Human Medicines Regulations 2012 Advisory Bodies

Annual Report 2019

Commission on Human Medicines

British Pharmacopoeia Commission

Medicines & Healthcare products Regulatory Agency

HUMAN MEDICINES REGULATIONS 2012
ADVISORY BODIES ANNUAL REPORT 2019

Laid before Parliament pursuant to Part 2, Regulation 12 (4) of the Human Medicines Regulations 2012

Commission on Human Medicines

British Pharmacopoeia Commission

Published by the Medicine & Healthcare products Regulatory Agency

This publication is available at **https://www.gov.uk/mhra**

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

Medicines & Healthcare products Regulatory Agency
Customer Services
10 South Colonnade
Canary Wharf
London E14 4PU

Tel: 020 3080 6000

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

ISBN 978-1-900731-19-5

Printed on paper containing 75% recycled fibre content minimum

Printed in the UK by the APS Group on behalf of the Controller of Her Majesty's Stationery Office

LIST OF CONTENTS

FOREWORD BY THE PARLIAMENTARY UNDER SECRETARY OF STATE FOR LIFE SCIENCES

It gives me great pleasure to present the annual reports for 2019 of the Human Medicines Regulations Advisory Bodies: the Commission on Human Medicines and the British Pharmacopoeia Commission. These reports include a record of members' interests in the pharmaceutical industry and code of practice.

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

Lord Bethell

COMMISSION ON HUMAN MEDICINES ANNUAL REPORT 2019

TERMS OF REFERENCE

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

2. The functions of the Commission on Human Medicines are:

    - to advise the Health Ministers and the Licensing Authority (LA) on matters relating to human medicinal products including giving advice in relation to the safety, quality and efficacy of human medicinal products where either the Commission thinks it appropriate or where it is asked to do so;

    - to consider those applications that lead to LA action as appropriate (i.e. where the LA has a statutory duty to refer or chooses to do so);

    - to consider representations made (either in writing or at a hearing) by an applicant or by a licence or marketing authorisation holder in certain circumstances;

    - to promote the collection and investigation of information relating to adverse reactions to human medicines for the purposes of enabling such advice to be given.

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

MEMBERSHIP

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

4. The Commission warmly congratulates **Professor Yvonne Perrie**, member of the Commission on Human Medicines' Chemistry, Pharmacy and Standards Expert Advisory Group, on receiving the Harrison Memorial Medal, in recognition of her outstanding contribution in advancing pharmaceutical science.

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

Expert Advisory Groups 2019

Cardiovascular, Diabetes, Renal, Respiratory and Allergy (CDRRAEAG)
Chaired by **Professor Jamie Coleman**

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

Clinical Trials, Biologicals & Vaccines (CTBVEAG)
Chaired by **Dr Siraj Misbah**

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 Angela E Thomas**

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

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

Working Groups 2019

E-Cigarettes Working Group
Chaired by **Professor Angela E Thomas**

Avastin Peer Review Group
Chaired by **Professor Kevin Taylor**

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

MEETINGS

7. The Commission held 11 meetings during 2019. Two-day meetings were held in January, May, June, July, September, November and December. One day meetings normally lasted between five and six hours. Meetings were held at the Medicines and Healthcare Products Regulatory Agency (MHRA), 10 South Colonnade, London, E14 4PU, United Kingdom.

SECRETARIAT

8. 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

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

FIRST CONSIDERATION BY THE COMMISSION

10. The Commission considered and advised on a total of 219 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	**2**	**29**
Abridged Applications	**17**	**143**

11. The Commission was extensively involved in applications made through the European Centralised Procedure. The Commission considered 34 new active substances, or new combinations of active substances, via the Centralised Procedure.

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

13. The Commission considered an average of 20 applications at each of its 11 meetings in 2019, in addition to clinical trial applications, appeals, reclassifications, pharmacovigilance issues and other matters.

APPEALS

14. The Commission considered four oral hearings, which covered two National applications, one Reclassification application and one Risk Assessment Review. The Commission advised against the grant of a marketing authorisation for the national applications and advised the grant of the reclassification application. Lastly, for the Risk Assessment Review, the benefit: risk balance did not remain positive.

15. The Commission considered a total of 25 written representations covering 46 applications. Of these, the Commission advised that marketing authorisations could be granted for one and granted subject to the resolution of the outstanding concerns for 26. For the remaining 19, the Commission advised against the grant of marketing authorisations.

EXTERNAL EXPERTS AND STAKEHOLDERS

16. The Commission received the following external experts who contributed to discussions:

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

Dr Kristien Boelaert MD, PhD, MRCP
Reader in Endocrinology, University of Birmingham & practising Consultant Endocrinologist in charge of the Thyroid Services at the UHB NHS Foundation Trust
(February)

Dr Maria Eugenicos MD MSC(Ed) PhD FHEA
Senior Lecturer/Gastroenterologist
Gastroenterology Department
Western General Hospital
(September)

Dr Chris Gallagher BSc PhD FRCP
Consultant Medical Oncologist, St Bartholomew's Hospital, Barts and the London NHS Trust and Member of the Oncology and Haematology Expert Advisory Group (OHEAG)
(July and October)

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
(April and July)

Professor Philip Hannaford MB ChB DRCOG DCH MD FRCGP FFSRH FFPH Professor of Epidemiology, Interim Senior Vice-Principal University of Aberdeen
(April)

Mrs Melanie Hingorani
Consultant Ophthalmologist, Moorfields Eye Hospital
(November)

Ms Claire Liew
from the Pharmacist Medicine Supply team
Medicines and Pharmacy Directorate, Department of Health and Social Care (DHSC), London
(December)

Professor Christopher Marriott PhD DSc Hon DSc FRPharmS CChem FRSC FRSM
Emeritus Professor of Pharmaceutics, King's College, London – Member of CPSEAG
(February, March and June)

Ms Sarah McAleer
from the Pharmacist Medicine Supply team
Medicines and Pharmacy Directorate, Department of Health and Social Care (DHSC), London
(December)

Professor Poulam M Patel PhD FRCP
Professor of Clinical Oncology, Academic Unit of Clinical Oncology, University of Nottingham
(November)

Dr Edward Seward BSc MBChB FRCP MD
Consultant Gastroenterologist
University College London Hospital
(May)

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

Professor Angela E Thomas OBE MB BS PhD FRCPE FRCPath
Consultant Paediatric Haematologist, Edinburgh
(March, May, July, October and November)

17. The Commission received the following observers to its meetings:

Dr Jonathan Crofts
Public Health England
(October)

Mrs Jenna Dilkes
Programme Manager, Technology Appraisals
National Institute for Health and Care Excellence (NICE)
(February, March, May, July, September, October and November)

Ms Maria Jose Vincente-Edo RMN BSc MA PhD
Health Technology Assessment Methodologist
Aragon Health Sciences Institute (IACS), Spain
(October)

Dr Aiden Fowler
NHS England
(June)

Ms Helen Jukes
CVMP member for the UK, Authorisations Division, Veterinary Medicines Directorate
(April)

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

Ms Jenniffer Prescott
Associate Director – Planning, Operations and Topic Selection
National Institute for Health and Care Excellence (NICE)
(February, September and December)

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

CONSIDERATION OF OTHER MATTERS

18. 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:

Isotretinoin and psychiatric reactions and persistent sexual dysfunction

19. In September the Commission on Human Medicines (CHM) recommended that the Isotretinoin Expert Working Group (EWG) should be reconvened to review the latest available data regarding the risk of psychiatric adverse reactions as well as the risk of sexual dysfunction associated with isotretinoin. The Commission endorsed the draft terms of reference for the Group: to advise on the latest available data on risk of psychiatric adverse reactions and risk of sexual dysfunction associated with isotretinoin, evaluate their impact on the risk benefit balance, consider whether further regulatory action is required to minimise these risks and to ensure that the product information effectively communicates the risks to healthcare professionals and patients.

Valproate in pregnancy

20. The Commission considered the latest data on the uptake of the valproate Pregnancy Prevention Programme (PPP) at their June meeting. The meeting was attended by the National Patient Safety Director and the patient group INFACT. The Commission advised that there was some evidence of the measures having an impact on prescribing of valproate to women and girls, particularly for new prescriptions, however the evidence of exposed pregnancies since the introduction of the PPP was concerning and further action was considered necessary. The Commission advised that there should be prompt exploration by the healthcare system of a mechanism for directly recalling women of childbearing age on valproate for specialist review, using models already put in place in some NHS areas. They also advised that there should be a move towards or closer specialist supervision of prescribing of valproate to women of childbearing age.

Anti-epileptic drugs (AEDs) in pregnancy

21. The advice that women of childbearing potential should only be treated with valproate if other AEDs are ineffective or not tolerated and the need for women to make informed choices about alternative treatments has increased the focus on the information available on the risks in pregnancy of other AEDs. The Commission considered a proposal for the available safety data relating to the use of AEDs in pregnancy at their July meeting. The Commission endorsed the proposed approach to prioritise certain AEDs for further review based on their clinical use and the available safety data. Based on the advice of the Commission, evidence on the use of carbamazepine, gabapentin, lamotrigine, oxcarbazepine, phenobarbital, (fos)phenytoin, pregabalin, topiramate and zonisamide in pregnancy have been prioritised for further review.

Esketamine

22. In November, the safe use in the UK of an esketamine nasal spray in the treatment of severe depression was discussed by the Commission following the receipt of concerns from UK healthcare professionals on the positive opinion of the Committee for Medicinal Products for Human Use (CHMP) further to the granting of an EU licence. The Commission agreed that the concerns raised had been adequately considered by the CHMP in their assessment of the supporting data and endorsed the positive benefit-risk opinion of the CHMP. However, the Commission acknowledged that the potential for addiction and withdrawal together with long-term safety issues would need to be monitored post-marketing and endorsed the need for additional pharmacovigilance as outlined in the Risk Management Plan. In particular, the Commission endorsed the need for robust controlled access to the product and the establishment of a Registry.

Safety of electronic cigarettes

23. In November, the Commission reviewed evidence relating to the use of e-cigarettes and the potential risk of lung injury (also known as e-cigarette or vaping associated lung injury or EVALI) following the outbreak in the USA which had started earlier in the year. The Commission considered data was insufficient to confirm any one underlying cause or pathology for EVALI. The volume and pattern of adverse respiratory events reported in association with e-cigarette use or vaping in the UK did not seem to reflect the trends emerging from the USA.

24. The Commission supported the need for enhanced surveillance and vigilance, based on requesting Yellow Card reporting and follow-up of reports for detailed information from healthcare professionals. The Commission agreed with the proposals for UK case definitions and with the possibility of evaluating the issue further within the UK including supplementary surveillance, working collaboratively with other agencies.

Medicines and dependence

25. In November, the Commission considered the report from Public Health England's (PHE's) review of the evidence for dependence on, and withdrawal from, prescribed medicines including benzodiazepines, Z-drugs, GABA-ergic medicines, opioid pain medications, and antidepressants. The Commission noted that PHE had made several recommendations for improvements across the healthcare system to build awareness and enhanced decision making for better patient treatment and support. The Commission noted a number of specific recommendations for the Commission and MHRA to address and recommended convening a dedicated ad-hoc Expert Working Group (EWG) to take these forward.

Medicines available without prescription applications

26. Commission considered six applications for change of legal classification during the year. Three applications were for Pharmacy Only (P) availability.

27. Firstly, in relation to a proposed increased pack size of a medicine indicated to reduce pain and inflammation, the Commission advised against the prescription only (POM) to P reclassification.

28. Secondly, following a preliminary hearing and subsequent oral hearing concerning the Commission's provisional advice against the P classification of a medicine used for the treatment of overactive bladder symptoms, the Commission advised that the application could be approvable subject to the resolution of certain points.

29. Lastly, the Commission considered that supplementary information was required before it could advise on an application to reclassify from POM to P a medicine for the treatment of premature ejaculation in adult men.

30. Three applications were for General Sales List (GSL) availability.

31. Firstly, following a preliminary hearing concerning CHM's provisional advice against an application for GSL availability for a medicine for the treatment of reducing fever and pain and the relief of cold and flu symptoms for children 7-12 years of age, the Commission advised that the objections it had raised in relation to the application remained outstanding.

32. Secondly, following a written representation regarding an application for GSL classification of an increased pack size for a product indicated to relieve pain and bring down fever for children 6 years and over, the Commission advised that the points raised in its preliminary advice had been resolved and that the application was therefore approvable.

33. Lastly, in relation to an application for GSL availability of a screening test for potential allergic contact dermatitis in people aged 16 years of age and over, having previously advised that the application was approvable, the Commission considered evidence submitted by stakeholders during the pubic consultation and to support the concerns raised by stakeholders about the proposed reclassification, advised that subject to certain further points being addressed, the application was approvable.

Reviews

34. The Commission considered the appropriateness of P classification for an oral antibiotic and advised that, in principle, P classification was not appropriate.

35. Having previously provided preliminary advice on a package of measures to manage the risk of abuse and misuse of stimulant laxative-containing products in the over the counter (OTC) setting, the Commission considered written representation from one company, data provided by three companies at a preliminary hearing and evidence provided by one company at an oral hearing. The Commission subsequently gave its final advice on the package of risk minimisation measures.

THE COMMISSION'S EXPERT ADVISORY GROUPS (EAGs)

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

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

37. In 2019, the CDRRAEAG convened three times via teleconference and provided advice by written correspondence on six occasions.

38. In March, the EAG provided written comments on:
    - a new medicine indicated for the treatment of transthyretin amyloidosis in adult patients with wild type or hereditary cardiomyopathy to reduce all cause mortality and cardiovascular-related hospitalisation.

39. Also in March, the EAG provided written comments on a paper on the risk of recurrent thrombosis in patients with antiphospholipid syndrome treated with direct acting oral anticoagulants (DOACs).

40. In April, the EAG provided written comments on a draft article for inclusion in Drug Safety Update in relation to the risk of diabetic ketoacidosis associated with GLP-1 receptor agonists when concomitant insulin is rapidly reduced or discontinued.

41. In June, the EAG provided written comments on:
    - a generic medicine indicated for the prophylactic management of mild, moderate or severe asthma in adults (including the elderly) and adolescents.
    - a new medicine indicated for the treatment of hypercholesterolaemia or mixed dyslipidaemia, as add-on to statin therapy or alone if a statin is not tolerated or is contraindicated; a fixed combination of the same medicine with ezetimibe was also considered.
    - proposed updates to product information for rivaroxaban to reflect the final results of the GALILEO study.

42. Also in June, the EAG provided further written comments on the draft Drug Safety Update article in relation to the risk of diabetic ketoacidosis

associated with GLP-1 receptor agonists when concomitant insulin was rapidly reduced or discontinued.

43. In July, the EAG convened via teleconference, discussed and made recommendations on:
    - a new medicine indicated for the treatment of adult patients with inoperable chronic thromboembolic pulmonary hypertension (CTEPH), or persistent or recurrent CTEPH after surgical treatment.

44. The EAG also discussed and made recommendations on a variation to extend the indications of a medicine used for the treatment of adult patients with type 2 diabetes mellitus, to include a new indication for the prevention of cardiac events in diabetic patients who have multiple cardiovascular risk factors or established cardiovascular disease.

45. In August, the EAG provided written comments on a paper on direct oral anticoagulants and bleeding risk.

46. In September, the EAG convened via teleconference, discussed and made recommendations on:
    - a new medicine indicated for the treatment of adult patients of adults with insufficiently controlled type 2 diabetes mellitus.
    - a new generic medicine indicated for the treatment of adult patients with idiopathic or hereditary pulmonary arterial hypertension.

47. In November, the EAG convened via teleconference, discussed and made recommendations on three papers on:
    - proposed updates to the product information for propranolol.
    - the use of e-cigarettes and risk of acute respiratory illness.
    - SLGT2 inhibitors and the risk of diabetic ketoacidosis in surgical patients and medical patients.

48. Also in November, the EAG provided written comments on:
    - a medicine indicated for the treatment of serious infections caused by bacteria sensitive to amikacin.
    - a new generic medicine intended for nutrition therapy in patients with impaired renal function.

Chemistry, Pharmacy and Standards Expert Advisory Group (CPSEAG)

49. In 2019, the CPSEAG met 11 times and provided advice by written correspondence on five occasions.
50. In January, the EAG convened and made recommendations on a medicine indicated for the treatment of:
    - inflammation and diseases of the immune system.
    - pain in muscles and joints.

- for the treatment mild and moderate hypertension (high blood pressure) and to reduce fluid build-up related to heart and kidney problems.
- spasticity (contraction of muscles) resulting from multiple sclerosis, other spinal lesions and cerebral palsy (movement disorders).
- respiratory tract problems due to excess mucous.
- rheumatoid arthritis, discoid lupus (auto immune disease affecting the skin), and systemic lupus (disease causing tissue damage and inflammation).

51. Also in January, the EAG provided written comments on a medicine indicated for the treatment of:
    - bacterial infections of the skin.

52. Also in January, the EAG were updated on the developments and action taken by the company, the UK-MHRA, the supervising authority HPRA-Ireland and the EMA with respect to a defective intravitreal implant (injected into the eye). Updates on the quality findings and the clinical risk assessments conducted by the MHRA and company were discussed and the EAG endorsed the strategy taken by the Agency.

53. In February, the EAG convened and made recommendations on a medicine indicated for the treatment of:
    - underactive thyroid gland (hypothyroidism).
    - underactive thyroid gland (hypothyroidism).
    - a variety of inflammatory diseases, including severe allergic reactions, asthma associated breathing difficulties, inflammation of the skin and severe skin conditions, problems of the immune system, certain kidney diseases, rheumatoid arthritis, bowel disorders, including ulcerative colitis and Crohn's disease, inflammation of the heart and certain blood disorders.
    - certain hormone dependent cancers including breast cancer.
    - major depressive disorders, neuropathic pain (damage or disease affecting the nervous system), chronic tension headache, migraine, treatment of nocturnal enuresis (bedwetting) in children.
    - health problems due to lack of testosterone.
    - serious bacterial infections.
    - underactive thyroid gland (hypothyroidism).
    - cancer, such as ovarian cancer, breast cancer, Kaposi's sarcoma (a cancer that forms masses in the skin, lymph nodes, or other organs)
    - inflammation and diseases of the immune system.
    - hyperparathyroidism and related conditions (where parathyroid glands produce too much hormone causing blood calcium levels to rise (hypercalcaemia).
    - infections caused by certain bacteria and other micro-organisms, which include chest, throat or nasal infections, ear infections, skin and soft tissue infections and sexually transmitted diseases.

- and prevention of vitamin A and D deficiency in adults and children over 6 years.

54. Also in February, the EAG were updated on requirements for bioequivalence studies for applications with multiple strengths of oral, solid dosage forms of levothyroxine.

55. In March, the EAG convened and made recommendations on a medicine indicated for the treatment of:
    - urinary tract and kidney infections.
    - infections caused by yeast (Candida).
    - external infections of the eye.
    - external inflammatory conditions of the eye.
    - fungal infections.
    - postmenopausal bone loss.
    - human immunodeficiency virus (HIV-1) infection.
    - moderate to severe pain.
    - and prevention of tooth decay.
    - transthyretin amyloidosis (a condition where abnormal deposits of proteins build up in tissues).
    - pain and inflammation.

56. Also in March, the EAG provided written comments on a medicine indicated for the treatment of:
    - acne on the face or the trunk.
    - certain types of cancer including breast and ovarian cancer.

57. In April, the EAG convened and made recommendations on a medicine indicated for the treatment of:
    - acne on the face or the trunk.
    - underactive thyroid gland (hypothyroidism).
    - and prevention of pain from gynaecological procedures in women.
    - urinary incontinence (uncontrollable urgency to urinate) and night time bedwetting.
    - high blood pressure (hypertension), treatment for patients with chronic heart failure.
    - acid indigestion and metabolic acidosis (a condition where body fluids and tissues are unusually acidic).
    - and prevention of anaemia in adults and children, in pregnancy, due to side effects from other medicines, and in those with damaged red blood cells or on kidney dialysis. Also used to prevent spina bifida (an abnormality of the spine) in babies.

58. Also in April, the EAG was updated and advised on the naming and labelling of 'generic' liposomal products due to important safety concerns arising following three fatalities due to confusion between lipid-based and non-lipid-based products. The EAG was provided with an overview of the problems identified by the MHRA for the ‘generic’ liposomal products,

particularly in light of the past experience with liposomal amphotericin and doxorubicin, the activities already undertaken to address the issues, and the future / on-going plan for mitigating the risks of product confusion and licensing of these ‘generic’ liposomal products.

59. In May, the EAG convened and made recommendations on a medicine indicated for the treatment of:
    - adults and paediatric patients with cancer cells which have faulty genes; and in adults with non-small cell cancer which has spread to another part of the body.
    - breast cancer known as advanced hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative breast cancer.
    - acute myeloid leukaemia (a form of cancer of certain white blood cells who have a defect in a gene called FLT3).
    - relapsed or refractory acute myeloid leukaemia (a cancer of the blood and bone marrow).
    - moderate to severe active rheumatoid arthritis.
    - epilepsy.
    - viral, bacterial or fungal infections that cause inflammation or pain of the mouth or throat, such as sore throat, tonsillitis, oral ulcers and gum disease.
    - and prevention of skin infection in minor wounds, grazes, burns, ulcers.
    - dizziness (vertigo), ringing in the ears (tinnitus), hearing loss due to Meniere's disease.
    - nasal congestion associated with, for example, the common cold, influenza, sinusitis, allergic rhinitis; also used for treatment after nasal surgery.
    - periodic paralysis (episodes of muscle weakness).
    - underactive thyroid gland (hypothyroidism).
    - certain types of cancer including types of leukaemia.
    - Certain chronic brain disorders including, bipolar disorder, major depression, schizophrenia.
    - severe acute allergic reactions triggered by allergens in foods, medicines, insect stings or bites, and other allergens as well as for exercise-induced or serious swelling, hives and lowered blood pressure.
    - peptic ulcer as an add-on therapy.
    - all types of depression including depression accompanied by anxiety.

60. In June, the EAG convened and made recommendations on a medicine indicated for the treatment of:
    - epileptic seizures associated with Dravet Syndrome.
    - high blood cholesterol.
    - high blood cholesterol.

