valve				
	Venus Medtech China	Consultancy - Venus P-valve				
	Occltech Inc	Proctor on an ad hoc basis - Occlutech occlusion devices				
Professor Amin Rostami	Certara	Shares via Certara's Holding Company, contribution to university salary	Simmons & Simmons LLP working on behalf of Eli Lilly	Consultancy Fee	No	Patent consultancy matter
	Diurnal	Shares				The following Pharmaceutical companies are part of the Simcyp Consortium and they are relied on to fund research in Simcyp:
	Zilico	Shares & a Non-Exec Director				Abbvie, Actelion, Amgen, Astellas Pharma Inc., AstraZeneca, Biogen Idec, Bristol Myers Squibb, Celgene Corporation, Daiichi-Sankyo, Dainippon-Sumitomo, Eisai, Eli Lilly, F. Hoffmann-La Roche Ltd, Forest Laboratories, GlaxoSmithKline, Grunenthal, H Lundbeck A/S, Johnson & Johnson Pharmaceutical Research & Development, Merck & Co., Merck KGaA, Nektar Therapeutics, Novartis

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						Pharma, Ono Pharmaceutical Co, Otsuka Pharmaceutical Group, Pfizer, Sanofi-aventis, Servier, Shionogi & Co., Taisho Pharmaceutical, Takeda, UCB Pharma, Vertex Pharmaceuticals. Prof Rostami-Hodjegan is also a member of the Centre for Applied Pharmacokinetic Research (CAPKR) group at the University of Manchester. CAPKR is a consortium operating in collaboration with, and supported by the pharmaceutical industry. CAPKR's industrial consortium members represent the following pharmaceutical companies: GlaxoSmithKline, Janssen Pharmaceutica NV, Eli Lilly, Pfizer.
Dr Lindsey Rylah	None	None	None	None	No	None
Dr Andrew Scarsbrook	None	None	None	None	No	None
Professor Alan Smyth	PTC Vertex	Consultancy Consultancy	Vertex	Consultancy	Yes	Orkambi (Ivacaftor/Lumacaftor)
Dr Neil Soni	None	None	None	None	No	None
Professor Paul Stewart	None	None	None	None	No	None
Professor Roger Sturrock	None	None	None	None	No	None
Professor Gilbert Thompson	Novartis Aegerion UK	Alisporivir - Member, Data & Safety Monitoring Committee Lomitapide - Consultancy	None	None	No	Shares held by GRT in AstraZeneca and GlaxoSmithKline

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Aegerion US	Lomitapide - Chairman, Data & Safety Monitoring Committee				
Dr Alison Thomson	GlaxoSmithKline	Education of GSK staff who are undertaking a part-time Mphil or PhD degree at the University of Strathclyde. During 2016, co-supervised a member of GSK staff, who is undertaking a part-time PhD. Received no fees, salary of grants for this work, which is conducted as part of contract at the University of Strathclyde	GlaxoSmithKline	Agreement between the University of Strathclyde Institute of Pharmacy and Biomedical Sciences to provide training for GSK staff leading to a master of philosophy or doctor of philosophy degree.	Yes	Husband provides occasional consultancy services to the Pharmaceutical Industry. In the past year, he has undertaken research, and provided educational sessions and consultancy advice for Bayer.
Dr David Tuthill	Time for Medicine	Unpaid director and advisor	None	None	No	None
	Mead Johnson	Advisory board member, periodic advice and speaker fees				
	Pfizer	Periodic advice and occasional speaker fees				
	Wyeth	Periodic advice and occasional speaker fees				
	Nestle	Periodic advice and occasional speaker fees				
	MSD	Periodic advice and occasional speaker fees				
	Meda	Advice on Epipen consultancy				
	Cardiff Paediatrics	Working as a Doctor and Director				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr David Wheeler	Amgen	Etelcaclitide - Consultancy, Speaker Fees	None	None	No	None
	Boehringer Ingelheim	Empagliflozin - Consultancy				
	Akebia	HIF Stabilizer - Consultancy				
	UCB Celltech	Consultancy				
	Vifor Fresenius	Ferrinject Patiromer - Consultancy, Speaker Fees				
	Otsuka	Tolvaptan - Consultancy				
	Janssen	Canagliflozin - Consultancy				
	ZS Pharma	Sodium Zirconium Cyclosilicate - Consultancy				
	AstraZeneca	Dapagliflozin - Consultancy				
Dr Alistair R W Williams	Bayer	Viliprisan - Consultancy	None	None	No	None
	HRA Pharma	Ulipristal acetate - Consultancy				
	Gedeon Richter	Ulipristal acetate (Esmya) - Consultancy				
Professor Sir Nicholas Wright	None	None	None	None	No	None

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Prof K Taylor (Chair)	None	None	AstraZeneca	Contribution to EPSRC Doctoral Training Centre in own department	Yes	None
			Boots	Contribution to EPSRC Doctoral Training Centre in own department	Yes	
			GlaxoSmithKline	Contribution to EPSRC Doctoral Training Centre in own department	Yes	
			Pfizer	Contribution to EPSRC Doctoral Training Centre in own department	Yes	
			Quadrant	Contribution to EPSRC Doctoral Training Centre in own department	Yes	
Prof M Almond	GlaxoSmithKline	Salary, Shares (family member)	None	None	No	None
Dr J Beaman	Pfizer	Salary, Shares	None	None	No	None
Dr A-M Brady	AstraZeneca GlaxoSmithKline Vernalis	Shares (family member) Shares (family member) Shares (family member)	Biologicals journal	Associate Editor (unpaid)	Yes	None
Dr G D Cook	Pfizer	Salary, Shares	None	None	No	None
Mr A Coulson	Pfizer (formerly Upjohn)	Pension	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	LabCorp (formerly Covance Ltd)	Pension				
	Veterinary Medicines Directorate	Non-Executive Director; meeting fees				
Prof A G Davidson (Vice-Chair)	None		None	None	No	None
Dr A Gleadle	Tesco PLC	Shares	None	None	No	None
Dr R L Horder	Abbott Laboratories	Shares	None	None	No	None
	AbbVie	Shares				
Dr M G Lee	None		None	None	No	None
Mr R Lowe	None		None	None	No	None
Dr B R Matthews	Alcon	Consultancy	None	None	No	None
	Association of Contact Lens Manufacturers	Consultancy				
	Association of British Healthcare Industries	Consultancy				
	Pharmaceutical Development Services	Consultancy				
Prof J Miller	None	None	None	None	No	None
Ms S Palser	None	None	None	None	No	None
Prof M Simmonds	None	None	College of Medicine	Member	Yes	None
			Hong Kong Department of Health - Pharmacopoeia International Advisory Committee	Member	Yes	
			Walgreen Boots Alliance	Research Grant	Yes	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Dr R Torano	GlaxoSmithKline	Salary, Shares	None	None	No	None
Dr P Varley	MedImmune AstraZeneca	Salary, Shares	None	None	No	None

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