- serious eye infection in patients with HIV/AIDS and Herpes simplex virus infection in patients with weakened immune systems.
- vitamin D deficiency.
- bacterial infections that affect the front surfaces of the eye.
- overactive thyroid gland (hyperthyroidism), and to restore normal function of the thyroid before (partial) removal by surgery.
- adults and children by relaxing muscles during operations and procedures.
- mild, moderate or severe asthma by prophylactic management.
- bacterial skin infections.
- anxiety and depression.
- depressive episodes; panic disorder, with or without agoraphobia; obsessive compulsive disorder; social anxiety disorder; post-traumatic stress disorder.
- high blood cholesterol.
- symptoms that occur with hay fever such as sneezing, itchy, runny or blocked nose and itchy, red and watery eyes.
- calcium and vitamin D deficiency.
- bacterial skin infections, syphilis, tropical skin infections; also used to prevent rheumatic fever.
- depressive disorder, neuropathic pain, chronic tension headache or migraine.

61. Also in June, the EAG provided written comments and advice on:
    - quality aspects of Adrenaline Auto Injectors
    - a Draft Guideline on the non-clinical requirements for radiopharmaceuticals.

62. In July, the EAG convened and made recommendations on a medicine indicated for the treatment of:
    - prostate cancer where there is a high risk of the disease spreading to other organs.
    - tenosynovial giant cell tumour (TGCT; a tumour around joints, reducing movement and causing pain or stiffness).
    - bacterial infections.
    - tuberculosis where the bacteria has become resistant to many other antibiotics.
    - non-operable high blood pressure in the blood vessels between heart and lungs (chronic thromboembolic pulmonary hypertension, CTEPH), or persistent or recurrent CTEPH after surgical treatment.
    - Relapsing Remitting Multiple Sclerosis (RRMS; a type of MS where attacks to the nerve cells are followed by periods of recovery.
    - patients with opioid drug dependence on opioids, such as morphine and heroin.
    - pain in combination with other painkillers.
    - anxiety and depression.

- alcoholism.
- moderate and severe depression and associated fear (phobia).
- depression or for bed-wetting in children.
- high blood pressure (hypertension) and angina.
- type 2 diabetes.
- and prevention of gout attacks.
- and prevention of skin infection in minor wounds, grazes, burns, ulcers.
- respiratory tract problems due to excess mucous.
- bacterial infections of the ear, throat, respiratory tract, skin and soft tissues.
- HIV infection in adults.
- pain and fever.

63. Also in July, the EAG provided written comments on a medicine indicated for the treatment of:
    - type 2 diabetes.

64. In August, the EAG provided written comments on a medicine indicated for the treatment of:
    - acromegaly (due to excessive growth hormone); relief of symptoms such as flushing and diarrhoea in patients with neuroendocrine tumours (NETs); control of the growth of advanced tumours of the intestine and pancreas (gastroenteropancreatic neuroendocrine tumours or GEP-NETs).
    - severe acute allergic reactions triggered by allergens in foods, medicines, insect stings or bites, and other allergens as well as for exercise-induced or serious swelling, hives and lowered blood pressure.

65. In September, the EAG convened and made recommendations on a medicine indicated for the treatment of:
    - neurodegeneration with brain iron accumulation.
    - insufficiently controlled type 2 diabetes.
    - non-infectious inflammation of the eyes.
    - bronchial asthma.
    - moderate to severe pain in cancer and postoperative pain.
    - hereditary Pulmonary Arterial Hypertension (a condition where the blood pressure in the arteries supplying the heart and lungs (pulmonary arteries) is too high.
    - epilepsy and neuropathic pain (long lasting pain caused by damage to the nerves).
    - pain from osteoarthritis; neuralgia (pain arising from nerves near surface of the skin associated with Shingles); painful diabetic peripheral polyneuropathy (nerve damage to hands or feet caused by diabetes).
    - acromegaly (a condition where the body produces too much growth hormone); symptoms such as flushing and diarrhoea in patients with neuroendocrine tumours (NETs); control of tumours

of the intestine and pancreas called gastroenteropancreatic neuroendocrine tumours or GEP-NETs.
- candida vaginitis.
- schizophrenia in patients currently stabilised with oral antipsychotics.
- chronic and acute leukaemia.
- influenza and prevention of post-exposure influenza including during a pandemic influenza outbreak.
- and prevention of high blood pressure (essential hypertension).
- and prevention of blood clots and stroke.
- Addison's disease and salt-losing adrenogenital syndrome.
- severe acute allergic reactions triggered by allergens in foods, medicines, insect stings or bites, and other allergens as well as for exercise-induced or serious swelling, hives and lowered blood pressure.
- peptic ulcer.
- overactive thyroid gland (hyperthyroidism), Graves' disease, thyrotoxicosis and thyrotoxic crisis (when levels of thyroid hormone are dangerously high).
- high blood pressure (hypertension) and angina.
- lung disorders including chronic obstructive airways disease.

66. Also in September, the EAG were updated:
    - on the outcome of CHMP and CMDh discussions including the publication of a joint position on the naming of liposomal formulations.
    - and advised on proposals to amend to the product name for Abelcet containing Amphotericin B.
    - and advised on a CHMP Draft Guideline on quality requirements for drug-device combinations.
    - and advised on quality defects in Emerade devices and consequent supply shortages.

67. In October, the EAG convened and made recommendations on a medicine indicated for the treatment of:
    - bacterial infections in the lungs (pneumonia).
    - a range of cancers (such as breast and ovarian), AIDs related Kaposi Sarcoma (a cancer that forms masses in the skin, lymph nodes, or other organs).
    - pain at site of surgery.
    - inflammation of the eyes due to seasonal allergic conjunctivitis such as from hayfever and other eye disorders caused by allergy to substances such as house dust mites or animal hair (perennial allergic conjunctivitis).
    - depression, neuropathic pain (long lasting pain caused by damage to the nerves), migraine and tension headaches, bed wetting in children.
    - mild to moderately severe Alzheimer's dementia (a progressive brain disorder that gradually affects memory, intellectual ability and behaviour).

- and prevention of urinary tract infections due to bacteria.
- acid indigestion and metabolic acidosis (a condition where body fluids and tissues are unusually acidic).

68. Also in October, the EAG were updated on:
    - the actions taken on a defective container of a single dose unpreserved eye drop product previously considered by the EAG.
    - on-going actions and new reports of defects in Emerade devices and consequent supply shortages.

69. Also in October, the EAG made recommendations on quality defects in a long-term female contraception product.

70. In November, the EAG convened and made recommendations on a medicine indicated for the treatment of:
    - cancer of the stomach, bowel or oesophagus (gastrointestinal stromal tumour (GIST)).
    - inflammation and prevention of infection associated with cataract eye surgery.
    - typhoid, meningitis and other serious infections caused by susceptible bacteria.
    - jet-lag.
    - multiple myeloma (a cancer of the bone marrow).
    - epilepsy and pain due to trigeminal neuralgia (painful condition of the face due to inflammation of trigeminal nerve).
    - underactive thyroid gland (hypothyroidism).
    - multiple sclerosis with related walking disability.
    - acute diarrhoea and IBS diarrhoea.

71. In December, the EAG convened and made recommendations on a medicine indicated for the treatment of:
    - severe rheumatoid arthritis (an inflammatory disease of the joints).
    - Human Immunodeficiency Virus type 1 (HIV-1) infection.
    - persistent lung infection.
    - adults and children by relaxing muscles during operations and other procedures.
    - serious fungal infections.
    - serious bacterial infections.
    - acute episodes of diarrhoea.
    - moderate to severe pain.
    - and prevention and control of seizures in patients with severe pre-eclampsia (high blood pressure associated with pregnancy) or eclampsia (convulsions as a result of pre-eclampsia).
    - cramps, pain in stomach and intestines, including irritable bowel syndrome (IBS).
    - of rheumatoid arthritis, osteoarthritis, and pain including muscular, traumatic and dental pain, headaches of most

aetiology, pain after operations and childbirth; pyrexia (fever) in children.
- cancer of the large bowel (stage III colon cancer, metastatic cancer of colon and rectum).
- a variety of inflammatory diseases, including severe allergic reactions, asthma associated breathing difficulties, inflammation of the skin and severe skin conditions, problems of the immune system certain kidney diseases, rheumatoid arthritis, bowel disorders, including ulcerative colitis and Crohn's disease, inflammation of the heart and certain blood disorders.
- epilepsy.

Also in December, the EAG were updated on:
- the situation as regards the recall of certain Adrenaline auto injectors.
- referrals concerning the potential for nitrosamines contamination in medicinal products.

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

72. In 2019, the CTVBEAG convened eight times and provided advice by written correspondence on one occasion.

73. In January, the EAG convened and made recommendations on:
- a solution for injection belonging to a group of medicines called anticoagulants which prevents blood clotting in veins and arteries and is used to prevent deep vein thrombosis, pulmonary embolism and heart attacks. It is also used during heart and lung operations and during kidney dialysis.
- a solution which is used in adults to treat several eye diseases causing vision impairment.

74. In February, the EAG convened and made recommendations on:
- a new active substance for a single treatment of spinal muscular atrophy (SMA) Type I, a serious and rare, genetically inherited condition that appears in newborns and babies that causes muscle weakness and difficulty moving.
- a medicine indicated for the treatment and prevention of leptospirosis, an infection humans can contract from animals most commonly rats, mice, cows, pigs and dogs.

75. In March, the EAG provided written comments on a medicine that is a monoclonal antibody linked to a substance intended to kill cancer cells. A monoclonal antibody is a protein which recognises certain molecules, e.g. those found on the surface of cancer cells.

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

- a medicine used for the treatment of a rare type of cancer that affects multiple organs including the skin, bone marrow and lymph nodes (swollen glands).
- a first in human medicine to produce functional mutase enzyme in the liver for the treatment of an inherited inborn error of metabolism which can affect multiple organ systems.

77. In June, the EAG convened and made recommendations on:
    - a vaccine to protect at-risk individuals ≥ 18 years of age against Ebola virus disease caused by Zaire Ebola virus, a rare but severe, often fatal illness in humans.
    - a medicine used to treat an eye disorder called neovascular (wet) age-related macular degeneration, which occurs when abnormal blood vessels that leak fluid or blood into the macula, which is located at the back of the eye, responsible for clear vision.
    - a medicine for desensitisation treatment of adult kidney transplant patients with positive crossmatch against an available deceased donor.

78. In July, the EAG convened and made recommendations on:
    - a vaccine to prevent infection caused by all known subtypes of hepatitis B virus in adults 18 years of age and older.
    - a first in human gene therapy medicine to be used in adults with Type III Spinal Muscular Atrophy (SMA), with similar symptoms as in SMA I described in February meeting, but occurs after 12 months.

79. In September, the EAG convened and made recommendations on:
    - a medicine indicated for the treatment of adult patients with very low- to intermediate-risk myelodysplastic syndromes (MDS)-associated anaemia who require red blood cell (RBC) transfusions and have received or are not eligible for erythropoiesis-stimulating agents (ESAs); and for the treatment of adult patients with beta-thalassaemia-associated anaemia who require RBC transfusions.
    - a medicine indicated in combination with pomalidomide and dexamethasone, for the treatment of patients with multiple myeloma (MM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.
    - an EAMS application indicated in combination with pomalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma (MM) who have received at least two lines of prior therapy including lenalidomide and a proteasome inhibitor (PI). In addition, for the purpose of EAMS, the indication is restricted to 4th line patients only.

80. In October, the EAG convened and made recommendations on:
    - a medicine indicated for the prevention of vaso occlusive crises in sickle cell disease patients aged 16 years and over.

- a medicine indicated in (1) the treatment of inhalational anthrax due to Bacillus anthracis in combination with appropriate antibacterial drugs in adults and paediatric patients and (2) post-exposure prophylaxis of inhalation anthrax when alternative therapies are not appropriate or are not available in adults and paediatric patients.
- an application indicated for the treatment of patients with relapsed / refractory B Cell acute lymphoblastic Leukaemia.

81. In November, the EAG convened and made recommendations on
    - a medicine indicated for the prevention of vaso occlusive crises in sickle cell disease patients aged 16 years and over.
    - a medicine indicated as oral immunotherapy (OIT) for patients aged 4 to 17 years with a confirmed diagnosis of peanut allergy to reduce the incidence and severity of allergic reactions, including anaphylaxis, after exposure to peanut.
    - a medicine indicated in adults for the treatment of neovascular (wet) age-related macular degeneration (AMD).
    - a study of a medicinal product indicated for the treatment of patients with relapsed / refractory B Cell acute lymphoblastic Leukaemia.
    - company written responses to questions raised on an application for a medicine indicated for the treatment of prophylaxis of deep vein thrombosis and pulmonary embolism, treatment of deep vein thrombosis and pulmonary embolism, unstable angina pectoris and acute peripheral arterial occlusion and Prophylaxis of mural thrombosis following myocardial infarction.

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

82. In 2019, the GRIDEAG provided written comments on four occasions.

83. In May, the EAG provided written comments on a paper on a medicine:
    - belonging to a group of medicines called Janus kinase inhibitors, which are disease modifying anti-rheumatic drugs.

84. In August, the EAG provided written comments on a medicine indicated for the treatment of:
    - inflammatory diseases including rheumatoid arthritis, psoriatic arthritis and ulcerative colitis.

85. In November, the EAG provided written comments on a medicine indicated for:
    - the treatment of adult patients with rheumatoid arthritis.

86. Also in November, the EAG provided comments on a paper for PBPK modelling for use of medicines in pregnancy.

87. In December, the EAG provided written comments on a safety review for a medicine indicated for:
    - topical (on the skin) treatment of actinic keratosis, also called solar keratosis, in adults. Actinic keratoses are rough areas of skin found in people who have been exposed to too much sunshine over the course of their lifetime.

Expert Group on meta-analysis published by *Heneghan et al* on oral hormone pregnancy tests (HPTs) and the risks of congenital malformations

88. In March, the Expert Group met to advise on the suitability and robustness of the methodology of the meta-analysis by *Heneghan et al*[1]. on oral hormone pregnancy tests (HPTs) and the risks of congenital malformations, including the selection and application of the data quality score and any clinical implications. The Group heard a presentation from the authors and requested some points of clarification.

89. The Expert Group questioned the application of the Newcastle Ottawa Scale (NOS) particularly with regard to confounding and timing of exposure in relation to outcome, the possibility of publication bias, and the use of unadjusted data in the meta-analysis. The Expert Group considered it was not possible to draw strong conclusions on the impact of bias on the observed association between HPTs and anomalies and that, due to the limitations in the design, reporting and analysis of the included studies there would be little value in re-analysing the data.

90. The CHM noted that the Expert Group considered that the additional information provided by the authors in response to some of the points that could not be answered at the meeting did not alter the conclusions that had been reached previously.

91. The advice of the Expert Group was fully endorsed by the Commission at its meeting in April.

Infection Expert Advisory Group (IEAG)

92. In 2019, the IEAG provided written comments on five occasions.

93. In February, the EAG discussed and made recommendations on:
    - an antibiotic for treatment of infections which are caused by organisms sensitive to trimethoprim and sulphonamide.

94. In June, the EAG discussed and made recommendations on:

[1] https://f1000research.com/articles/7-1725/v2

- an antibiotic medicine that belongs to a group of antibiotics called cephalosporins.

95. In July, the EAG discussed and made recommendations on:
    - appropriate warnings for use of co-trimoxazole during pregnancy.
    - the representation of susceptibility breakpoints in the Summary of Product Characteristics (SmPC) of antimicrobial agents.

96. In September, the EAG discussed and made recommendations on:
    - a medicine to treat bacterial infections of the lung in adults aged 18 or over.

97. In November, the EAG discussed and made recommendations on:
    - a medicine to be used as a part of a combination antibacterial drug regimen for the treatment of bacterial lung infections in adults aged 18 or over.
    - priority drugs for physiologically based pharmacokinetic (PBPK) modelling for use of medicines in pregnancy.

Medicines for Women's Health EAG (MWHEAG)

98. The MWHEAG met on 5 occasions during the year and provided comments by written communication on 5 further occasions. Summary reports based on the minutes of each meeting are published on the GOV.UK website.

99. The MWHEAG considered the latest evidence and made recommendations on the following issues with marketed medicines:
    - risks of breast cancer and VTE with use of hormonal replacement therapy products.
    - the effects of progesterone-only contraceptives on lactation.
    - proposals to reduce migration of nexplanon implants away from their site of insertion.
    - regulatory requirements for submissions of levothyroxine medicines used in the treatment of under active thyroid glands.

100. The MWHEAG considered the evidence and made recommendations on applications related to new uses of existing medicines or new medicinal products for postpartum haemorrhage, treatment of under active thyroid glands, and local anaesthesia for gynaecological procedures.
101. The MWHEAG considered and made recommendations on Prescription Only Medicine (POM) to Pharmacy Only (P) reclassification of a medicine for treatment of overactive bladder symptoms.

Safety of Medicines during pregnancy

102. During the year the MWHEAG considered and made recommendations on medicines used during pregnancy for which knowledge from modelling

of pharmacokinetics would be helpful to inform dosing requirements during pregnancy.

103. During the year the MWHEAG monitored all reports of suspected Adverse Drug Reactions (ADRs) associated with use of medicines in pregnancy received by MHRA. The MWHEAG reviewed 587 new reports of suspected ADRs associated with use of medicines in pregnancy received from October 2018 to August 2018. The majority of reports received during this period did not raise any new concerns.

104. The MWHEAG reviewed potential safety signals following use of the following medicines during pregnancy and recommended that no regulatory action was warranted in each case: olanzapine, paracetamol, lopinavir boosted with ritonavir.

105. The MWHEAG considered further review and/or regulatory action should be taken for use of the following medicines during pregnancy:
    - Ondansetron: a review of the evidence regarding risks of congenital malformations with use of ondansetron in pregnancy was conducted following publication of two large epidemiological studies which reported a small increased risk of orofacial malformations in babies born to women who used ondansetron in early pregnancy. The EAG considered that the absolute risk was low and highlighted its use off-label for hyperemesis gravidarum which is difficult to treat with other anti-emetics. Consequently, the EAG supported the provision of information on the small increase in frequency of oral clefts in the Product Information without further restrictions on use and that healthcare professionals and patients should be informed of the potential risk highlighted by these studies via Drug Safety Update.
    - Trimethoprim-containing products: use in pregnancy is contraindicated in trimethoprim single-constituent products; however, a contraindication is not present in the product information for trimethoprim multi-constituent products (co-trimoxazole). The MWHEAG recommended that this should be reviewed further and, if appropriate, the product information should be updated for consistency. Further advice was sought from the anti-infectives EAG who recommended that the current differences in contraindications and warnings between trimethoprim and co-trimoxazole are appropriate since co-trimoxazole is used during pregnancy for severe infections.
    - Intravenous iron products: some products, but not all intravenous iron products contain warnings that foetal bradycardia may occur. This is usually transient and a consequence of a hypersensitivity reaction in the mother. The MWHEAG recommended that this reaction should be reviewed further for intravenous iron products and, if appropriate, the product information should be updated for consistency. This is being taken forward through periodic safety update reports for relevant products.

Neurology, Pain & Psychiatry Expert Advisory Group (NPPEAG)

106. In 2019, the NPPEAG met on one occasion in November.

107. The EAG provided recommendations on:
    - an EAMS (early access to medicines scheme) submission of a medicine indicated for short-term treatment, co-administered with oral antidepressant therapy, for the rapid reduction of depressive symptoms in adult patients with a moderate to severe episode of major depressive disorder who have active suicidal ideation with intent.
    - a centralised marketing authorisation application of a medicine indicated as monotherapy or in combination with immunosuppressive therapy for the treatment of adult and adolescent patients from 12 years of age with neuromyelitis optica spectrum disorders.

108. The EAG also considered new data on the risk of suicidality in depressed adults receiving treatment with antidepressant medicines, provided guidance on a medicine indicated for refractory depression and advised on suitable medicines with neurological or psychiatric indications for the development of physiologically-based pharmacokinetic modelling in pregnancy.

Oncology and Haematology Expert Advisory Group (OHEAG)

109. In 2019, the OHEAG met once, convened three times by teleconference and provided advice by written correspondence on one occasion.

110. In March, the EAG provided written comments on a medicine indicated for:
    - treatment for adult patients with “diffuse large B-cell lymphoma” that has come back or has not got better with at least one previous therapy and when you a stem cell transplant is not possible.
    - treatment of adult patients with previously untreated multiple myeloma.

111. In May, the EAG convened and made recommendations on a medicine indicated for:
    - the treatment of adult and paediatric patients with advanced solid tumours that have a genetic defect called NTRK fusion and treatment of patients with advanced non-small cell lung cancer that have a genetic defect called ROS1.
    - the treatment of advanced breast cancer with a certain mutation in a gene called PIK3CA.
    - the treatment of relapsed or refractory acute myeloid leukaemia (AML)with a defect in a gene called IDH.

- the treatment of relapsed or refractory acute myeloid leukaemia with a defect in a gene called FLT3.

112. In June, the EAG convened via teleconference and made recommendations on a medicine indicated for:
    - for the treatment of adults who have acute myeloid leukaemia (AML) (a type of blood cancer) which has the gene abnormality FLT3-ITD.

113. In July, the EAG convened via teleconference and made recommendations on a medicine indicated for the treatment of:
    - adult men with prostate cancer that has not spread to other parts of the body.
    - adult patients with symptomatic tenosynovial giant cell tumour (TGCT), also referred to as giant cell tumour of the tendon sheath (GCT-TS) or pigmented villonodular synovitis (PVNS) that cannot be treated with surgery.

114. In October, the EAG convened via teleconference and made recommendations on a medicine indicated for the treatment of:
    - adults with a certain type of stomach, bowel, or oesophageal (gullet) cancer called gastrointestinal stromal tumour (GIST) that cannot be treated with surgery (unresectable) or that has spread to other parts of the body (metastatic), and has a specific mutation (change) in the tumour DNA, or has been treated with other medicines that did not work or are no longer working.

Paediatric Medicines Expert Advisory Group (PMEAG)

115. The PMEAG advises the Commission on the safety, quality and efficacy of medicines for paediatric use, including all matters relating to the implementation of the EU Paediatric Regulation. The PMEAG met four times in 2019 and provided advice through written correspondence for six papers.

Paediatric Investigation Plans (PIPs)

116. The PMEAG advised on an application in the therapeutic area of neurology.

Work-sharing procedures

117. The PMEAG considered 3 products which were being assessed under work-sharing procedures, (coordinated at European level by Member States) for which the UK was Rapporteur. The therapeutic areas for these procedures included infectious diseases, oncology and cardiovascular diseases.

Marketing authorisation applications supported by paediatric data

118. The PMEAG advised on 2 applications for a variation request on existing products. The products covered indications including the treatment of leg

swelling caused by varicose veins in children and the treatment of spasticity of upper limbs in children with cerebral palsy.

Safety of medicines in children

119. In 2019 the PMEAG reviewed monthly statistics on suspected adverse drug reactions in paediatric patients reported to MHRA, and an overview of all identified paediatric signals. The PMEAG advised on paediatric signals with regards to a product for the diagnosis and reversal of Opioid (class of addictive drugs) overdose, a paper on a medicine for the treatment of low blood pressure in new-born babies and a paper concerning the safety of a product used for the treatment of fever. The PMEAG also advised on a review on use of paracetamol during labour. Lastly, the PMEAG considered a paper on the monitoring of adverse reactions of medicines exposures during breastfeeding.

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

120. The PMEAG discussed and advised on several draft or revised Guidance Papers being developed at European or international level. The topics included the role of clinical pharmacology in the development of medicinal products in the paediatric population, the use of complex study designs in particularly in rare diseases and a guidance on clinical trials preparedness.

121. In addition, the PMEAG considered an array of papers including topics such as prescribers' concerns on changing between brands of drugs used in paediatric hyperactivity and ADHD.

Discontinuations of paediatric medicinal products

In 2019, the PMEAG gave advice on the clinical implications of the proposed discontinuation of 8 medicinal products for children: a drug used for pain relief, a drug used in children with metabolic disease, an antihypertensive drug, a drug used in diabetes, two drugs used for lung diseases, a drug used in vital infections and an anti-inflammatory drug.

Pharmacovigilance Expert Advisory Group (PEAG)

122. The Commission's Pharmacovigilance Expert Advisory Group (PEAG) membership includes expertise in pharmacovigilance, pharmacogenomics, clinical pharmacology, toxicology, epidemiology, general practice, and pharmacy and includes lay representation. Additional 'Experts for the Day' often attend PEAG meetings to inform the Group's advice on specialist topics.

123. The PEAG met eleven times in 2019, including twice by teleconference, and provided advice by written procedure on one further occasion. The June 2019 meeting was a joint meeting with the CHM Expert Working Group on Sodium Valproate, at which the Groups gave advice on the

implementation and impact of the Valproate Pregnancy Prevention Programme.

124. During 2019, the PEAG considered papers and advised on the following:
    - new information about the risk of progressive multifocal leukoencephalopathy (PML) with different dosing regimens of natalizumab in the treatment of highly active relapsing remitting multiple sclerosis.
    - alemtuzumab treatment of relapsing remitting multiple sclerosis and the risk of immune mediated disorders and cardiovascular adverse events.
    - the need for a comprehensive review of the benefit-risk balance and appropriate risk minimisation measures for yellow fever vaccine following fatal cases of yellow fever vaccine-associated viscerotropic adverse reactions (YEL-AVD) and yellow fever vaccine-associated neurotropic disease (YEL-AND).
    - maternal use of paracetamol during pregnancy or perinatally and neurocognitive outcomes in the child.
    - reports of lung injury with e-cigarettes or vaping.
    - appropriate screening of patients for DPD (dihydropyrimidine dehydrogenase) deficiency prior to treatment with fluorouracil and related products.
    - the risk of pulmonary embolism and increased mortality in patients with rheumatoid arthritis treated with tofacitinib compared to those treated with a TNF inhibitor.
    - the risk of type-2 diabetes in men receiving 5α-reductase inhibitors (dutasteride, finasteride or tamsulosin with dutasteride) for symptomatic treatment of benign prostatic hypertrophy.
    - the risk of recurrent thrombosis in patients with antiphospholipid syndrome treated with direct-acting oral anticoagulants (DOACs).
    - the results of an EU commissioned observational study on bleeding risk with DOACs.
    - a signal of increased mortality, excess thrombo-embolic and major bleeding events in patients post-transcatheter aortic valve replacement (TAVR) treated with rivaroxaban.
    - fluoroquinolone antibiotics and the risk of aortic and mitral valve regurgitation.

125. The PEAG also considered matters raised by Coroners under Regulation 28 of the Coroners (Investigations) Regulations 2013. These Coroner's reports to Prevent Future Deaths raised matters relating to the possible need for plasma level monitoring of clozapine and clomipramine to prevent toxicity, and appropriate risk minimisation measures for carfilzomib relating to known cardiac adverse effects.

126. The PEAG gave advice on updated guidance for appropriate dose adjustments for the antibiotic trimethoprim when used in patients with renal impairment, as well as on the appropriate measure of kidney function (CrCl or eGFR) when initiating or adjusting the dose of narrow

therapeutic index drugs in elderly patients or patients at extremes of body weight with concurrent renal impairment.

127. The PEAG considered the proposed Risk Management Plan (RMP) for one new medicine and provided advice on the appropriate design of post-authorisation safety studies for one medicine and one vaccine.

128. The PEAG's advice on these issues was subsequently taken forward for further discussion within the European medicines regulatory system or was implemented nationally. The outcome of these European discussions can be found on the website of the European Medicines Agency. The PEAG's advice also underpins key medicines safety advice provided to UK healthcare professionals in MHRA's monthly Drug Safety Update newsletter (www.mhra.gov.uk/drug-safety-update).

129. The Group also gave advice on the need for active risk communications, their format and appropriate recipients. During 2019 the PEAG advised on risk communications for modafinil and the risk of major congenital anomaly following maternal use during pregnancy; new driving warnings for Mysimba (naltrexone/bupropion); and for montelukast and psychiatric adverse events.

130. In accordance with its responsibility for oversight of the UK Yellow Card Scheme, the PEAG considered Yellow Card reporting statistics at each of its meetings in 2019 and advised on an analysis of factors contributing to the decrease in Yellow Card reporting rates observed in 2018. The PEAG also commented on MHRA proposals for development of a Yellow Card BioBank.

131. Summary reports based on the minutes of each meeting are published on the GOV.UK website.

Avastin Peer Review Group

132. A peer review group was convened in July 2019 to consider MHRA proposals for amended guidance on supply and use of medicines outside the terms of their marketing authorisation. The review of MHRA guidance was prompted by followed from the judgment in the case of [Bayer PLC v NHS Darlington Clinical Commissioning Group & others[2] concerning the policy of the Clinical Commissioning Groups to recommend the use of Avastin (bevacizumab) for the treatment of wet age-related macular degeneration (AMD). This indication is not included in the marketing authorisation of Avastin. The peer review endorsed MHRA recommendations for updating its published guidance[3] to differentiate between the responsibilities of practitioners in prescribing medicines

[2] https://www.bailii.org/ew/cases/EWHC/Admin/2018/2465.html
[3] https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities

outside of the terms in a marketing authorisation and the conditions under which unlicensed medicines may be supplied.

E-Cigarettes Expert Working Group

133. Following a report from the House of Commons Select Committee on Science and Technology which recommended that the Government review with the MHRA and the e-cigarette industry how its system for approving stop smoking therapies could be streamlined the CHM's e-cigarettes Expert Working Group (EWG) was set up to review emerging evidence and advise as to how the licensing process could be streamlined There were three main aims: to reduce regulatory burden and also in particular to identify the toxicological data requirements and safety to support use of different flavourings and excipients in e-cigarettes and risk benefit of use; whether there were sufficient data to recommend the route to sale and supply for use in adolescents and children 12-17 years of age and to review the standards for dose delivery uniformity.

134. The EWG was chaired by Professor Angela Thomas and membership included expertise in toxicology, epidemiology, respiratory medicine, tobacco control and tobacco addiction, behavioural medicine, general practice and pharmacy, with observers from PHE, DHSC and NICE.

135. In April 2019, the EWG met for the first time and agreed the terms of reference. A paper was presented outlining the different routes to introducing e-cigarettes to the UK market, recommendations on e-cigarettes from the House of Commons Select Committee on Science and Technology report, current licensing requirements and issues raised by companies and trade associations. The EWG considered whether the currently applied limits for uniformity of delivered dose were appropriate. The GSL medicine status for e-cigarettes for adolescents and children 12-17 years of age was discussed. A brief review of excipients present in e-cigarettes was provided and the EWG were asked to consider what toxicological data should be required to support use of excipients in e-cigarettes.

136. In May 2019 the EWG convened, a paper on the legal status of e-cigarettes and a comparison of the licensing fees for TPD consumer products and medicinal e-cigarettes were provided for information. Results of a survey completed by companies who had previously contacted the MHRA for advice and/or made a marketing authorisation application (MAA) were presented. The survey covered aspects such as reasons for not submitting an MAA, advantages and disadvantages in obtaining an MAA, and changes to licensing requirements that would make the medicinal route more attractive. Revised non-clinical requirements were presented and the EWG considered whether the proposed requirements were appropriate to assess safety. Two papers on the use of e-cigarettes were presented by the CEO of ASH and papers

on the toxicity of two flavourings previously discussed by COT were presented by the Chair of COT for information.

137. In June 2019, a paper on potential strategies for comparative bioavailability studies for medicinal e-cigarettes and one on use of post-marketing human studies to substitute for a lack of non-clinical data were discussed. The toxicological data requirements required to support the safety of excipients were endorsed by the EWG. Draft conclusions and recommendations to CHM were discussed along with a communication strategy.

138. In October the EWG met for the final time following the emergence of a pattern of severe vaping related illness in the USA. They discussed the emerging evidence from the US, UK and other parts of the world and considered whether there were changes or impacts on the final conclusions of the EWG.

139. The conclusions and recommendations from the EWG were presented and discussed at the CHM meeting in November 2019.

Opioid Expert Working Group (EWG)

140. There is increasing concern internationally and in the UK about overuse and misuse of opioid analgesics, particularly in non-cancer indications, leading to a growing problem of dependence and addiction. The Commission advised that an ad hoc expert working group (EWG) should be formed to review available evidence on opioid dependence and addiction, recommend ways to strengthen risk minimisation measures and to improve communication and the education of healthcare professionals and patients. The EWG met four times in 2019, in February, March, June and October to consider the use of opioids in the treatment of chronic pain in the UK.

141. At the February meeting the EWG agreed the terms of reference and reviewed information on the current use of opioids and risks of dependence and addiction. The EWG also considered potential routes of communication to provide information for patients and healthcare professionals on the risks of dependence and addiction.

142. At its March meeting, the EWG recommended that information for healthcare professionals and patients should be improved to provide consistent warnings and information of the risk of addiction and dependence. The EWG recommended that product labelling for all opioids contain the warnings “Can cause addiction” and “contains opioids” in a rectangle to be displayed prominently on the front of the packaging and that a common patient leaflet warning about the risk of dependence and addiction should be developed, for distribution to the patient with their medicine. The EWG also recommended that the CHM re-considered access of pharmacy medicines containing codeine and

dihydrocodeine to prescription only (POM). Finally, the EWG recommended additional risk minimisation measures for transdermal patches and transmucosal fentanyl products, including the addition of warnings to product information in treatment of opioid naïve patients. The EWG also considered the oxycodone/naloxone combination product with an additional indication for the symptomatic relief of restless legs syndrome and recommended additional guidance should be given for healthcare professionals for monitoring of patients.

143. In June, the EWG asked that the evidence for dependence, addiction and abuse of potential opioid-containing medicines available without a prescription be reviewed. The EWG also advised that the pharmacology of these medicines met that of an opioid.

144. In October, the EWG recommended the provision of consistent information for healthcare professionals and patients of opioid medicines currently available from the pharmacy or general sales, to highlight that the medicine is an opioid, and the associated risk of dependence and addiction as a class effect. The EWG also advised that the legal classification of three opioids medicines previously not examined by the EWG and currently available without a prescription did not meet the criteria for prescription supply, based on current evidence of dependence, addiction and abuse. The EWG also advised that based on evidence of abuse of one opioid available without prescription, consideration should be given to whether additional measures to minimise risk were needed. Finally, the EWG considered Public Health England's report of dependence and withdrawal associated with prescribed medicines and advised on topics for further exploratory work relevant to the work of the EWG.

145. The CHM fully endorsed the recommendations of the EWG at its meetings in February, April, July, November and December 2019.

Optimising Data on Medicines used in Pregnancy Expert Working Group

146. In response to the recommendations of the Report of the Expert Working Group on Hormone Pregnancy Tests published in November 2017[4], an Expert Working Group was set up to consider better ways to collect and monitor data on the safety of medicines during pregnancy and breastfeeding. The Group convened in July and met on a further two occasions in October and December.

147. The Group has put together and discussed a comprehensive summary of key UK sources of observational data on medicines used in pregnancy and breastfeeding including ongoing and proposed developments for

[4] https://www.gov.uk/government/publications/report-of-the-commission-on-human-medicines-expert-working-group-on-hormone-pregnancy-tests

improved data. This summary has formed the basis for the Group to identify gaps in the currently available data and discuss potential opportunities to optimise data collection of medicines, outcomes and other relevant data elements for research.

148. The Group has also discussed barriers and challenges to accessing data on medicines used in pregnancy and lactation including issues relating to, information governance and patient confidentiality and considered how this might be addressed in the recommendations. It is anticipated that the Group will meet again in Q1 2020 to discuss its conclusions and recommendations and publication of a report.

Expert working Group on Yellow Fever

149. A yellow fever vaccine Expert Working Group was convened by the Commission in response to two fatal adverse reactions, to consider the balance of risks and benefits of the vaccine and the measures necessary to minimise risks. The Group met in May, July, and October. The Group found that the balance of benefits and risks of yellow fever vaccine remains favourable for most travellers when used as indicated but recommended a series of additional precautions and measures to minimise risks to those with a weakened immune system, those aged 60 years or older and anyone who has had their thymus removed. The Commission fully endorsed the conclusions and recommendations of the Expert Group at its meeting in November. The recommendations were communicated on 21 November 2019 via MHRA's Drug Safety Update bulletin and a letter to Yellow Fever Vaccine Centres.

APPEALS REPORTING OF SUSPECTED ADVERSE DRUG REACTIONS 2019

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

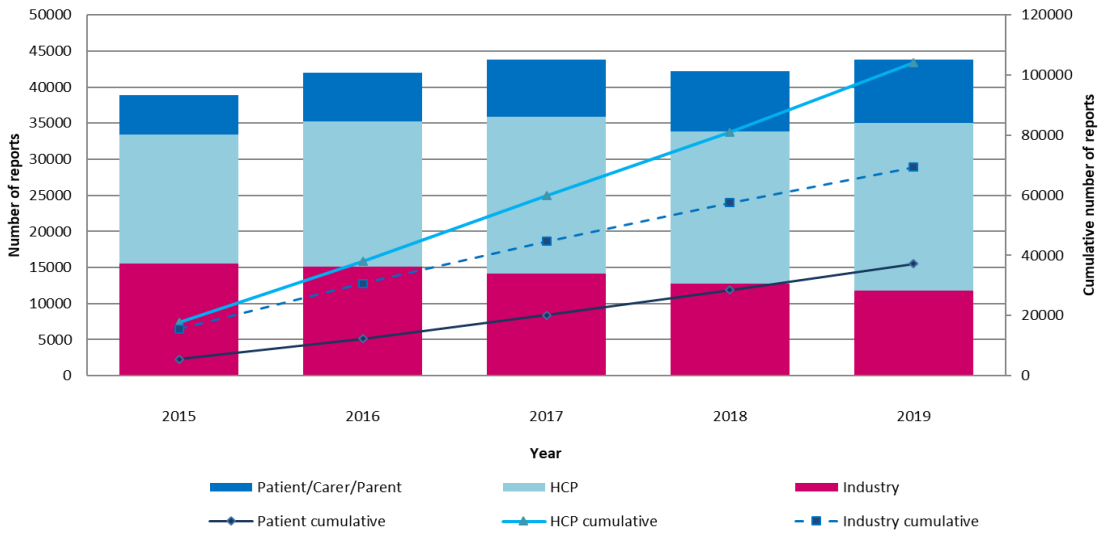
151. The total number of UK spontaneous suspected ADR reports received from all sources over the last five years shows an increasing trend of 13% (4,874 additional reports) as shown in Figure 1 below. Overall, reporting levels remain robust; in 2017 we received the highest number of reports since the Scheme was established over 50 years ago. This was closely matched by reporting levels in 2019 which saw the second highest

reporting levels to date. An additional 1,536 reports were received in 2019 when compared to 2018, showing a 4% increase.

152. Direct Yellow Card reporting from healthcare professionals accounted for 53% (23,222 reports) of all suspected ADR reports received in 2019 and 20% (8,794 reports) of all reports were received from members of the public (including patients, parents and carers). Yellow Card reports from members of the public and healthcare professionals increased by 6% and 10% respectively in 2019.

153. In 2019, suspected ADR reporting from the pharmaceutical industry accounted for 27% (11,799 reports) of all reports received by the MHRA. This represents a decline of 8% (989 reports). The decrease in reports appears to have been experienced across multiple pharmaceutical companies and follows no particular pattern with regards to which drugs have seen a decrease in reports. The pharmaceutical companies have been contacted and we are assured that they are reporting appropriately.

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



Year	2015	2016	2017	2018	2019
Number of Reports	38,902	42,085	43,935	42,240	43,776

Patient ADR Reporting

154. The highest number of Yellow Card reports from members of the public since the launch of the Scheme was seen in 2019, with 8,794 Yellow Card reports received. These reports accounted for 20% of all reports received over the year. There has been a 59% (3,275 reports) increase in patient, parent and carer reports over five years, since 2015. This can be

attributed to the MHRA's Yellow Card strategy work and its 5 Yellow Card Centres where significant efforts have been made to proactively encourage the reporting of suspected ADRs from this important reporter group. The increase has been achieved by engagement to reach patients through their associations and organisations as well as via healthcare professionals, and through the Patient and Public Stakeholder Engagement outreach work.

155. A new video on how to report a Yellow Card was produced through working with patient organisations. This was subsequently disseminated to over 300 patient organisations followed by supplementary promotion on social media. The video, in addition to previous Yellow Card promotional videos, is hosted on the MHRA's YouTube channels. It was added to the Yellow Card reporting website in a number of places as well as on the MHRA GOV.UK pages. Through stakeholder engagement this was picked up by numerous organisations.

156. In addition, credit card sized information cards for the public were designed and printed. They were then distributed to various patient organisations as well as being disseminated via our five Yellow Card Centres. In 2019, Yellow Card paper forms have been updated, reprinted and distributed to those requesting them, including the introductory information within the patient form translated into Welsh. This was supplemented by an appearance on a local radio station in their health and wellbeing segment to promote Yellow Card reporting and answer information about suspected side effects.

157. MHRA exhibited at the Royal Pharmaceutical Society pharmacy conference to encourage ADR reporting from the pharmacy healthcare team as well as to encourage a dialogue between patients to discuss side effects and self-reporting. This was supplemented through engaging with the Community Pharmacy Patient Safety Group, with the view to encourage reporting and raise awareness with patients about the Yellow Card Scheme.

158. Collaboration continued with National Association of Patient Participation (N.A.P.P.) which is a UK umbrella organisation for patient-led groups in general practice. MHRA, together with support from Yellow Card Centre Wales promoted and presented to the Patient Participation Groups in England at their annual conference which included the importance of reporting to the Yellow Card Scheme.

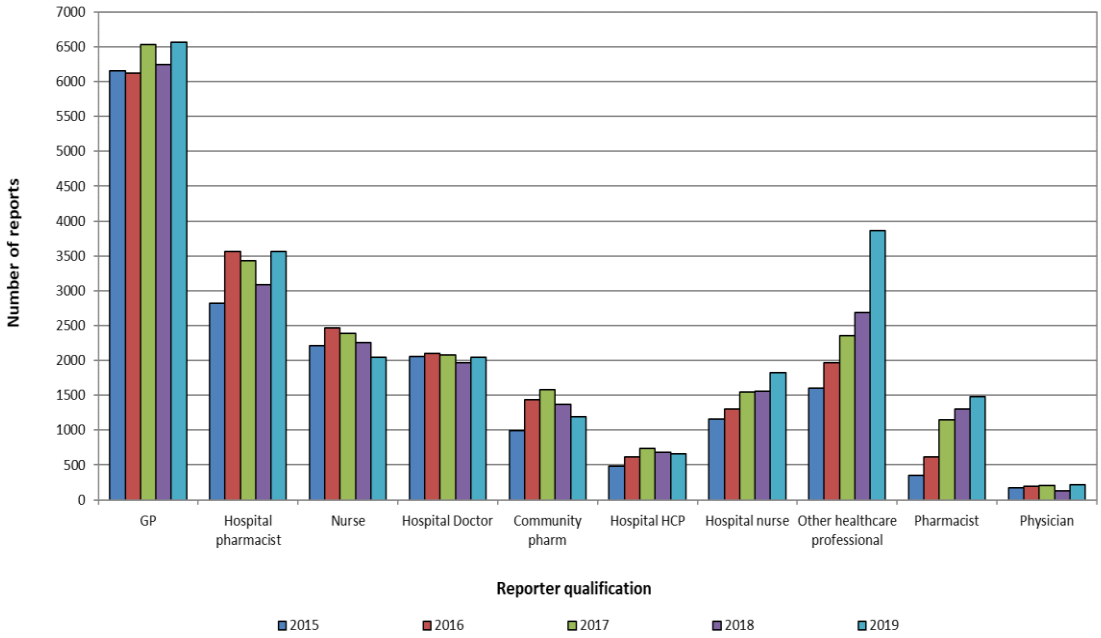
159. In 2019, the MHRA also worked with the Science Museum on a contribution to their newly launched Medicines Gallery. There is now a display containing Yellow Card patient forms and leaflets which explains how reporting can result in new advice, labelling or changes to how medication is prescribed. Further educational work is planned in 2020 to supplement the information for those coming to learn about objects relating to the Yellow Card Scheme.

160. A consultation seeking views on how the MHRA engages and involves patients was also conducted in 2019 and this will inform future campaigns and messages.

Healthcare professional ADR reporting

161. Yellow Card reports received directly from healthcare professionals in 2019 increased by 10% (2,104 reports) when compared to 2018. A breakdown of direct healthcare professional reports by reporter qualification between 2015 and 2019 is shown in Figure 2.

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



**Other health professionals include dentists, optometrists, coroners, healthcare assistants, paramedics, chiropodists, medical students, pre-reg pharmacists, pharmacy technicians and other non-specified health professionals.*

162. As in previous years, GPs reported the most suspected ADR reports (6,566 reports) compared to all other healthcare professionals to the Yellow Card Scheme in 2019 and accounted for 28% of all direct healthcare professional reports. Following the 4% decline seen in GP reporting in 2018, the number of Yellow Cards submitted by GPs in 2019 has risen to a similar value as seen in 2017 which could be attributed to the increased number of reports received via clinical systems, which is discussed in further detail below. Along with GPs, Figure 2 shows the increase in the number of reports received from hospital pharmacists, hospital doctors and hospital nurses, with increases of 16%, 4% and 16% compared with the previous year. This was a result of several strategic

efforts to encourage a reversal in a declining trend seen, such as a Drug Safety Update Article[5] to healthcare professionals, which led to more requests for reporting forms.

163. In 2019, the number of Yellow Cards from pharmacists, that did not specify their speciality as community or hospital based, increased by 14% (184 reports) compared to the year before, although there was a decreasing trend in reports from community pharmacists. Based on the address of the reporter, approximately 63% of the pharmacist (unspecified specialty) reports were from Clinical Pharmacists practicing within General Practice. This trend reflects the increasing role of clinical pharmacists in primary care and can be attributed to direct strategic engagement with the Primary Care Pharmacy Association (PCPA) and work with the Practice Pharmacy Group (PPG) on the importance of reporting to the Yellow Card Scheme.

164. Reports from 'other healthcare professionals' increased by 44% (1,183 reports). The most frequently reported professions within this group were unspecified other healthcare professionals (61%); followed by radiographers (12%), pharmacy assistants (12%) and pre-registration pharmacists (9%).

165. We have continued to work with stakeholders such as General Pharmaceutical Council, Royal Colleges, professional associations and groups of networks such as the National Medication Safety Network to reverse the small decline seen in healthcare professional reporting from the previous year. This resulted in articles within their professional publications and newsletters about the Yellow Card Scheme with a call to report, when and how to submit a Yellow Card, case studies, and the message that reporting helps to increase patient safety and improve information on the safe use of medicines.

166. The MHRA worked alongside the National Institute for Health and Care Excellence (NICE) Medicines and Prescribing Centre, to develop a medicines evidence commentary on new MHRA drug safety advice: March 2019 to May 2019. Added to this was a call to report any suspected side effects of medicines to the MHRA on a Yellow Card as well as highlighting that there is now a mobile app available for download for reporting via your device.

167. The trends within these reporter qualifications highlight positives in certain reporter groups that are reflected in a change in clinical care but also highlight a need to re-engage with some professional groups, like nurses and community pharmacists as part of Yellow Card strategic efforts in 2020.

[5] https://www.gov.uk/drug-safety-update/yellow-card-please-help-to-reverse-the-decline-in-reporting-of-suspected-adverse-drug-reactions

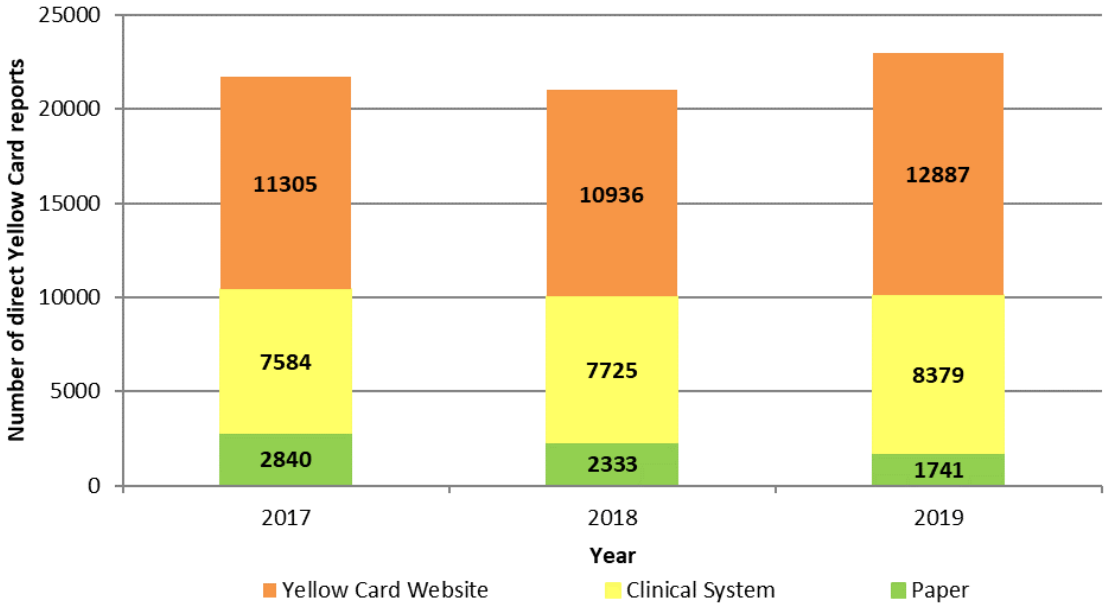
Electronic ADR Reporting

168. Electronic reporting is the most popular method of reporting for both healthcare professionals and members of the public.

169. In 2019, 93% (8,164 reports) of all ADR reports from patients, parents and carers were reported electronically, with a 3% (245 reports) increase in reports via the Yellow Card website compared to 2018.

170. In 2019, 93% (21,480 reports) of all direct healthcare professional reports were received electronically, with 55.5% (12,887 reports) through the Yellow Card website, which is promoted the most, and 36% (8,379) via clinical systems. Paper reports formed the majority of the remaining 7.5% (1,741 reports) of direct healthcare professional reports. A breakdown of the methods of reporting from healthcare professionals can be found in Figure 3.

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



171. The number of suspected ADR reports received directly from the Yellow Card form being integrated into clinical IT systems has increased by 8.5% (654 reports) compared to 2018. A key part of the MHRA's Yellow Card strategy is a focus on making Yellow Card reporting easier and more accessible to its users, including healthcare professionals. Integration of the Yellow Card form directly into a clinical IT system is a key tool to reaching this goal.

172. The MHRA continues to strive to expand Yellow Card reporting functionality into further clinical systems. The MHRA, with support from NHS Digital, worked with EMIS Health to develop integrated Yellow Card reporting in EMIS Web. The specifications for clinical system providers to

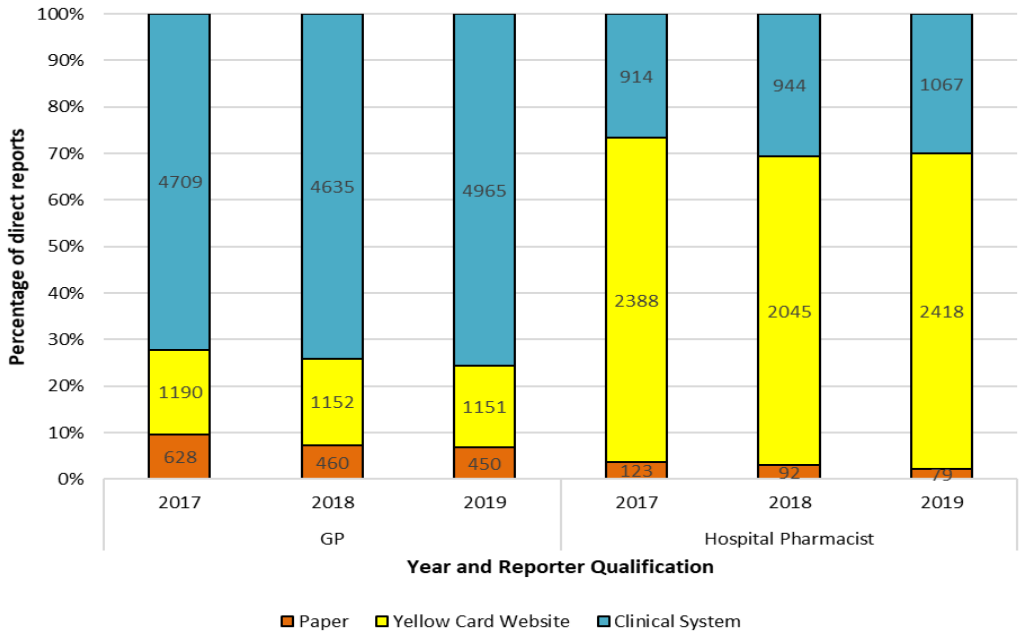
integrate reporting into their systems was used and is outlined within the Information Standard DCB 1582. Following a period of development and successful testing, the functionality was rolled out in 60 early adopter practices towards the end of 2019. Full roll out into approximately 4,000 GP practices in England is expected in early 2020. In addition to the existing GP clinical system providers, this collaboration with EMIS Health signifies an important milestone. Reporting of suspected ADRs to the Yellow Card Scheme will become available in 93% of all GP practices across the UK, which is envisaged to significantly increase reporting from GPs.

173. The MHRA also works to increase reporting in secondary care systems, with a pilot of a redesigned reporting form launched in Cerner Millennium at Oxford University Hospitals NHS Foundation. Results from this pilot will be used to influence further uptake by other Trusts. However, progress with systems like Cerner and Ulysses are limited by a higher number of conflicting priorities seen in a secondary care setting, such as Trust administrative restructuring and merges between Trusts.

174. Reports from all clinical systems formed 36% of all direct reports from healthcare professionals. Further work continues to engage other clinical system providers to integrate Yellow Card reporting functionality and further extend this proven method of increasing reporting.

175. Figure 4 shows the ways in which suspected ADR reports are submitted to the Yellow Card Scheme from GPs and hospital pharmacists over the last 3 years. There is a steady decreasing trend in the numbers of paper reports received from GPs and pharmacists compared to an increase in use of electronic methods to report a Yellow Card.

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



176. In 2019, 93% of all GP reports were received electronically, with GP reports via clinical systems accounting for 76% (4,965 reports) of all reports from GPs. Of this, SystmOne accounted for 61% (3,981 reports) of suspected ADR reports from GPs. Reports from Vision accounted for 15% (984 reports) of all GP reports in 2019 which saw an increase of 30% (227 reports) compared to the previous year.

177. Similarly, reports received via hospital pharmacists via clinical systems (MI Databank) increased by 12% (117 reports), as well as through the Yellow Card website with an increase of 18% (357 reports).

178. As part of the WEB Recognising Adverse Drug Reactions (WEB-RADR) 2 project, work was undertaken by the MHRA together with MedDRA MSSO and SNOMED International to map common MedDRA reaction terms (used in regulatory practice) to SNOMED CT terms (used in clinical practice) and vice versa. More than 7000 terms were mapped in 2019 and these will be tested in reports from clinical systems in 2020. With most clinical systems using SNOMED CT, this work is expected to significantly reduce the level of manual reclassification needed of SNOMED CT terms received in reports from clinical systems.

The Yellow Card App

179. The Yellow Card App was initially designed with both healthcare professionals and patients as target users, however reporting trends have shown that the app is particularly used by patients as a route of reporting. Suspected ADR reporting through the app continues to increase, with a 119% increase in reporting from 2018 (302 reports) to 2019 (662 reports). Of these reports, 68% (449 reports) were from members of public.

180. The Yellow Card App was a topic of discussion at the Agency Board meeting, which had attendance from members of the public. While it was acknowledged that the app is not a major source of reports, positive feedback was received from members of the public regarding the app as a source of information. Attendees felt the Yellow Card App empowers them by providing more control and knowledge of their healthcare through the news and watchlist functionalities. This demonstrates the potential of the app to act as a useful tool to increase engagement with members of the public. The MHRA has been further exploiting the app and these benefits through the WEB-RADR 2 project, based on patient and healthcare professional feedback. Enhancements implemented in 2019 include the ability to share news articles from the app to social media channels. This enables better dissemination of important safety information, as well as general performance improvements.

181. A key focus of the WEB-RADR 2 project has also involved migrating the Yellow Card app onto a new Vigilance Hub. This Vigilance Hub provides the MHRA team greater control and flexibility with the app, for example, allowing the MHRA to more easily update the drug list available to

reporters to ensure it reflects the latest medicines licenced by the MHRA. Migration of the Yellow Card app onto a 'Vigilance Hub' has enabled application programming interfaces (APIs) to be used. These APIs allow features of the Yellow Card app, such as the reporting form, to be embedded into third party websites, apps and electronic health record systems. Reports submitted through the API are directly received in the MHRA database. Initial discussions have been held with several organisations interested in implementing the Yellow Card API. The MHRA has also reached out to NHS Digital and NHSX to make the Yellow Card App available on the NHS Apps Library as well as embed the Yellow Card API within the NHS app.

UK Yellow Card Centres

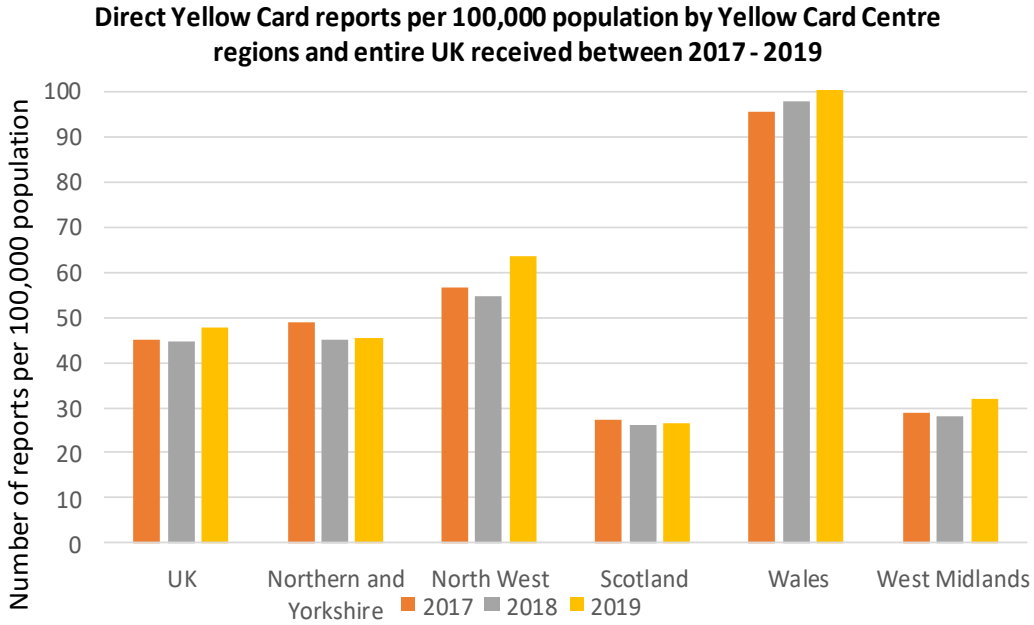
182. The MHRA works with five Yellow Card Centres (YCCs) based in the United Kingdom to increase awareness of the Yellow Card Scheme and increase ADR reporting rates within their regions. The YCCs operate in Wales, Scotland, Northern & Yorkshire, North West and the West Midlands. The YCCs are involved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

183. The YCCs continue to promote the Yellow Card Scheme and provide educational services to both undergraduate and postgraduate healthcare students, as well as qualified healthcare professionals, in the form of lectures, education materials and other resources. The YCCs also work with local charities and support groups to provide useful insight into the Yellow Card Scheme. The YCCs play an important part in social media campaigns by supporting through their YCC social media pages.

184. The YCCs also attend relevant events and conferences where they are able to discuss the importance of ADR reporting with attendees. YCC Northern and Yorkshire have engaged with a number of various different patient groups. They have also worked alongside YCC North West on an Undergraduate study day at the University of Bradford and as a result presented a poster at the UKMI professional development Seminar to promote education of the Scheme. YCC Scotland's Twitter page has seen an increase in the number of followers in the UK as well as across Europe with particular interest in their e-learning ADR modules. They have also been involved in a Q & A session on a radio health show. YCC West Midlands held an ADR study day with a range of consultants and patients which proved successful and plan to hold another in 2020. They also have seen an increase in their social media engagement with members of the public. YCC Wales invited practice-based pharmacists to join their Yellow Card Champion Training Day to for the first time in 2017. Since then YCC Wales has gone on to hold their Yellow Card Champion Training Day annually and are currently planning their 2020 event.

185. The YCCs' dedication and continued support of the Yellow Card Scheme can be seen by the steady ADR reporting rates in Figure 5. In 2019 two YCCs had a higher reporting rate per 100,000 people than the UK average (48): North West (63) and Wales (104).

Figure 5 – Graph showing the number of direct Yellow Card reports per 100,000 population for the UK and each Yellow Card Centre over the last 3 years.



Signal Detection

186. The MHRA signal management system is designed for the timely detection of new and changing drug safety issues. Changes in the frequency of ADRs already known to be associated with medicines are also closely monitored through the MHRA's signal detection process. The drug-event combinations from Yellow Card reports are assessed on a weekly basis to identify potential safety signals. In 2019, there were a total of 98 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 can result in regulatory action, such as updates to product information, or may contribute to wider reviews alongside other sources of data. Each signal is prioritised and assigned a timeframe during which a regulatory position on the action required is reached. A breakdown of the signals and assigned priorities is provided in Table 1.

Table 1: Number of signals assessed in 2019

	Signal Priority		
	Top	**Increased**	**Standard**
Number of signals	1	5	92

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

187. In 2019, information (ADR reports, enquiries) received directly from members of the public contributed towards 34 signals being detected. Of these signals 25 were initiated for investigation from information from members of the public. Pharmacovigilance Information received from health care professionals contributed to 51 signals being detected, of which 23 reports were the index case.

188. 25 signals originated from other sources of information, including information directly from the medical literature (12), other international regulatory authorities, via the IPMS data exchange and other health authorities within the UK (NHS England, Healthcare safety Investigation Branch).

189. Some examples of signals which stimulated regulatory action in 2019 include ferric carboxymaltose and foetal bradycardia, where the possible occurrence of foetal bradycardia as a consequence of hypersensitivity reaction in the mother was added to section 4.6 of the SmPC for all intravenous iron containing medicinal products. A further example is of Glucagon-like peptide 1 receptor agonists (GLP-1) and delayed gastric emptying which can lead to serious complications such as aspiration pneumonia during surgery. Following review, the product information for Liraglutide was updated, with further review in PSURs for the GLP-1 receptor agonists. Stakeholders were also notified via the Safe Anaesthesia Liaison Group.

190. An example of a signal which originated directly from a pregnant patient includes labetalol and nipple pain, regulatory action was taken to ask the Market Authorisation Holder (MAH) to update their Patient information Leaflet (PIL) to include nipple pain as a possible symptom of Raynaud's Phenomenon.

191. In August 2018, the MHRA introduced a pilot of a dedicated Pregnancy Signal Detection meeting to support our routine signal detection activities. The aim of the meeting is to review all reports of drug exposures in pregnancy received each week as well as all reports of abnormal pregnancy outcomes to develop a safety profile of the medicines use during pregnancy. The reports are assessed and reviewed by a multidisciplinary team. The meetings have generated several validated signals that have been taken forward for discussion at Signal Management Review Meetings. All validated signals and reports of interest identified through the Pregnancy Signal Detection meetings are highlighted to the Medicines for Women's Health EAG (MWHEAG) for comment or advice. Further details of this process can be seen in the MWHEAG section of the report. The pilot was finalised in 2019, with the Pregnancy Signal Meeting incorporated into the MHRA's routine signal detection processes, with Standard Operating Procedures developed.

192. In 2019, the MHRA continued to contribute to the International Post-Market Surveillance (IPMS) group. The group is comprised of the US Food and Drug Administration (FDA), Health Canada, Therapeutic Goods

Administation (TGA), Medsafe, Health Sciences Authority (HSA) and Swissmedic. Every two months, each agency has the opportunity to propose topics to the other agencies for discussion, who subsequently provide written responses, followed up with a telephone conference if required. In general, the topics relate to potential drug safety issues, but may also entail more general pharmacovigilance questions. The MHRA have proposed a number of topics in 2019, through which further information and worldwide evidence has been obtained to aid the assessment of signals. For example, information on previous reviews and details of case reports were requested for a signal regarding mirtazapine and amnesia. The responses received provided insight into the strength of the evidence for the signal, which enabled an informed decision that the signal would be referred to the European Pharmacovigilance Risk Assessment Committee (PRAC) for further review.

E-Cigarette Reporting

193. The MHRA is the UK competent authority for the regulation of nicotine-containing e-cigarettes and refills under the terms of the Tobacco and Related Product Regulations. All nicotine containing products have had to be notified to the MHRA. During 2019 there have been 27 adverse reaction reports (including 3 reports which are not considered valid), 2 reports of product safety concerns and 2 reports of product quality concerns relating to nicotine containing e-cigarettes. This rate of Yellow Card reporting is an increase on the rate of 2018 and 2017 with 17 and 24 reports respectively. This in part may be due to the increased press interest particularly around vaping related lung injury reported in the United States. We have also received notification of 1 product recall from industry, due to identified potential safety concerns. We continue to liaise closely with Trading Standards authorities to share information regarding product device-related safety and quality concerns.

Appendix I

MEMBERSHIP OF THE COMMISSION ON HUMAN MEDICINES

Chair

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

Members

Ms Susan Bradford
Lay Representative

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

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

Professor Jonathan S Friedland MA PhD FRCP FRCPE FRCPI FESCMID FMedSci
Deputy Principal, St. George's, University of London

Dr Richard J C Gilson MD FRCP
Associate Professor in Sexual Health and HIV and Honorary Consultant Physician, Central and North West London NHS Foundation Trust.
Director, UCL Centre for Clinical Research in Infection and Sexual Health;
Deputy Director, Institute for Global Health, University College London

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

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

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

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

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

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

Professor Shirley Price MSc PhD FBTS FRSB ERT FHEA FRSC MBPharmacol Soc
Visiting Professor of Toxicology, University of Surrey

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

Mrs Helen M Ward MSc, BSc (Hons), Senior Fellow HEA, RGN, RCN Nurse Practitioner, PGCEA, PG Cert NMP, Queens Nurse
Advanced Nurse Practitioner

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

Invited Experts to Commission Meetings

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

Dr Kristien Boelaert MD, PhD, MRCP
Reader in Endocrinology, University of Birmingham & practising Consultant Endocrinologist in charge of the Thyroid Services at the UHB NHS Foundation Trust

Dr Maria Eugenicos MD MSc(Ed) PhD, FHEA
Senior Lecturer/Gastroenterologist
Gastroenterology Department
Western General Hospital

Dr Chris Gallagher BSc PhD FRCP
Consultant Medical Oncologist, St Bartholomew's Hospital, Barts and the London NHS Trust and member of the Oncology and Haematology Expert Advisory Group (OHEAG)

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

Professor Philip Hannaford MB ChB DRCOG DCH MD FRCGP FFSRH FFPH Professor of Epidemiology, Interim Senior Vice-Principal University of Aberdeen

Mrs Melanie Hingorani
Consultant Ophthalmologist, Moorfields Eye Hospital

Professor Christopher Marriott PhD DSc Hon DSc FRPharmS CChem FRSC FRSM
Emeritus Professor of Pharmaceutics, King's College, London and member of Chemistry, Pharmacy and Standards Expert Advisory Group (CPS EAG)

Professor Poulam M Patel PhD FRCP
Professor of Clinical Oncology, Academic Unit of Clinical Oncology, University of Nottingham

Dr Edward Seward BSc MBChB FRCP MD
Consultant Gastroenterologist
University College London Hospital

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

Professor Angela E Thomas OBE MB BS PhD FRCPE FRCPath
Consultant Paediatric Haematologist, Edinburgh

Observers of Commission Meetings

Mrs Jenna Dilkes
Programme Manager, Technology Appraisals
National Institute for Health and Care Excellence (NICE)

Dr Aiden Fowler
NHS England

Ms Helen Jukes
CVMP member for the UK, Authorisations Division, Veterinary Medicines Directorate

Ms Claire Liew
Pharmacist Medicine Supply team
Medicines and Pharmacy Directorate, Department of Health and Social Care (DHSC), London

Ms Sarah McAleer
Pharmacist Medicine Supply team
Medicines and Pharmacy Directorate, Department of Health and Social Care (DHSC), London

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

Ms Jenniffer Prescott
Associate Director – Planning, Operations and Topic Selection
National Institute for Health and Care Excellence (NICE)

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

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

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

Members

Dr Amanda Adler[6] MD PhD FRCP
Consultant Physician, Diabetes, Addenbrooke's Hospital, Cambridge University Hospitals

Professor Iolo J Doull DM MRCP FRCPCH
Consultant Respiratory Paediatrician, Children's Hospital for Wales, Cardiff
Deputy Medical Director Welsh Health Specialised Services Committee

Dr John Firth[7] BA BM ChB DM FRCP
Deputy Medical Director, Cambridge University Hospitals FT, Consultant Physician and Nephrologist, Addenbrooke's Hospital, Cambridge

Dr Andrew Grace[8] MB PhD FRCP FACC FESC
Consultant Cardiologist, Papworth and Addenbrooke's Hospitals Cambridge & Research Group Head, Department of Biochemistry, University of Cambridge

Dr Philip W Ind BA Cantab MB BChir MA Cantab FRCP
Honorary Consultant Physician, Hammersmith Hospital, Adjunct Reader NHLI, Imperial College London

Professor Patrick Mark MB CHB (Hons) PhD FRCP (Glasg)
Professor of Nephrology & Honorary Consultant Nephrologist, University of Glasgow and Glasgow Renal and Transplant Unit, Queen Elizabeth University Hospital, Glasgow

[6] Reappointed 12/12/2019
[7] Reappointed 10/12/2019
[8] Reappointed 12/11/2019

Professor Theresa McDonagh BSc (Hons), MB ChB (Hons), MD (Distinction), FRCP, FESC, FHFA
Consultant Cardiologist, King's College Hospital, London & Professor of Heart Failure King's College, London

Professor Pallav L Shah[9] MD MBBS FRCP -
Consultant Physician, Royal Brompton Hospital and Chelsea & Westminster Hospital, Professor of Respiratory Medicine, Imperial College

Dr Caroline Vaughan[10] PhD
Lay Representative of MHRA EAGS. Governor of the Surrey and Sussex Hospital

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

Professor Ann Millar[11] MBChB MD FRCP
Emeritus Professor in Respiratory Medicine, Bristol University & Honorary Consultant, North Bristol NHS Trust

Professor Hilary Pinnock MB ChB (Hons) MRCGP MD
Professor of Primary Care Respiratory Medicine, Asthma UK Centre for Applied Research, Allergy and Respiratory Research Group, Usher Institute of Population Health Sciences and Informatics, University of Edinburgh; General Practitioner, Whitstable Medical Practice

[9] Reappointed 17/09/2019
[10] Reappointed 12/11/2019
[11] End of appointment 11/11/2019

MEMBERSHIP OF THE CHEMISTRY, PHARMACY AND STANDARDS EXPERT ADVISORY GROUP

Remit

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

Chair

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

Vice Chair

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

Members

Professor Graham Buckton[12] BPharm PhD DSc FRPharmS FRSC
Emeritus Professor of Pharmaceutics, UCL School of Pharmacy

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

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

Professor Geoffrey W Hanlon[13] BSc PhD
Emeritus Professor of Pharmaceutical Microbiology, School of Pharmacy & Bio-Molecular Sciences, University of Brighton

Dr Gillian M Hawksworth[14] MBE PhD FFRPS FRPharmS (Hon) DSc
Academic Community Pharmacist, Visiting Fellow at University of Huddersfield & Past President of the RPSGB

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

[12] Reappointed 17/09/2019
[13] Reappointed term ending 16/09/2021
[14] Reappointed 09/11/2019

Dr Majella Lane[15] BSc PhD
Senior Lecturer in Pharmaceutics, UCL School of Pharmacy

Mr Robert Lowe[16] BPharm FRPharmS
Practising Hospital Pharmacist, Specialist Pharmacy Services - East of England

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

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

Professor Peter York[17] PhD BSc DSc FRPharmS CChem FRSC FAAPS
Emeritus Professor of Pharmaceutics, Bradford University

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

Professor Ruth Duncan[18] PhD
Professor Emerita in Cell Biology and Drug Delivery, Cardiff University and Visiting Professor at the University of Greenwich

[15] Reappointed 10/11/2019
[16] Reappointed 11/11/2019
[17] Reappointed 11/11/2019
[18] Retired 03/12/2019

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 advise
- other clinical trials involving classes of compound where MHRA may wish to seek external expert advice or CHM may wish to have oversight
- whether a product's mechanism of action is novel and comes within the scope of the EAG
- pre-meeting scientific advice documentation for within scope compounds
- other clinical trials where MHRA may wish to seek advice or where there is a difficult risk benefit balance
- other clinical trials involving products where a new class safety issue has been identified
- the quality, safety and efficacy of medicinal products of biological or biotechnological origin including vaccines which are the subject of marketing authorisation applications and to advise on such other matters as are referred to it.

Chair

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

Members

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

Professor Helen J Lachmann[19] MD FRCP FRCPath **(Vice Chair)**
Reader and Honorary Consultant in Amyloidosis and Renal Medicine, University College London

[19] Reappointed 15/09/2019

Professor B Kevin Park BSc PhD FMedSci HonFRCP FBTS HonFBPhs
Professor of Pharmacology, 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 Robin Thorpe PhD FRCPath
Retired, Head, Division of Biotherapeutics, National Institute for Biological Standards and Control (NIBSC)

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

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

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

[20] Reappointed 12/11/2019

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[21] BSc MBBS DPhil FRCP
Associate Professor, University of Southampton and Consultant Dermatologist

Professor Qasim Aziz[22] MRCP PhD FRCP
Professor of Neurogastroenterology, Director Wingate Institute of Neurogastroenterology, Centre for Neuroscience, Trauma and Surgery, Blizard Institute, Barts and the London School of Medicine and Dentistry, Queen Mary University of London

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

Professor Kevin Moore[23] BSc MB BS PhD FRCP
Professor of Hepatology, Royal Free Hospital, London

Professor Celia Moss OBE BA(Hons) MB BS MA MRCP DM FRCP MRCPCH
Consultant Dermatologist, Birmingham Women's and Children's NHS FT
Honorary Professor of Paediatric Dermatology, University of Birmingham

Dr Frances MK Williams[24] PhD FRCP(E)
Professor and Hon Consultant, Dept Twin Research and Genetic Epidemiology King's College London

[21] Reappointed 17/09/2019
[22] Reappointed 21/03/2019
[23] Reappointed 14/10/2019
[24] End of appointment 22/05/2019

MEMBERSHIP OF THE AD HOC EXPERT GROUP ON META-ANALYSIS OF ORAL HPTs

Chair

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

Members

Professor Julian Higgins BA(Hons) PhD
Professor of Evidence Synthesis and Director of Research for Population Health Sciences, Bristol Medical School

Professor Jonathan Sterne BA, MSc, PhD
Professor of Medical Statistics and Epidemiology, University of Bristol

Professor Ruth Newbury-Ecob MB, ChB, MD FRCPCH FRCP
Consultant in Clinical Genetics and Honorary Professor, University Hospital of Bristol

Invited Expert

Professor Liam Smeeth MBChB FRCGP FFPH FRCP MSc PhD FMedSci
Professor of Clinical Epidemiology, Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine

Visiting Expert

Professor Carl Heneghan BM, BCH, MA, MRCGP, DPhil
Professor of Evidence-Based Medicine, Medical Sciences Division, Nuffield Department of Primary Care

Dr Jeffrey K Aronson MA DPhil FRCP HonFBPhS HonFFPM
Consultant Physician and Clinical Pharmacologist
Centre for Evidence-Based Medicine, Nuffield Department of Primary Care Health Sciences

Observers

Mr Nick Dobrik, MBE
Volunteer, The Thalidomide Trust

Mrs Marie Lyon
Association for Children Damaged by Hormone Pregnancy Tests

Dr Sonia Macleod
Independent Medicines and Medical Devices Safety Review Representative

Ms Linda Pepper BA MA
Independent Consultant: Patient and Public Involvement in Healthcare

Providing written comments only

Dr Sarah Floud BSc, MSc, PhD
Senior Epidemiologist, Cancer Epidemiology Unit, University of Oxford

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 FESCMID FMedSci
Deputy Principal, St. George's, University of London

Members

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

Dr Andrew Freedman[25] 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 J C Gilson MD FRCP
Associate Professor in Sexual Health and HIV and Honorary Consultant Physician, Central and North West London NHS Foundation Trust.
Director, UCL Centre for Clinical Research in Infection and Sexual Health; Deputy Director, Institute for Global Health, University College London

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

Dr Susan Hopkins[26] BA MB BCh BAO (Hons) FRCPI FCRP
Consultant in Infectious Diseases & Microbiology, Royal Free London NHS Foundation Trust, Healthcare Epidemiologist, Public Health England, Honorary Senior Lecturer, University College London

Dr Katie Jeffery FRCP FRCPath
Deputy Director of Infection Prevention and Control, Consultant Microbiologist (Clinical Lead), Oxford University Hospitals NHS Foundation Trust

Professor Martin Lombard[27] MD MSc FRCP (Lond)
Consultant Hepatologist & Gastroenterologist, Royal Liverpool University Hospitals NHS Trust

[25] Reappointed 11/12/2019
[26] Reappointed 24/03/2019
[27] End of appointment 11/12/2019

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[28] BSc MB BS PhD FRCP
Professor of Hepatology, Royal Free Hospital, London

Dr Matthias Schmid MD FRCP DTMH
Consultant Physician, Head of Department of Infection & Tropical Medicine, Directive of Elective Studies Newcastle University, Royal Victoria Infirmary, Newcastle upon Tyne

Ms Hilary A Shenton[29] CPFA
Lay Representative. Retired Secretary to the School of Medicine, University of Sheffield

[28] Reappointed 14/10/2019
[29] Reappointed 24/03/2019

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 MB ChB FRCOG FRCPEdin FFSRH
Retired Consultant Gynaecologist

Members

Professor Philip Hannaford[30] MB ChB DRCOG DCH MD FRCGP FFSRH FFPH
Professor of Primary Care, University of Aberdeen

Ms Linda Pepper[31] BA MA (Education)
Independent Consultant: patient and public involvement in healthcare

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

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

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

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

Dr Clare Spencer[32] MA MB BCHIR DM MRCOG MRCGP DFFPRHC
GP Partner

[30] Reappointed 17/09/2019
[31] Reappointed 17/07/2019
[32] Reappointed 15/01/2019, Resigned 04/07/2019

MEMBERSHIP OF THE NEUROLOGY, PAIN & PSYCHIATRY EXPERT ADVISORY GROUP

Remit

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

Chair

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

Members

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

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

Dr David Hunt MBMS MRCP PhD
Honorary Consultant Neurologist/Wellcome Trust Senior Clinical Fellow, Anne Rowling Clinic, University of Edinburgh

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

Dr Waqar Rashid[33] MBBS BSc MRCP(UK) PhD
Consultant and Honorary Clinical Senior Lecturer in Neurology, Brighton and Sussex University Hospitals NHS Trust, member of the Multiple Sclerosis Society

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

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

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

[33] Reappointed 12/12/2019

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

MEMBERSHIP OF THE ONCOLOGY & HAEMATOLOGY EXPERT ADVISORY GROUP

Remit

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

Chair

Professor Angela E Thomas MB BS PhD FRCPE FRCPath
Consultant Paediatric Haematologist, University of Edinburgh

Members

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

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

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

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

Dr Robert Marcus
Consultant Haematologist at Kings College Hospital London, UK

Dr Geoff Shenton[34] FRCPath MRCP MBChB (Distinction) BMedSci
Consultant & Associate Clinical Lecturer in Paediatric and Adolescent Haematology & BMT, Great North Children's Hospital, Newcastle upon Tyne

[34] Resigned 17/04/2019

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

Mrs Catrin Barker
Chief Pharmacist, Pharmacy Department, Alder Hey Children's NHS FT, Eaton Road, Liverpool

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

Professor J Helen Cross[35] OBE MB ChB PhD FRCP FRCPCH
The Prince of Wales's Chair of Childhood Epilepsy, Deputy Head of Developmental Neurosciences Programme, UCL Institute of Child Health

Professor Steven Cunningham MBChB PhD FRCPCH (Vice Chair)
Professor of Paediatric Respiratory Medicine, University of Edinburgh and Honorary Consultant, Royal Hospital for Sick Children, NHS Lothian, Edinburgh.

Professor Meriel Jenney MBChB MRCP MD FRCPCH
Consultant Paediatric Oncologist, Clinical Board Director, Clinical Diagnostics and Therapeutics Clinical Board, Assistant Medical Director (Cancer Services), University Hospital of Wales

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

[35] Reappointed 14/05/2019

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

Dr Rubin Minhas[36] MB ChB MBA
GP Principal

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

Professor Anthony Nunn[37] 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[38] BA CPE LPC
Lay Representative. Solicitor

Dr Guido Pieles PhD MD
Consultant Congenital Cardiologist
Congenital Hear Unit, Bristol Heart Institute

Professor Heather M Wallace PhD FRCPath FRSC FSB FBPhS FBTS
European Registered Toxicologist (ERT)
Professor of Biochemical Pharmacology and Toxicology, Institute of Medical Sciences, University of Aberdeen

Dr Morris Zwi[39] MBBCh, FRCPsych
Consultant Child & Adolescent Psychiatrist & Clinical Lead, Child & Adolescent Mental Health Services, Whittington Health, Child & Adolescent Mental Health Services

Dr Mark Whiting[40] Nursing MSc PhD
Consultant Nurse, Children's Community and Specialist Nursing, Peace Children's Centre, Hertfordshire Community NHS Trust

[36] Reappointed 15/07/2019
[37] Resigned 11/07/2019
[38] Reappointed 10/03/2019
[39] Reappointed 21/02/2019
[40] End of appointment 15/01/2019

MEMBERSHIP OF THE PHARMACOVIGILANCE EXPERT ADVISORY GROUP

Remit

To advise the Commission on the following in relation to human medicines including herbal products:

- The public health importance of potential new safety signals.
- The confirmation and quantification of risks identified.
- Appropriate risk minimisation measures including communications.
- Design and progress of pharmacovigilance plans.
- Methodologies for pharmacovigilance.
- Review and advise the MHRA on applications for Type II Yellow Card data, which fall outside of Freedom of Information provisions.

Chair

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

Members

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

Professor Ann Daly BA PhD FBPhS
Professor of Pharmacogenetics, Faculty of Medical Sciences, Newcastle University

Professor Ian J Douglas[41] BSc MSc PhD
Senior Lecturer in Pharmacoepidemiology, London School of Hygiene & Tropical Medicine

Dr Mark Glover[42] BA MA MB BChir MRCP PhD
Associate Professor and Honorary Consultant Physician, Clinical Pharmacology and General Medicine, University of Nottingham

Dr Daniel Hawcutt BSc (Hons), MB ChB (Hons), MD, MRCPCH
Senior Lecturer in Paediatric Clinical Pharmacology, Women's and Children's Health, Institute of Translational Medicine, University of Liverpool

[41] Reappointed 15/09/2019
[42] Appointed 24/01/2019

Ms Susan Hunneyball BSc (Hons)
Lay Member

Dr Karen Miller[43] BSc MBBS DRCOG DCH DFFP FRCGP
GP Partner, Adelaide Medical Centre, London

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

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

Dr Ruben Thanacoody[44] MD FRCP FRCP (Edin)
Consultant Physician, Royal Victoria Infirmary, Newcastle upon Tyne Hospitals NHS Foundation Trust
Honorary Clinical Senior Lecturer in Clinical Pharmacology, Newcastle University
Honorary Consultant Clinical Toxicologist, Public Health England
Director National Poisons Information Service (Newcastle unit)

Dr Mark Whiting[45] Nursing MSc PhD
Consultant Nurse, Children's Community and Specialist Nursing, Peace Children's Centre, Hertfordshire Community NHS Trust

Professor Simon R J Maxwell[46] MD PhD FRCP FRCPE FBPhS FHEA
Professor of Student Learning/Clinical Pharmacology, Western General Hospital, Edinburgh & University of Edinburgh

[43] Reappointed 15/09/2019
[44] Reappointed 15/09/2019
[45] End of Appointment 15/01/2019
[46] End of appointment 09/12/2019

MEMBERSHIP OF THE AVASTIN PEER REVIEW GROUP

Chair

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

Members

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

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

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

MEMBERSHIP OF THE E-CIGARETTES EXPERT WORKING GROUP

Chair

Professor Angela E Thomas OBE MB BS PhD FRCPE FRCPath, Consultant Paediatric Haematologist, University of Edinburgh

Members

Toxicology

Professor Shirley Price MSc, PhD, FBTS, FRBS, ERT, FHEA, FRSC, MBritPharmacolSoc,
Visiting Professor of Toxicology, University of Surrey

Professor Alan Boobis OBE PhD CBiol FRSB FBTS, FBPhS
Professor of Biochemical Pharmacology and Director of Toxicology Unit (funded by PHE & DHSC), Faculty of Medicine, Imperial College London.

Epidemiology

Professor John R Britton MB BS MD FRCP FFPHM
Professor of Epidemiology and Director, UK Centre for Tobacco Control Studies, Head of Division of Epidemiology and Public Health, University of Nottingham, chair of Royal College of Physicians Tobacco Advisory Group and member of board of Trustees of Action, Smoking and Health (ASH).
Respiratory Medicine

Professor Steven Cunningham MBChB, PhD, FRCPCH
Professor of Paediatric Respiratory Medicine, University of Edinburgh and Honorary Consultant, Royal Hospital for Sick Children, NHS Lothian, Edinburgh

Professor Pallav Shah MD MBBS FRCP
Consultant Physician, Royal Brompton Hospital and Chelsea & Westminster Hospital, Professor of Respiratory Medicine, Imperial College

Pharmacy

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

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

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

Tobacco Control

Ms Deborah Arnott
Chief Executive of Action, Smoking and Health (ASH).

Professor Paul Aveyard PhD, MRCP, FRCGP and FFPH
Professor of Behavioural medicine, University of Oxford
General Practitioner, Knowle

Professor Ann McNeill
Tobacco Addiction, King's College London. Deputy Director of the UK Centre for Tobacco & Alcohol Studies, Member of the Royal College of Physicians Tobacco Advisory Group (UKCTAS) Committees on Toxicity, Carcinogenicity and Mutagenicity.

Observers

Mr Martin Dockrell
Tobacco Control Programme Lead for Public Health England

Mr Matthew Birkenshaw
Team Leader-Tobacco Control and Alcohol Labelling Policy Lead
(key subject areas: FCTC, E-cigarettes, novel tobacco and alcohol labelling)
Healthy Behaviours Team
Global and Public Health Group
Department of Health and Social Care

Ms Alison Walker
Department of Health and Social Care

Ms Sarah Willet
Associate Director
NICE - Centre for Guidelines
National Institute for Health and Care Excellence

Mr Qasim Chowdary
Tobacco Control Manager – Health Improvement: Alcohol, Drugs, Tobacco & Justice Division
Public Health England

MEMBERSHIP OF THE OPIOIDS EXPERT WORKING GROUP

Chair

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

Members

Anaesthesia

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

Epidemiology

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

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

General Practitioner

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

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

Geriatrician

Professor Peter Crome MD PhD DSc FRCP FFPM FBPharmacolS
Emeritus Professor, Keele University, Honorary Professor, UCL

Lay member

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

Nursing practice

Mrs Helen M Ward MSc, BSc (Hons), Senior Fellow HEA, RGN, RCN Nurse Practitioner, PGCEA, PG Cert NMP
Queens Nurse, Advanced Nurse Practitioner

Paediatric

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

Pain Management

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

Pain Medicine

Professor Lesley Colvin
Chair in Pain Medicine, University of Dundee/ Consultant in Anaesthesia & Pain Medicine, NHS Tayside, Deputy Head of Division, Population Health and Genomics, Hon. Professor in Pain Medicine, University of Edinburgh

Pharmacist

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

Psychiatry and Substance Abuse

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

Rheumatology

Professor Frances MK Williams PhD FRCP(E)
Professor of Genomic Epidemiology & Hon Consultant Rheumatologist Dean St Thomas' Campus Dept of Twin Research and Genetic Epidemiology King's College London

Toxicology and Pharmacology

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

Visiting Expert

Dr Meghna Jani
NIHR Academic Clinical Lecturer at the Arthritis Research UK Centre for Epidemiology, University of Manchester and Honorary Consultant in Rheumatology (Salford Royal Foundation Trust)

Dr Richard Davenport DM FRCP (Edin) BM BS (Hons) BMedSci
Consultant Neurologist, Western General Hospital, Edinburgh

Observers

Dr Martin Allably
Consultant Clinical Advisor, Centre for Guidelines
National Institute for Health and Care Excellence, London

Mr Steve Taylor
Programme Manager, PHE Alcohol, Drugs, Tobacco & Justice

MEMBERSHIP OF THE OPTIMISING DATA ON MEDICINES USED IN PREGNANCY WORKING GROUP

Chair

Professor Jane Norman MB ChB, MD, FRCOG, F MedSci, FRCP Edin, FRSE
Dean, Faculty of Health Sciences, University of Bristol

Members

Professor Peter Brocklehurst MBChB, MSc, FRCOG, FFPH, FMedSci
Professor of Women's Health, Director for Birmingham Clinical Trials Unit (BCTU)

Mr Paul Brown
Clinical Lead NHS Digital, Prescribing, Medicines and Pharmacy

Ms Caroline Cake
Chief Operating Officer at Health Data Research UK

Dr Rachel Charlton
Dept of Pharmacy and Pharmacology
University of Bath

Mr Chris Dickson
Senior Clinical Lead Platforms and Infrastructure, Paediatric Nurse, Digital Child Health and Digital Maternity

Professor Helen Dolk
Professor of Epidemiology & Health Services Research
School of Nursing Institute of Nursing and Health Research Jordanstown campus
University of Ulster

Professor Elizabeth Draper
Professor of Perinatal & Paediatric Epidemiology
Director of Learning & Teaching

Dr Kenneth Hodson MD MBChB MRCP(UK) MRCOG
Head of UK Teratology Information Service, UK Teratology Information Service, Consultant in Obstetrics and Maternal Medicine

Dr Matthew Jolly
National Clinical Director for the Maternity & Women's Health, Acute Medical Directorate, NHS England & NHS Improvement

Professor Neena Modi MB ChB MD FRCP FRCPCH FFPM
Professor of Neonatal Medicine, Consultant, Imperial College London

Professor Joan Morris
Professor of Medical Statistics, Population Health Research Institute, St George's, University of London

Dr Puja Myles
Head of Observational Research, Clinical Practice Research Datalink (CPRD)

Ms Katharine Robbins
Information Analysis Lead Manager, Maternity, Child Health and Community at NHS Digital Leeds, West Yorkshire

Dr Sarah Stevens
Public Health Consultant, Service Lead, The National Congenital Anomaly and Rare Disease Registration Service (NCARDRS)
Public Health England

Dr Sarah Stock
Senior Clinical Lecturer in Maternal and Fetal Health, The Queen's Medical Research Institute, Edinburgh BioQuarter

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

Dr Sonia Macleod
Independent Medicines and Medical Devices Safety Review Representative

Dr Mel Ramasawmy
Independent Medicines and Medical Devices Safety Review Representative

Mr Dave Roberts
Head of Business and Operational Delivery for NHS Digital

Dr Llion Davies
Public Health Wales

Dr Rachael Wood
Information Service Division

Ms Alison Little
HSC Public Health Agency

Ms Adele Graham
HSC Public Health Agency

MEMBERSHIP OF THE YELLOW FEVER EXPERT WORKING GROUP

Chair

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

Members

Professor Guruprasad P. Aithal
Professor of Hepatology and the Head of the Division for the Nottingham Digestive Diseases Centre and Deputy Director of Nottingham Molecular Pathology Node

Professor David Gunnell MB ChB PhD (Bristol), FFPH, MRCGP MFPHM DSc, F Med Sci
Professor of Epidemiology
University of Bristol

Sir Michael Jacobs
Consultant & Hon. Senior Lecturer in Infectious Diseases
Royal Free London NHS Foundation Trust

Professor Paul Klenerman FMedSci
Sidney Truelove Professor of Gastroenterology, Nuffield Department of Medicine,
University of Oxford

Dr Donald Palmer
Associate Professor of Immunology, Royal Veterinary College, University of London

Ms Madeleine Wang, BA (Hons)
Lay Representative, Patient Advocate

Dr Annelies Wilder-Smith
Professor of Infectious Diseases Research
World Health Organisation

Dr David Hunt BA MB PhD
Wellcome Trust Senior Clinical Fellow, Anne Rowling Clinic, University of Edinburgh

Professor Alan Barrett BS MS PhD
Department of Pathology,
The University of Texas

Dr Lance Turtle PhD MBBS MRCP
Senior clinical lecturer/honorary consultant in infectious diseases
Institute of Infection and Global Health
University of Liverpool

Professor Simon Kroll
Professor of Paediatrics and Molecular Infectious Diseases
Imperial College London

Invited Experts

Dr Richard Dawood
BSc MB BS MD DTM&H FRCR DRCOG FFTM RCPS (Glasgow) CTH CTropMed
Medical Director and specialist in travel medicine

Dr Alisdair MacConnachie
Representative from UK based YF vaccine Centre
NHS Greater Glasgow & Clyde

Dr Andrew J Pollard BSc MBBS PhD (Lond), DIC, MRCP (UK), FHEA, FIDSA, FRCPCH, MA, FMedSci
Professor of Paediatric Infection and Immunity,
Director of Graduate Studies
University of Oxford
JCVI Chairman

Dr Joachim Hombach, PhD, MPH
Senior Health Adviser
Executive Secretary SAGE
Immunization, Vaccines & Biologicals
World Health Organization

Ms Margaret Umeed MSc RGN FQNIS FFTM (RCPS, Glas)
Specialist Nurse Practitioner (GPN)/Trainee ANP
The Green Practice

Dr Shirley Marshall
Health Protection Scotland

Dr Dipti Patel
Director, National Travel Health Network and Centre (NaTHNaC)

Dr Kali Perrow
Medical Lead, Travel and International Health Team
Health Protection Scotland

Ms Hilary Simons MSc RGN RSCN Dip N
Liverpool School of Tropical Medicine
Specialist Nurse, National Travel Health Network and Centre (NaTHNaC)

Mr Jake Dunning
Public Health England

Dr Mary Ramsay
Public Health England

Observers

Dr Jonathan Crofts
Public Health England

Dr Martin Broadstock
Programme Manager for Immunology and Vaccines
Medical Research Council

Dr Raj Long
Gates Foundation

MEMBERSHIP OF THE OPHTHALMIC EXTERNAL EXPERT PANEL

Dr Sajjad Ahmad MB BS PhD FRCOphtp
Ophthalmic Surgeon and Academic Clinical Lecturer,
Royal Victoria Infirmary and North East England Stem Cell Institute, Newcastle upon Tyne,

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

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

Professor Paul N Bishop B Med Sci (Hons) BM BS DO FRCS FRCOphth PhD CCST
Professor of Ophthalmology & Matrix Biology Consultant Ophthalmologist
Theme Lead, Manchester NIHR Biomedical Research Centre, University of Manchester and Hon Consultant Ophthalmologist, Manchester Royal Eye Hospital

Professor Baljean Dhillon BMed Sci BM BS FRCPG FRCSE FRCOphth
Princess Alexandra Eye Pavillion, Edinburgh

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

Mr Teifion Emlyn James FRCP Ed. FRCP Lond. FRCS Ed. FBCLA FRCOphth
Consultant Ophthalmologist (Uveitis), Calderdale Royal Hospital, Department of Ophthalmology
Halifax

Professor Sir Peng T Khaw PhD FRCP FRCS FRCOphth CBiol FSB FRCPath FMedSci
Professor of Glaucoma and Ocular Healing, and Consultant Ophthalmic Surgeon
Director of Research & Development, Moorfields Eye Hospital NHS Foundation Trust
Director, National Institute for Health Biomedical Research Centre for Ophthalmology,
Moorfields Eye Hospital and UCL Institute of Ophthalmology, London, UK
Programme Director, Eyes & Vision, UCL Partners Academic Health Science Centre

Mr Anthony J King MD MMedSci FRCOphth
Consultant Ophthalmologist, Queens Medical Centre, Nottingham

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

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

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

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

COMMISSION ON HUMAN MEDICINES/EXPERT ADVISORY GROUPS SECRETARIAT

Commission on Human Medicines (CHM)

Dr Krishna Prasad
Principal Assessor, Licensing

Ms Ebru Agca
Secretary

Mrs Munise Guler **(from September 2019)**
Assistant Secretary

Chemistry, Pharmacy and Standards Expert Advisory Group (CPSEAG)

Dr Linda A Anderson
Principal Assessor, Licensing (Pharmaceutical)

Mrs Munise Guler
Secretary

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

Dr Julian Bonnerjea
Principal Assessor, Licensing (Biologicals)

Dr Anne Cook
Principal Assessor, Licensing (Biologicals)

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

Ms Pauline Edwards
Secretary

Pharmacovigilance Expert Advisory Group (PEAG)

Ms Claire Davies
Principal Assessor, VRMM

Ms Pauline Edwards
Secretary

Paediatric Medicines Expert Advisory Group (PMEAG)

Dr A Siapkara
Principal Assessor, Paediatric Care

Mrs M Guler
Secretary

Glossary of Acronyms and Abbreviations

ABHI: Association of British Healthcare Industries

ABPI: Association of the British Pharmaceutical Industry

ABRHP: Advisory Board on the Registration of Homeopathic Products

ADHD: Attention Deficit Hyperactivity Disorder

ADR: Adverse Drug Reaction

AI: Adverse Incident

AIMDD: Active Implantable Medical Devices Directive

AITS: Adverse Incident Tracking System

ANDPB: Advisory Non-Departmental Public Body

AR: Assessment Report

ALB: Arms Length Body

ARM: Application to Reclassify a Medicine

ASMF: Active Substance Manufacturer

ASPR: Anonymised Single Patient Report

ART: Assisted Reproductive Technology

ATC: Anatomical, Therapeutic, Chemical

AT: Assistive Technology

ATE: Arterial Thromboembolic Events

BAN: British Approved Names.

BCPNN: Bayesian Confidence Propagation Neural Network

BGMA: British Generic Manufacturers Association

BHMA: British Herbal Medicines Association

BIR: British Institute of Radiology

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

BMA: British Medical Association

BNF: British National Formulary

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

BP: British Pharmacopoeia

BPC: British Pharmacopoeia Commission

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

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

BSE: Bovine Spongiform Encephalopathy

BSI: British Standards Institution

BVEAG: Biologicals and Vaccines Expert Advisory Group

CA: Competent Authority

CAS: Current Awareness Service

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

CCG: Clinical Commissioning Group

CD: Controlled Drug

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

CDF: Competence Development Framework

CDRH: The Centre for Devices and Radiological Health

CE(O): Chief Executive (Officer)

CE MARK: European mark of approval for medical devices.

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

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

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

CFC: Chlorofluorocarbons

CHM: Commission on Human Medicines

CHMP: Committee for Medicinal Products for Human Use

CI: Confidence Interval

CIOMS: Council for International Organisations of Medical Sciences

CJD: Creutzfeldt-Jakob Disease

CLIN: Clinical Devices division of the MHRA

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

CMS: Concerned Member State

COMMS: Communications division of the MHRA

COPD: Chronic Obstructive Pulmonary Disease

CP: Chinese Pharmacopoeia

CPD: Continuing Professional Development

CPRD: Clinical Practice Research Datalink

CPSEAG: Chemistry, Pharmacy and Standards Expert Advisory Group

CQC: Care Quality Commission

CR: Computed Radiology

CSD: Committee on the Safety of Devices

CT: Computed tomography

CTA: Clinical Trial Authorisation

CTBVEAG: Clinical Trials, Biologicals & Vaccines Expert Advisory Group

CTD: Clinical Trials Directive

CTD: Common Technical Document

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

DHSC: Department of Health and Social Care

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

ECG: Electrocardiogram

ECPHIN: European Community Pharmaceutical Information Network

eCTD: Electronic Common Technical Document

EDQM: European Directorate for the Quality of Medicines & Healthcare

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

EFTA: European Free Trade Association

EFPIA: European Federation of Pharmaceutical Industries Associations

EFQM: European Foundation for Quality Management

EHTPA: European Herbal and Traditional Medicine Practitioners Association

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

EMA: European Medicines Agency

EP: European Pharmacopoeia

EPAR: European Public Assessment Report for medicines

EPID: Extended (also Expanded) Public Information Document

EQA: European Quality Award (see also EFQM)

ERA: European Regulatory Affairs

ETSI: European Telecommunications Standards Institute

EU: European Union

EUDRA: European Union Drug Regulatory Authorities

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

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

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

EUDRALINK: As EudraNet II can only be accessed and used by the national competent authorities, the EudraLink secure communication service has been

developed to allow secure information exchange between the pharmaceutical industry, research institutes and pharmaceutical experts via the public internet.

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

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

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

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

EUDRAPORTAL: The central entry point for all the Eudra applications.

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

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

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

EVMPD: EudraVigilance Medicinal Product Dictionary

EWP: Efficacy Working Party

FARAW: Fairness & Respect at Work

FDA: Food and Drug Administration

FIN: Finance division of the MHRA

FOI: Freedom Of Information

FTCM: Federation of Traditional Chinese Medicines

FVAR: Final Variation Assessment Report

GBS Guillain-Barre Syndrome

GCP: Good Clinical Practice

GDP: Good Distribution Practice

GHTF: Global Harmonisation Task Force

GLP: Good Laboratory Practice

GLPMA: Good Laboratory Practice Monitoring Authority

GMDN: Global Medical Device Nomenclature

GMO: Genetically Modified Organism

GMP: Good Manufacturing Practice

GMPLA: Good Manufacturing Practice Licensing Authority

GVP: Good pharmacovigilance Practices - *see also GPvP*

GP: General Practitioner

GPRD: General Practice Research Database

GPvP: Good Pharmacovigilance Practice

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

GSI: Government Secure Intranet

GSL: General Sales List

GxP: General abbreviation for Good Practice standards.

HCPC: Health and Care Professions Council

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

HFMA: Health Food Manufacturers' Association

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

HLT: High Level Term - part of the Medical Dictionary for Drug Regulatory

Affairs (MedDRA) terminology

HMAC: Herbal Medicines Advisory Committee

HMPC: European committee on Herbal Medicinal Products

HMR: Human Medicines Regulations

HPV Human Papillomavirus

HRT: Hormone Replacement Therapy

HSE: Health & Safety Executive

HTA: Human Tissue Authority/Act

I&AC: Imaging and Acute Care

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

ICES: Integrating Community Equipment Services

ICH: International Conference on Harmonisation

ICNIRP: International Commission on Non-Ionising Radiation Protection

ICS: Inhaled Corticosteroids

ICSR: Individual Case Safety Report

ICT: Information and Communications Technology

IEC: International Electrotechnical Commission

IEPS: Inspections, Enforcement and Standards Division of the MHRA

IM: Intramuscular

IMD: Information Management Division of the MHRA

IMP: Investigational Medicinal Products

ImPACT: Imaging Performance Assessment of CT scanners

IMS: Information Management Strategy

INN: International Non-proprietary Name

INR: International Normalised Ratio

IP: International and Parliamentary function

IP: Intra-peritoneal or Intra-pleural

IPEM: Institute of Physics and Engineering in Medicine

IPU: Information Processing Unit

IRAS: Integrated Research Application System

IRC: Industrial Relations Council

IRG: Independent Review Group on silicone gel breast implants

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

IRR: Ionising Radiation Regulations

IVDMDD: In Vitro Diagnostic Medical Device Directive

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

ISBN: International Standard Book Number

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

ITT: Intention To Treat

ITU: Intensive Therapy (care) Unit

IU: International Unit (or UI)

IU(C)D: IntraUterine (Contraceptive) Device

IVD: In Vitro Diagnostic Medical Device

IT: Information Technology

IV: Intravenous

LA: Licensing Authority

LABA: Long Acting β2 Agonist

LFT: Liver Function Test

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

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

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

LOCF: Last Observation Carried Forward

MA: Marketing Authorisation

MAA: Marketing Authorisation Application

MAC: Microbiology Advisory Committee

MAH: Marketing Authorisation Holder

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

MDA: Medical Device Alert

MDD: Medical Devices Directive

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

MDLO: Medical Device Liaison Officer

MEDDRA: Medical Dictionary for Drug Regulatory Affairs

MedDRA: Medical Dictionary for Regulatory Activities

MGPS: Multi-item Gamma Poisson Shrinker

MEDS: Management of Electronic Document Strategy

MHRA: Medicines and Healthcare products Regulatory Agency

MISG: Ministerial Industry Strategy Group

ML: Manufacturer’s Licence

MLWP: The Working Party on Community Monographs and Community List

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

MORE: Manufacture’s On-line Reporting Environment

MR: Mutual Recognition

MRA: Mutual Recognition Agreement

MRI: Magnetic Resonance Imaging

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

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

MTS: Medicines Testing Scheme

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

MWHEAG: Medicines for Women's Health Expert Advisory Group

NAHS: National Association of Health Stores

NAO: National Audit Office

NAS: New Active Substance

NB: Notified Body

NBOG: Notified Body Operations Group

NCAS: National Clinical Assessment Service

NCE: New Chemical Entity

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

NHS: National Health Service

NIBSC: National Institute for Biological Standards and Control

NICE: National Institute for Health and Care Excellence

NIGB: National Information Governance Board [for Health and Social Care]

HIHR: National Institute for Health Research

NOAEL: No Observed Adverse Effect Level

NOEL: No Observed Effect Level

NOP: Non-Orthodox Practitioner

NOS: Not Otherwise Specified

NPPEAG: Neurology, Pain and Psychiatry Expert Advisory Group

NRLS: National Reporting and Learning System

NRPB: National Radiological Protection Board

NUI: Non-Urgent request for Information

OH: Occupational Health

OHEAG: Oncology and Haematology Expert Advisory Group

OG: Open Government

OGD: Other Government Department

OIS: The Department of Health's IT system.

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

Orphan drug: A drug for a rare disease

OTC: Over-The-Counter [product]

P (Medicine): Pharmacy medicine

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

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

PA: Persons Appointed

PACS: Picture Archiving and Communications Systems

PACSnet: Picture Archiving and Communications Systems National Evaluation Team

PAGB: Proprietary Association of Great Britain

PAR: Public Assessment Report

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

PCT: Primary Care Trust

PCS: Public and Commercial Services Union

PDA: Performance and Development Agreement

PDCO: European Paediatric Committee

PDP: Personal Development Plan

PEAG: Pharmacovigilance Expert Advisory Group

PEG: Paediatric Expert Group

PEM: Prescription Event Monitoring

PET: Positron Emission Tomography

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

PGD: Patient Group Directions

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

Ph. Eur.: European Pharmacopoeia

PhVWP: Pharmacovigilance Working Party

PHE: Public Health England

PI: Principal Investigator

PIC: Pharmaceutical Inspection Convention

PICS: Pharmaceutical Inspection Co-operation Scheme

PIEAG: Patient Information Expert Advisory Group

PIL: Patient Information Leaflet

PIP: Paediatric Investigation Plan

PIQ: Patient Information Quality

PK: Pharmacokinetic(s)

PL: Product Licence

PLAT: Product Licensing Assessment Teams

PL(PI): Product Licence (Parallel Import)

PLR: Product Licence of Right

PMDD: Premenstrual Dysphoric Disorder

PMEAG: Paediatric Medicines Expert Advisory Group

PMH: Past medical history

PMS: Post-Marketing Surveillance

PO: Private Office

POM: Prescription Only Medicines

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

PPEEAG: Patient and Public Engagement Expert Advisory Group

PPI: Patient Pack Initiative

PPI: Proton Pump Inhibitor

PQ: Parliamentary Question

PRAC: Pharmacovigilance Risk Assessment Committee [of the EMA]

PRR: Proportional Reporting Ratio

PRR: Proportioned Reporting Ratio

PSE WG: Pseudoephedrine Working Group

PSG: Professional Skills for Government

PSUR: Periodic Safety Update Report

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

PUMA: Paediatric Use Marketing Authorisation

PUWER: Provision and Use of Work Equipment Regulations

PV: Pharmacovigilance

PVAR: Preliminary Variation Assessment Report

QA: Quality Assurance

QC: Quality Control

QOS: Quality Overall Summary

QP: Qualified Person

QWP: Quality Working Party

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

RCGP: Royal College of General Practitioners

RCHM: Register of Chinese Herbal Medicines

RCR: Royal College of Radiologists

RCT: Randomised (controlled) Clinical Trial

RFI: Request for Further Information

rINN: Recommended International Non-proprietary Name

RMP: Risk Management Plan

RMS: Reference Member State

ROR: Reporting Odds Ratio

RPPS: Regulatory Pharmacovigilance Prioritisation System

RP: Responsible Person

RPSGB: Royal Pharmaceutical Society of Great Britain

RMS: Records Management System

RSC: Royal Society of Chemistry

RSI: Request for Supplementary Information

RSM: Royal Society of Medicine

Rx: Abbreviation for a medical prescription

SABS: Safety Alert Broadcast System

SAE: Serious Adverse Effect

SAG: Scientific Advisory Group [of the EMA]

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

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

SD: Standard Deviation

SEAC: Spongiform Encephalopathy Advisory Committee

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

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

SI: Statutory Instrument

SLA: Service Level Agreement

SMF: Site Master File

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

SmPC: Summary of Product Characteristics - *see SPC*

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

SOL: Department of Health Solicitor's Branch.

SOP: Standard Operating Procedure

SPC: (see also SmPC) Summary of Product Characteristics

SPC: Special Precautions and Contra-indications

SPECT: Single Photon Emission Computed Tomography

SSRI: Selective Serotonin Reuptake Inhibitor

SUSAR: Suspected Unexpected Serious Adverse Reaction

SWP: Safety Working Party

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

TAG: Technical Advisory Group

TCM: Traditional Chinese Medicine

TGA: Therapeutic Goods Administration (Australia)

THM: Traditional herbal medicine

THMPD: Traditional Herbal Medicinal Products Directive

THMRS: Traditional Herbal Medicines Registration Scheme

THR: Traditional Herbal Registration

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

TOPRA: The Organisation for Professionals in Regulatory Affairs

TOTO: Top Of The Office

TS: Tuberous Sclerosis

TSE: Transmissible Spongiform Encephalopathy

UKPAR: United Kingdom Public Assessment Report for Medicines

UKRC: United Kingdom Radiological Conference

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

USP: United States Pharmacopoeia

UTI: Urinary Tract Infection

vAIC: Virtual Adverse Incident Centre

vCJD Variant Creutzfeldt-Jakob Disease

VMD: Veterinary Medicines Directorate
VRMM: Vigilance and Risk Management of Medicines division of the MHRA

VTE: Venous Thromboembolism

WHMP: Western Herbal Medicine Practitioner

WL: Wholesale dealer’s Licence

YCC: Yellow Card Centre

BRITISH PHARMACOPOEIA COMMISSION

ANNUAL REPORT FOR 2019

INTRODUCTION

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

MEMBERSHIP

2. A list of members of the British Pharmacopoeia Commission during 2019 is shown in **Appendix I**.

3. The term of office for several members of the BP Commission was due to end on 31st December 2019. Following a review carried out in collaboration with the Department of Health and Social Care Appointments and Honours Team, seven members were successfully re-appointed for periods between two to four years with effect from 1st January 2020.

4. A list of members of the supporting Expert Advisory Groups, Panels of Experts and Working Parties for 2019 is given in **Appendix II**.

CODE OF PRACTICE

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

MEETINGS

6. The British Pharmacopoeia Commission met three times during 2019. Seventeen meetings of the Expert Advisory Groups, Panels of Experts and Working Parties were also held during the year. These meetings were held at the Medicines and Healthcare products Regulatory Agency (MHRA), 10 South Colonnade, Canary Wharf, London E14 4PU except for three meetings which were conducted by teleconference.

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

SECRETARIAT

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

LABORATORY

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

COSTS

10. For each meeting that they attend, members of the British Pharmacopoeia Commission are entitled to claim a taxable attendance fee of £325 (Chair's fee, £500). Members of the Expert Advisory Groups, Panels of Experts and Working Parties are entitled to claim a taxable attendance fee of £200 per meeting attended (Chair's fee, £325). Travel and subsistence is also payable within MHRA guidelines.

PROGRESS AND PUBLICATIONS

British Pharmacopoeia 2019

11. Following publication of the British Pharmacopoeia 2019, three online updates were issued providing users with the text of Supplements 9.6 to 9.8 of the 9th Edition of the European Pharmacopoeia.

British Pharmacopoeia 2020

12. The British Pharmacopoeia 2020 was published in August 2019. This new edition is available as a package containing the five volumes of the British

Pharmacopoeia 2020, the one volume of the British Pharmacopoeia (Veterinary) 2020 and access to the electronic versions of both publications (online BP and offline download format).

13. This new edition contains over 4000 monographs for substances and articles used in the practice of medicine and almost 500 infrared reference spectra, together with the necessary appendices and supporting material. The effective date of the British Pharmacopoeia 2020 is 1st January 2020.

14. All monographs published within the 9th Edition of the European Pharmacopoeia, as amended by Supplements 9.1 to 9.8, 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.

15. The British Pharmacopoeia 2020 contains 35 new monographs of national origin which were not published in previous editions. These include two new monographs for Traditional Herbal Medicines and five new monographs for unlicensed formulations. Six new infrared reference spectra have been added to this edition.

16. The titles of over 100 monographs were amended in the British Pharmacopoeia 2020. These were mainly changes to national monographs to remove split standard terms in order to ensure that BP titles reflect current regulatory requirements for naming medicines. They also included changes to a number of European Pharmacopoeia monographs arising as a result of the European Pharmacopoeia policy on specifying the degree of hydration in the monograph title. In accordance with established policy the former titles have been retained as subsidiary titles, which have the same legal weight as the main title.

17. The opening statements in monographs for unlicensed medicines were amended to reflect that such monographs have been developed to cover unlicensed formulations. This was to prevent the inclusion of potentially misleading statements should licensed formulations become available.

18. The General Monograph for Unlicensed Medicines was amended to include an expanded section on Sterility. This highlights that alternative approaches to the pharmacopoeial test for Sterility may be required for aseptically prepared unlicensed medicines that are prepared extemporaneously or in small batches.

19. The response to the 2017 public consultation on “Dissolution Testing in BP Finished Product Monographs for Solid Oral Dosage Forms” was published on the BP website in February and the Expert Advisory Group on Pharmacy are developing an updated pharmacopoeial policy on dissolution

testing. As a first step towards implementing the new policy, and in order to improve clarity for users, changes to Appendix XII B (Dissolution) and Supplementary Chapter I E (Dissolution Testing of Solid Oral Dosage Forms) were made in the British Pharmacopoeia 2020.

20. Three new Appendices were added to harmonise with the European Pharmacopoeia: Appendix II M – Direct Amperometric and Pulsed Electrochemical Detection; Appendix XI O – Foam Index; Appendix XVI H – Microbiological Examination of Live Biotherapeutic Products.

21. A comprehensive review of published monographs was undertaken during the year. As a consequence of this review, 73 national monographs were omitted from the British Pharmacopoeia 2020 following consultation. In accordance with Regulation 252(2)(c) of the Human Medicines Regulations 2012, omitted monographs continue to remain in force.

British Pharmacopoeia (Veterinary) 2020

22. The British Pharmacopoeia (Veterinary) 2020 was published as a companion volume to the British Pharmacopoeia 2020 in August 2019. 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) 2020 is 1st January 2020.

23. The British Pharmacopoeia (Veterinary) 2020 contains one new monograph of national origin which was not published in previous editions. As a result of the comprehensive review of monographs noted above, seven national monographs were omitted from the British Pharmacopoeia (Veterinary) 2020.

24. 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

25. The third Supplement to British Approved Names 2017 (Supplement No. 3) was published in August 2019. The Supplement identifies and defines 35 new chemical and biological entities that are used in medicines in the UK. The majority of the new names are for active substances used in medicinal products that have been licensed through the European Medicines Agency and have not previously been marketed in the UK.

Digital Publications

26. Access to the online version (www.pharmacopoeia.com) and the offline download edition of the publications is provided as a component of the complete British Pharmacopoeia 2020 package. The offline download edition is updated to include the European Pharmacopoeia Supplement updates at the same time as the online BP.

27. The BP website (www.pharmacopoeia.com) has continued to be positively received by users. The website incorporates a Document Review Tool (DRT) which is used by the BP Secretariat and members of the BP Commission to ensure the quality of monographs and other texts for inclusion in the BP and BP (Vet) publications.

28. Following the regular public consultation schedule for new and revised monographs, four three-month consultation periods were held during 2019. The opportunity to contribute to the monograph development and revision process is appreciated by users and the comments received help to ensure that the monographs are robust.

29. A regular programme of user research has been initiated to further develop the BP website and products. Undertaken at the start and mid points of the year, this research has resulted in a number of improvements including an update of the BPCRS catalogue, providing additional information and making it easier to search, the development of a guide on how to use the BP and enhancement of the timeline feature highlighting when monographs have changed. In addition, several enhancements were made to improve the reliability and security of the website. A track changes feature is in development for a future update, which will identify the changes within individual monographs.

Prices and Availability

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

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

Future Publications

32. By the end of 2019 work was progressing on the preparation of the next editions of the British Pharmacopoeia and British Pharmacopoeia (Veterinary). These will be published during 2020 and will have an effective date of 1st January 2021.

33. A digital update to the British Pharmacopoeia 2020 was issued in December 2019 providing users with the text of the 10th Edition of the European Pharmacopoeia which came into effect on 1st January 2020. Further updates will be issued to coincide with the implementation of Supplements 10.1 and 10.2 on 1st April and 1st July 2020 respectively. These updates will only be available via the online BP and the offline download. The texts will subsequently be included in the BP 2021 publications.

OTHER PHARMACOPOEIAL MATTERS

Biological Medicines

34. In September 2019, the Agency published a public update on its strategy on pharmacopoeial public quality standards for biological medicines. The update outlined the continued importance of pharmacopoeial standards to medicines quality, to supporting innovation and the life sciences and the work undertaken to implement the strategy. The strategy has remained unchanged following its original publication in 2017. The Agency's combined expertise, through the incorporation of regulatory, pharmacopoeial and NIBSC physical standards functions, places it in a unique position to develop its commitments to exploratory work in the areas of biotherapeutics and advanced therapy medicinal products (ATMPs). The strategy continues to recognise the importance of engaging with stakeholders and international peer organisations and the need for mutual knowledge building.

35. The BIO-DPS Working Party, established in 2018 to explore the potential of performance and class-based standards for biotechnological products, continued to develop its work throughout 2019. The Working Party, which includes international expert membership, has continued to develop a deeper understanding of these concepts, which are to be evaluated through real-world case studies coupled with supporting laboratory evaluation. The project is on track to deliver robust, evidence-based recommendations to the Agency, the BP Commission and wider stakeholders with an expectation of a report of findings by the end of 2020.

36. The Agency has continued to develop its understanding around the challenges faced in the development of ATMPs and their associated analytics and how these could be supported by documentary and physical standards. The Agency has focussed on engaging and developing networks with stakeholders and recognised the system wide approach required for these medicines. This has included engagement with international and national regulatory, research, NHS and manufacturing peers and stakeholders including site visits and informal workshops. This included a workshop, supported by the BioIndustry Association and UK Cell and Gene Therapy Catapult, on quality and analytics for ATMPs. A Working Party comprised of external and internal experts is to be

established to fully consider the outputs of this workshop and the next phase of the Agency's work in this area.

37. Engagement with users and knowledge building are key objectives of the strategy and the Agency has undertaken a programme of continual stakeholder engagement throughout the year, connecting with trade associations, international peer organisations, other UK government and standard setting organisations, the NHS and industry. Members of staff from the Agency have presented on the work involved in developing the strategy and how it links to the Agency's broader support for innovation at several international conferences, including Bio Integrates 2019 London and the Parenteral Drug Association's 2019 ATMP conference in Vilnius. These events have provided important opportunities to engage with relevant stakeholders and provide visibility of the work involved in developing the strategy. Through this engagement mutual understanding has been developed, which will be enhanced as the strategy continues to be implemented.

Unlicensed Medicines

38. Monographs that have been developed to cover unlicensed formulations are identified as such in the British Pharmacopoeia.

39. The inclusion of BP monographs for unlicensed medicines has been widely recognised as a valuable addition to the publication since they provide legally enforceable standards for such products which may be widely used or are required for certain patient populations.

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

Herbal and Complementary Medicines

41. The Expert Advisory Group on Herbal and Complementary Medicines has continued to demonstrate the importance of producing monographs for herbal substances and a number of new herbal monographs have been added to the BP 2020. The BP will continue to focus on targeting herbal materials that are routinely used in the UK.

42. The BP-NIBSC Herbal Project was completed during the year. This included the publication of an additional DNA sequence in Appendix XI V: Deoxyribonucleic Acid (DNA) Based Identification Techniques for Herbal Drugs. Panel DNA: Identification Techniques was disbanded following completion of the project.

Nomenclature

43. The BP continued to provide advice and comments to the World Health Organization (WHO) Committee on International Nonproprietary Names (INN). Recommended INN (rINN) for products licensed in the UK are formally adopted as British Approved Names when they are first included in licensed medicines. UK Experts provided input into two meetings during the year and contributed to the evaluation of INN requests and the development of WHO policies on drug nomenclature. One rINN List (81) was published by WHO during the year.

44. 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) Names Review Group. During the year 650 proposed invented names were assessed on behalf of the EMA. Members of the BP staff were pivotal in the shaping of the EMA naming policy for liposomal products; there is now a requirement for the term “liposomal” to be included in the name of products where the posology of the formulation allows a higher amount of the product to be administered to patients than of the corresponding non-liposomal formulation. The BP continues to provide advice to manufacturers on the acceptability of invented names and remains the expert on the acceptability of invented names within the MHRA.

Analytical Quality by Design

45. The Analytical Quality by Design (AQbD) Working Party completed a feasibility study to investigate the application of Quality by Design concepts to analytical methods and the Pharmacopoeia in 2018. Significant learnings were made relating to the Analytical Target Profile (ATP) concept. Several theoretical ATPs have been evaluated by the Laboratory, in collaboration with the Australian Therapeutic Goods Administration and statistical experts on the Working Party.

46. Findings from the overall feasibility study were published in 2019 as part of an MHRA consultation on the application of Analytical Quality by Design Principles to Pharmacopoeial Standards. A significant number of responses were received from stakeholders who positively supported and valued its application to pharmacopoeial standards. A summary of these responses and an outline of the future work of the Working Party will be detailed in a report to be published in 2020.

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

Liaison with Other UK Organisations

48. The BP continues to work with academic institutions and has welcomed the opportunity to work and collaborate with universities as part of the process of establishing and revising monographs. A number of practical reports have been received and presented at our Expert Advisory Group meetings. The monographs for the Furosemide preparations will be revised in a future publication using data provided by the University of Hertfordshire.

49. The BP and Veterinary Medicines Directorate (VMD) continue to collaborate closely on the development of monographs for veterinary medicines and on a range of regulatory and policy issues relating to veterinary medicine. This collaboration has been facilitated through the appointment of representatives from the VMD on relevant Expert Advisory Groups and Panels of Experts.

Laboratory

50. The Laboratory has continued to support the work of the British Pharmacopoeia Commission and the wider MHRA remit relating to public health. In addition to supporting the development and revision of about 40 BP monographs, work has been continuing to support the Agency's response to the detection of nitrosamines in drug substances. This work, as part of a cross-European laboratory network, involves developing methods to detect these contaminants in active substances and in drug products. The data obtained from this work informed the Agency's risk assessment and regulatory actions.

BP Reference Materials

51. Twenty new British Pharmacopoeia Chemical Reference Substances (BPCRS) were established to support the British Pharmacopoeia and British Pharmacopoeia (Veterinary) publications, 61 were replaced and 181 were re-tested to ascertain their continued stability.

52. New BPCRS were available at the time the BP 2020 publications were published, ensuring that users were ready to comply with the new and revised monographs before they came into force.

53. The demand for these reference materials remained high throughout the year. 30636 vials were sold within the UK and to countries worldwide, representing an approximate 4.5% increase in sales from the previous year.

European Pharmacopoeia

54. The 10th Edition of the European Pharmacopoeia and its first Supplement (Supplement 10.1) were published in July 2019 and October 2019 respectively. The 10th Edition came into effect on 1st January 2020 and Supplement 10.1 will come into effect on 1st April 2020. The second Supplement (10.2) was published in January 2020 and will come into effect on 1st July 2020. 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 supporting the work of the European Pharmacopoeia Commission and its 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 UK led discussions and a webinar regarding dissolution testing in finished product monographs, providing an opportunity to show how the British Pharmacopoeia and the regulator work together. By sharing the experiences of the BP with both finished product monographs and dissolution testing, the BP has contributed to the development of European Pharmacopoeia Commission policies in these areas.

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

58. 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.

59. A comprehensive review of UK membership of the Expert Groups and Working Parties of the European Pharmacopoeia Commission was undertaken during the year. The review identified those groups that were most relevant to the UK market and where UK representation was required. 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 2019, is included in **Appendix V**.

International Liaison and Collaboration

60. 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.

61. Representatives from the BP attended a number of technical meetings in order to support the work of the European Pharmacopoeia during the year. A range of issues had been discussed including the approach to dissolution testing and the proposal to increase the number of finished product monographs. BP staff, along with representatives from the UK delegation, also attended and gave presentations on some key areas of work at the conference organised by the European Directorate for the Quality of Medicines and HealthCare to celebrate the publication of the 10th Edition of the European Pharmacopoeia which had been held at the offices of the EDQM in Strasbourg in June.

62. In May, the BP and Laboratory Services group, working with colleagues from across the MHRA and NIBSC and also with colleagues from the Veterinary Medicines Directorate, hosted the 24th Annual Meeting of the Official Medicines Control Laboratories Network in London. This brought together a total of 260 delegates from regulatory authorities throughout Europe and across the globe. During the event several presentations were given which highlighted the varied expertise across the wider agency and how this relates to protecting the health of patients worldwide This included a presentation from the BP on how Analytical Quality by Design could be used in the developments of BP monographs. The event was very successful and positive feedback was received.

63. BP Staff attended the Tenth International Meeting of World Pharmacopoeias which was organised by the World Health Organization (WHO) and was held in Geneva in March. This meeting provides the opportunity for the major pharmacopoeial authorities to discuss models of collaboration and how pharmacopoeias add value to standards in public health. A wide range of items were discussed, including: the preparation of a White Paper on the Value of Pharmacopoeia Standards; the nitrosamine contamination in drug substances; the potential for a pharmacopoeial alert system for issues that require a rapid response. The meeting also provided BP staff with an opportunity to hold meetings with representatives from other pharmacopoeias to discuss current and potential future collaboration opportunities between the BP and these organisations.

64. Throughout the year BP Secretariat staff have provided feedback to WHO on draft monographs for the International Pharmacopoeia, which has been greatly appreciated. Many of the standards included in the International Pharmacopoeia, and the policies employed, are consistent with those in the British Pharmacopoeia.

65. The BP attended the WHO Consultation on Screening Technology, Laboratory Tools and Pharmacopoeial Specifications for Medicines in May. Draft documents relating to general texts and monographs for the International Pharmacopoeia were discussed, including the finalisation of

Moxifloxacin Tablets, the first monograph to be informally harmonised between the BP and the International Pharmacopoeia.

66. BP staff attended the 68th WHO Consultations on International Non-proprietary Names in May and provided input to the 69th Consultations which were held in October. The number of names requested for biological substances continues to increase, with about half of new names requested now being for biologicals.

67. A member of the BP staff represented the MHRA at meetings of the European Medicines Agency Names Review Group during the year. The invented names for medicinal products are used in Centralised Licence Applications and must be acceptable in all Member States. The group had supported the BP/MHRA proposals for the naming of liposomal formulations and several names incorporating the term “liposomal” had been agreed.

68. BP staff, together with a member of the BP Commission, attended the second Parenteral Drug Association (PDA) Conference on International Developments in the Pharmacopoeial Landscape, which had been held in Geneva in May. The focus of the event was a workshop which had been split into steams on Analytics, Biotherapeutics and Continuous Manufacture. The BP had given a presentation on Analytical Quality by Design and the Pharmacopoeia which had been very well received.

69. A member of BP staff attended the PDA Advanced Therapy Medicinal Products Conference held in Vilnius in June, which had provided a forum for international experts on cell and gene therapies. The BP had given a presentation on the development of standards for ATMPs and the challenges and opportunities of this work. Positive feedback had been received regarding the BP/MHRA approach for the regulation of these products.

70. Representatives from the BP visited the USA in July during which they attended several meetings with key regulatory and industry stakeholders. A bilateral meeting was held at the headquarters of the United States Pharmacopeia (USP) during which a range of topics were discussed in order to expand the current successful joint working between the BP and the USP. A Memorandum of Understanding between the BP/MHRA and the USP was signed during the meeting which will enable greater collaboration and knowledge sharing in the future.

71. During the visit meetings were held with representatives from several companies to discuss the BP policy on Dissolution testing, the application of Analytical Quality by Design in the pharmacopoeia, together with future projects and potential areas for collaboration. A meeting with key US standards setting stakeholders for Advanced Therapy Medicinal Products had also been held. This had included representatives from the US Standards Coordinating Body and the Food and Drug Administration Office of Tissue and Advanced Therapies.

72. Progress continues on informal harmonisation projects. The BP 2020 saw the publication of new monographs for Temozolomide Capsules and Temozolomide for Injection, which were developed through an informal harmonisation process with the USP, and a revised monograph for Pyrimethamine Tablets which was progressed with the International Pharmacopoeia. Work is continuing on a number of other informal harmonisation projects, the outcomes of which will be included in future editions of the BP.

73. The BP attended several meetings in China in June. These included CPhI in Shanghai, which had included a session from international regulators, the Symposium on International Standards Formulation and Certification and the Symposium on the History of Worldwide Pharmacopoeias, during which the Museum of Pharmacopoeias had been inaugurated. These meetings provided an opportunity to engage with stakeholders in China, to strengthen the relationship between the BP and the Chinese Pharmacopoeia and to raise the international profile of the BP.

74. BP staff participated in a teleconference with the British Standards Institute (BSI) in January to discuss the Commonwealth Standards Network project to increase the understanding and provision of standards within Commonwealth countries. The BP/MHRA had been invited to liaise with BSI regarding the inclusion of medicinal standards required within the UK on their website in order to generate wider awareness and understanding.

75. The UK left the European Union on 31st January 2020. Whilst this report relates to activities undertaken in 2019, the following statements reflect the position at the time of publication.

76. The BP continues to be part of the Medicines and Healthcare products Regulatory Agency's public health role. The UK was a founding member of the Convention on the Elaboration of a European Pharmacopoeia and continues to be a member of the European Pharmacopoeia as the UK continues to be a member of the Council of Europe in its own right. The standards of the European Pharmacopoeia will continue to be adopted in the UK and the European Pharmacopoeia will continue to be reproduced in the BP for the convenience of users.

ACKNOWLEDGEMENTS

77. The Commission wishes to place on record its sincere thanks to the following members who retired from the British Pharmacopoeia Commission at the end of the year: Dr Gerard Lee and Professor Matthew Almond. Dr Lee had made a significant contribution to the work of the British Pharmacopoeia Commission over many years, serving as Secretary and Scientific Director between 2002 and 2011 and then as a member of the Commission for 8 years. He had been instrumental in establishing the Expert Advisory Group on Unlicensed Medicines and would continue in his role as Chair of EAG ULM. Dr Lee had also been involved with the work of

the European Pharmacopoeia Commission serving as a member and Chair of several Expert Groups and Working Parties of that Commission. Professor Almond had been a member of the British Pharmacopoeia Commission for 4 years and would be remaining in his role as Chair of Expert Advisory Group MC3: Medicinal Chemicals.

78. 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.

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

80. The Commission wishes to place on record its gratitude to the members of the BP-NIBSC Herbals Team and to recognise their outstanding scientific and personal contributions throughout the duration of the project.

81. The Commission wishes to acknowledge the advice of the publishing team at The Stationery Office in the production of the British Pharmacopoeia 2020, the British Pharmacopoeia (Veterinary) 2020 and Supplement No. 3 to British Approved Names 2017.

82. The Commission also wishes to acknowledge the staff at the Medicinal Plant Names Services at the Royal Botanic Gardens, Kew, who provided advice on the Latin scientific names cited in the new national monographs for Traditional Herbal Medicines.

OBITUARIES

83. Members were saddened to learn of the death of Professor Peter Hylands, a former long-standing member of the Expert Advisory Group on Herbal and Complementary Medicines.

APPENDIX I

MEMBERSHIP OF THE BRITISH PHARMACOPOEIA COMMISSION DURING 2019

Chair

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

Members

Professor Matthew Almond[1] BSc DPhil DSc CChem FRSC PFHEA NTF
Professor of Chemistry Education, University of Reading

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

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

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

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

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

Dr Gerard Lee[1] BPharm PhD FRPharmS MRSC CChem
Former Group Manager, British Pharmacopoeia and Laboratory Services, MHRA; former Secretary & Scientific Director, British Pharmacopoeia Commission

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

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 member)
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, Kymab Limited

Secretary and Scientific Director

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

[1]*Retired, 31st December 2019.*

APPENDIX II

MEMBERSHIP OF EXPERT ADVISORY GROUPS, PANELS OF EXPERTS AND WORKING PARTIES OF THE BRITISH PHARMACOPOEIA COMMISSION DURING 2019

EXPERT ADVISORY GROUPS

ABS: Antibiotics	R L Horder (**Chair**), G D Cook (**Vice Chair**), G Blake, G Clarke, E Flahive, V Jaitely, W Mann, J Miller, M Pires, J Sumal, I R Williams
BIO: Biological and Biotechnological Products	P Varley (**Chair**), A-M Brady (**Vice-Chair**), L Bissett*, C Braxton, C Burns, K Chidwick*, A Cook*, J Cook*, B Cowper, S Gill, E Griffiths, C Jones*, A Kippen, V Loh, K Nordgren*, B Patel, A M Pickett*, T Pronce, L Randon, I Rees*, S Schepelmann*, P Sheppard, P Stickings*, R Thorpe, L Tsang, M Wadhwa*, W Zunic
HCM: Herbal and Complementary Medicines	M Simmonds (**Chair**), R Middleton (**Vice-Chair**), L A Anderson, P Anderson, A Booker, C Etheridge, C Leon, B Moore, M Pires, E Reich, M Rowan, A Slater, K Strohfeldt-Venables, J Sumal*, C Welham, E Williamson, K Zhao (*Corresponding members SS Handa, A Krauss, Z-T Wang*)
MC1: Medicinal Chemicals	A G Davidson (**Chair**), D Cairns (**Vice-Chair**), S Bale, H Batchelor, J C Berridge, E Bush, A J Caws, D Deutsch, P Fleming, E Gray, W J Lough, D J Malpas, S Nolan
MC2: Medicinal Chemicals	G Cook (**Chair**), C T Goddard (**Vice-Chair**), J Birchall, K Bracht, J Cowie, K Foster, E Hook, J Lim, J Miller, A Ruggiero, N Wynne (*Corresponding members* M Brits, W Sherwin)
MC3: Medicinal Chemicals	M Almond (**Chair)**, J Beach (**Vice-Chair**), J Beaman, K Foster, C T Goddard, P Hampshire, W K L Pugh, B Rackstraw, R Torano, M Tubby, I R Williams
NOM: Nomenclature	J K Aronson (**Chair**), A McFarlane, D Mehta, G P Moss, R Thorpe (*Corresponding member* R G Balocco Mattavelli)

PCY: Pharmacy	R L Horder (**Chair**), R A Lowe (**Vice-Chair**), M Ahmed*, E Baker, J Beach, D Elder, J Lim*, J MacDonald, A McFarlane, J F McGuire, T Purewal, K M G Taylor, S Wicks (*Corresponding member* J Churchill)
ULM: Unlicensed Medicines	M G Lee (**Chair**), V Fenton-May (**Vice-Chair**) A Bosley, M Godber, W Goddard, S Hartley, D Kirby, J Ramada-Magalhaes, 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	C Mroz (**Vice-Chair**), H Batchelor, R Cawthorne, D Deutsch
DNA: Identification Techniques (*Disbanded, 30th June 2019*)	A Slater (**Chair**), M Carine, I Feavers, J Hawkins, E Mee, E Williamson
IGC: Inorganic and General Chemicals	C T Goddard (**Chair**), M Almond, S Atherton[1], S Boland, P Henrys, G Lay
MIC: Microbiology	V Fenton-May (**Chair**), B Alexander, S Denyer, C Iverson, V Jaitely, J Silva
RAD: Radioactive Materials	I Boros, J Brain, D Graham, G Inwards, R D Pickett, R Smith,
VET: Veterinary Medicines	E Williamson (**Chair**), A Cairns, S Cockbill, D Evans, E Flahive, B Ward
VIP: Veterinary Immunological Products	A-M Brady (**Chair**), R Banks, R Cooney, M Johnson, K Redhead, J Salt, C Stirling, R Woodland

WORKING PARTIES

AQbD: Analytical Quality by Design	G Cook (**Chair**), P Borman, S Brown, M Chatfield, S Ellison, C Gray, M Hanna-Brown, S Jones, P Nethercote, E Razzano (*Corresponding members* K Barnett, B Harrington, W Sherwin)

BIO-DPS: Alternative Approaches for Documentary and Physical Standards for Biotechnological Products	P Varley (**Chair**), A-M Brady (**Vice-Chair**), C Burns, B Cowper, N Czeloth[1], L Duhau, V Ganeva, C E Giartosio, A Ramzan, B Rellahan, M Wild

AD-HOC GROUP

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

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

APPENDIX III

MEMBERS OF THE BRITISH PHARMACOPOEIA COMMISSION STAFF DURING 2019

Secretary and Scientific Director
Mr J Pound

Secretariat
Mr A Gibb (*Editor-in-Chief*)
Mr S Young (*Head of Analytical Science*)
Ms H Ashraf
Ms H Bowden (*from September*)
Ms H Corns
Mr P Crowley
Mr L Elanganathan
Mr A Evans
Dr A Gardiner (*until March*)
Ms S Gomersal (*until May*)
Dr G Kemp
Ms G Li-Ship
Mr S Maddocks
Mr H Makwana (*until July*)
Mr R Smith (*from September*)
Dr F J Swanson
Mr M Whaley

DHSC Staff
Ms N Clothier (*until September*)

NIBSC Based Staff
Mr L Gibson (*until January*)
Ms C Gkouva (*until February*)
Dr C Howard (*until March*)
Ms C Lockie-Williams (*until March*)

Laboratory Management Board
Mr J Pound (*Secretary & Scientific Director, BP)*
Mr S Young (*Head of Analytical Science, BP)*
Mr M Whaley (*Laboratory Services Manager, BP*)
Mr R Adams (*Service Delivery Manager, LGC – until June*)
Ms I Reydellet (*Service Delivery Manager, LGC – from June*)
Mr P Bedson (*Operations Director, LGC*)
Dr D Craston (*Chief Scientific Officer, LGC*)

Administrative
Ms F Chughtai (*from April*)
Mr B Delahunty
Miss J Paine
Ms U Rothna

APPENDIX IV

BRITISH PHARMACOPOEIA COMMISSION PUBLICATIONS DURING 2019

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

British Pharmacopoeia 2020 package

Consisting of:-

British Pharmacopoeia 2020

British Pharmacopoeia (Veterinary) 2020

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

BP Download Edition (single-user licence)
(Subscription price £1000; £875 for print, online or download edition only)

Individual BP Monograph (only supplied electronically)

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

British Approved Names

British Approved Names 2017: Supplement No. 3

(Price £20)

APPENDIX V

EUROPEAN PHARMACOPOEIA COMMISSION

MEMBERS OF THE UNITED KINGDOM DELEGATION DURING 2019

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

Alternates: R L Horder, S Young

MEMBERS OF GROUPS OF EXPERTS FROM THE UNITED KINGDOM DURING 2019

Group 1	Microbiology	V Fenton-May (***Chair***)[1], I Venet[1], M Whaley[2]
Group 6	Biological Substances	B Cowper, C Burns[1]
Group 6B	Human Blood and Blood Products	A R Hubbard[1], C Thelwell[2]
Group 7	Antibiotics	J Sumal
Group 9	Inorganic and Organic Chemistry	C T Goddard[1]
Group 9G	Medicinal Gases	M G Lee (***Chair***)[1], 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)	A Lucatelli[1], H Corns[2]
Group 12	Dosage Forms and Methods	R L Horder (***Chair***), S Wicks[1]
Group 13B	Phytochemistry (B)	P Anderson
Group 13H	Fatty Oils and Derivatives	R Cawthorne[1], M Evans (*Specialist*)[1]
Group 14	Radioactive Compounds	R D Pickett
Group 15	Sera and Vaccines	S Schepelmann, P Stickings

Group 15V	Veterinary Sera and Vaccines	A-M Brady *(Specialist*), R Cooney
Group 16	Plastic Containers for Pharmaceutica Use	C O'Neill[1]
Group 17	Medicinal Products Containing Chemically Defined Active Substances	S Young[2]
Group P4	Procedure 4	S Young[1], A Evans[2]

MEMBERS OF WORKING PARTIES FROM THE UNITED KINGDOM DURING 2019:

Alkyl Mesilates	J Midgley (***Chair***)
Allergens	A Cook[1]
Bacterial Endotoxins Test	K Nordgren
Chromatographic Separation Techniques	S Young
Dialysis Solutions	M G Lee (***Chair***)[1]
Extracts	L Anderson, M Pires
Excipient Performance	C Mroz[1]
Gene Therapy Products	Y Zhao
General Methods	S Boland[1], E Gray, O McPolin (*Specialist*)
Heavy Metals	A Evans[1]
Homoeopathic Manufacturing Methods	R A Pask-Hughes[1], J Sumal[1]
Homoeopathic Raw Materials and Stocks	R A Pask-Hughes[1], J Sumal[1]
Host-cell Proteins	A Kippen
Inhalanda	K M G Taylor
Live Biotherapeutic Products	A Stevenson[1]

Monoclonal Antibodies	P Varley, S Prior, M Wadhwa
Paediatric Formulary	K Bracht, A Nunn[1]
Pharmaceutical Preparations	V Fenton-May[1] (***Chair***), M G Lee[1]
Procedure 4 for Biologicals	M Wadhwa, L Both
Pyrrolizidine Alkaloids	S MacDonald
Raw Materials for the Preparation of Cellular and Gene Therapy Products	L Bisset
Rules of Procedure	J Pound
Special Revision Programme	A Evans
Standard Terms	M Ahmed
Statistics	R Gaines Das
Sutures	L Ferris[1]
Traditional Chinese Medicines	C Lenihan[1]
Water for Pharmaceutical Use	M G Lee (***Chair***) [1]

[1]*Retired, 31st December 2019.*

[2]*Appointed from 1st January 2020*.

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

INTRODUCTION

Purpose of the Code

1.1 This Code of Practice sets out the rules to be followed by chairpersons 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 chairpersons 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 the chairperson and members of the various committees, and the actions taken to manage potential conflicts of interest are made public. In addition, where an individual has declared in advance of a meeting an interest that would exclude him or her from the relevant discussions, this information will be used by the secretariat to ensure that, wherever possible, the relevant committee papers are not sent to that individual.

SCOPE

Committees and groups to which this Code applies

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

- Commission on Human Medicines (CHM)
- The following committees ("the Committees"):
    - Herbal Medicines Advisory Committee (HMAC);
    - The Advisory Board on the Registration of Homeopathic Products (ABRHP)
- The Expert Advisory Groups (EAGs) established by the CHM and/or the Committees.

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

DEFINITIONS

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

Pharmaceutical Industry

3.2 "Pharmaceutical industry" means:

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

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

Immediate family

3.3 "Immediate family" means:

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

INTERESTS WHICH NEED TO BE DECLARED

Summary of interests that need to be declared

4.1 It is the responsibility of each individual to identify and to declare all relevant interests. The following types of interest must be declared by the chairperson 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 chairperson 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 the chairperson 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 the chairperson 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 chairperson 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 chairperson of the Chemistry, Pharmacy and Standards EAG, the Pharmacovigilance EAG and the Biologicals and Vaccines EAG by virtue of their membership of the CHM. The chairperson and members of the CHM and the chairperson and members of the HMAC and ABRHP, and the chairperson 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 chairperson 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 chairperson 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 the chairperson and members of the CHM, HMAC and ABRHP (including the chairperson of the Chemistry, 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 chairperson and members of CHM, HMAC, ABRHP and the three EAG chairperson 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 chairperson 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 chairperson 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 chairperson 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 the chairperson and members of EAGs, apart from the chairperson of the three EAGS described at paragraph 4.8 above, and for the reasons set out in paragraph 4.4 above. Therefore, these experts may attend meetings sponsored by the pharmaceutical industry and accept funding of expenses, but these must be declared.

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

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

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

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

DECLARATION OF INTERESTS

6.1 Chairpersons 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. Chairpersons 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 chairperson 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 chairpersons 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 chairperson 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 chairpersons 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 Chairpersons 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 chairperson as early as possible before the meeting takes place, and in any event before discussion of the relevant agenda item. The chairperson of the committee is responsible for taking the decision on how declared interests should be handled.

PARTICIPATION IN DISCUSSIONS WHEN AN INTEREST HAS BEEN DECLARED

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

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

Personal Interests

7.3 A personal specific interest will have been declared if an individual has worked on the product under consideration and is receiving or has received payment for that work. As a general rule, the individual will normally not be allowed to take part in discussions as they relate to that product, except where the chairperson 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 chairperson'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 Chairperson'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 chairperson's discretion to answer questions from other members. The chairperson and/or the MHRA Secretariat will advise on these matters. The chairperson of the committee is responsible for taking the decision on how declared interests should be handled.

Rival Products

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

7.11 If a product is being discussed and an individual is aware that he or she has an interest in a company which markets a rival product, the business of which will directly benefit or suffer as a result of the advice that is given, the individual must declare that interest at the meeting. An example might be where an application for a generic product is being considered and the individual holds an interest in the current brand-leader, or where a new active substance is under consideration that will directly affect the market of another company for a similar product in which an individual has an interest. Whether the individual will be

permitted to take part in discussions will depend upon the circumstances and the extent to which the business of the competitor is likely to be affected

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

Consideration of Classes of Products

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

RECORD OF INTERESTS

8.1 A record is kept in the MHRA of:

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

PUBLICATION

9.1 Interests declared to the MHRA by chairpersons 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 chairpersons and members will be included in the Annual Reports. This information will provide only the name of the committee chairperson 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 Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Stuart H Ralston	None	None	Abbvie Alexion Amgen Celgene Internis Janssen Eli-Lilly Pfizer Roche Sandoz Sanofi-Genzyme UCB	Sponsorship of clinical meeting	No	None
			Astra-Zeneca	Clinical registry study		
			Kyowa Kirin	Clinical trial		
			Kyowa Kirin	Clinical registry study		
			Gilead	Clinical trial		
			Amgen / UCB			
			Eli Lilly	Donation of IMP for a clinical trial		
Ms Susan Bradford	None	None	None	None	No	None
Professor Jamie Coleman	None	None	None	None	No	None
Dr Jamie Fraser	None	None	None	None	No	None

Professor Jonathan S Friedland	None	None	Astra Zeneca Chiesi Limited Edixomed Limited FairCourt Capital Fondazione PENTA ONLUS GSK Gilead Sciences Ltd HelperBy Therapeutics LDN Pharma Merck Serono Ltd McColl's Retail Group Pfizer QuantuMDX Group Becton Coulter Boston Scientific Celigene Jay Pharma Inc Merck Sharpe & Dohme Ltd Oxford Gene Technologies Shockwave Medical Incorporated SPD Development Co Ltd St Jude Medical, AFD Inc Takeda UK Ltd VBI Vaccines	All commercial non-personal, non-specific conflicts are due to the sponsor/funder supporting research at St. George's, University of London but they do not directly support my own research	Yes	None
Dr Richard Gilson	None	None	ViiV	Department is a clinical site for trials sponsored by ViiV, who have provided research funds to the department	No	None

	(received by UCL and Central and North West London NHS Trust).
Gilead Sciences	Department is a clinical site for trials sponsored or funded by Gilead, who have provided research funds to the department (received by UCL and Central and North West London NHS Trust). Principal investigator for one of these studies.
Janssen	Department is a clinical site for trials sponsored or funded by Janssen, who have provided research funds to the department (received by UCL and Central and North West London NHS Trust).
Merck	Department is a clinical site for trials sponsored and funded by Merck, who have provided research funds to

	the department (received by UCL and Central and North West London NHS Trust).
Mylan	Department is a clinical site for a trial using a product supplied by Mylan, funded by NHS England (received by UCL and Central and North West London NHS Trust). Principal investigator for this study.
Pfizer	Department was a clinical site for a trial sponsored by Pfizer, who have provided research funds to the department (received by UCL and Central and North West London NHS Trust).
GSK	Department is a clinical site for a trial sponsored and funded by GSK, who have provided research funds to

				the department (received by UCL and Central and North West London NHS Trust).		
Professor Malcolm Macleod	None	None	The EQIPD IMI consortium	MM is academic coordinator of the consortium: details of consortium membership is given in the next section	Yes	I am academic coordinator of the EQIPD consortium, an IMI funded consortium which draws support from the European Union, and in-kind and cash support from 11 EFPIA members, Teva having joined in late 2020. UoE funding is derived from European Union funds, while 2 PhD studentships are shared with (and are partly funded by) Janssen Pharmaceutica NV. Details of the consortium are available at https://quality-preclinical-data.eu/about-eqipd/members/ Pharmaceutical industry project members are AbbVie Inc; Boehringer Ingelheim International GmbH; F. Hoffmann-La Roche AG; Institut de Recherches Servier; Janssen Pharmaceutica NV; Novartis Pharma AG; Orion Corporation; Pfizer Ltd.; Sanofi-Aventis Recherche & Dévelopement; Teva pharmaceuticals; Ucb

						Biopharma SPRL. For profit (SME) non pharmaceutical project members are Arlenda SA; concentris research management GmbH; Noldus Information Technology BV; PAASP GmbH; Porsolt SAS; PsychoGenics Inc.; Science Exchange Inc.; Synaptologics BV.
Dr Rebecca Mann	None	None	Sanofi	Unsalaried PI in multicentre trial evaluating conjugate menACYW vaccine in the UK infant schedule	Yes	None
Professor Sarah Meredith	None	None	Abbott	Grant & Product donated for a trial - Financial support for a virolgy sub-study (no drug)	No	None
			Astellas	Grant and product donated for a trial		
			AstraZeneca	Grant & Product donated for a trial Product donated for a trial Drug supply and financial support		
			Bayer	Grant & Product donated for a trial Product donated for a trial		

Boehringer Ingelheim, Bristol-Myers Squibb	Grant/Product donated for a trial
Cipla	Product donated for a trial
Gilead Sciences	Grant & Product donated for a trial Product donated for 4 trials; Grant for the Proud study
GSK	Grant/Product donated for a trial
Janssen	
Janssen-Cilag	
Lilly	
Merck	
Pilatus	
Roche	
Sanofi-Aventis	
Sanofi Pasteur	
Tibotec	
Virco	Product donated for a trial
Emergent Biosolutions	
Emcure	
FIT Biotech	
INSERM-ANRS	
Merck-Serono	Grant and product donated for a trial
Takeda	Product donated for a trial
Amgen	Product donated for a trial
Novartis	Grant and product donated for a trial

Dr Siraj Misbah	None	None	None	None	No	None
Professor David Griffith Cunningham Owens	None	None	None	None	No	Declared no interests under the MHRAs Code of Conduct for committee chairs and members. Hosted by the University of Edinburgh Division of Psychiatry, which has received monies from the Mortimer and Teresa Sackler Family Trust, an independent charitable trust which has disbursed funds to a number of academic departments around the world to support the study of the psychobiology of major psychiatric disorders, especially schizophrenia. The University of Edinburgh Division of Psychiatry has applied these grants independently and almost exclusively to analyse brain imaging data acquired in MRC or other non-industry funded projects. Played no role in administration, allocation or accounting for these funds and neither Purdue Pharma nor any member of the Sackler family has had any influence in determining their utilisation. These funds have not had any psychopharmacological utilisation and have not been

						used to generate/support/investigate any questions, clinical or theoretical, related to pharmaceutical products, whether manufactured by Purdue Pharma or other commercial companies. In relation to the Code of Conduct, can confirm that no member of the Sackler family nor representative of Purdue Pharma has sought to influence in any way advice that given to the Commission on Human Medicines.
Professor Sir Munir Pirmohamed	None	None	Eli Lily	Research grant to UOL to support clinical training fellowships jointly with MRC	No	Academic research grants Research funding paid to the University of Liverpool from: - MRC, NIHR, Health Education England, EU Commission
			Novartis	Research grant to UOL to support clinical training fellowships jointly with MRC		
			Roche	Research grant to UOL to support clinical training fellowships jointly with MRC		
			UCB Pharma	Research grant to UOL to support clinical training		

				fellowships jointly with MRC		
			Astra-Zeneca/EPSRC	Research grant to UOL to support PHD in drug interactions		
			BMS (Bristol Myers Squibb)	Unrestricted educational grant to UOL to support UK pharmacogenentics and Stratified Medicine network open meeting		
			MC Diagnostics	Funding from NIHR i4i academic grant to UOL with MC Diagnostics to develop a HLA gene panel		
Shirley Price	None	None	None	None	No	None
Prof Kevin Taylor	None	None	None	None	No	None
Helen Ward	None	None	None	None	No	None
Martin Wilson	None	None	None	None	No	None

CARDIOVASCULAR, DIABETES, RENAL, RESPIRATORY & ALLERGY EXPERT ADVISORY GROUP MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Jamie Coleman	None	None	None	None	No	None
Dr Amanda Adler	None	None	BI	Grant to cover salary of colleagues; Grant awarded to my predecessor	No	Chair of a NICE Technology Appraisal Committee
Professor Iolo Doull	None	None	None	None	No	none
Dr John Firth	None	None	AMGEN ASTELLAS GENZYME NOVARTIS ROCHE SHIRE WYETH	Occasional support of renal unit educational meetings	No	No conflicts of interest to declare. Family member(s) do not have personal interests in the pharmaceutical industry.
Dr Andrew Grace	None	None	None	None	No	None
Dr Philip W. Ind	None	None	Chiesi	Accepted a sandwich at the recent British Thoracic Society meeting (December 2019) and have been asked to consider speaking on behalf	No	none

				of Chiesi at a GP meeting (on the management of COPD to involve their Trimbow - FM/BDP/glycopyrronium inhaler). No invitations accepted as of yet		
Professor Patrick Mark	Napp	consultancy, speaker fees	None	None	No	Attend grants committees and/or have charitable funding from Kidney Research UK. This charity receives donations etc from multiple pharmaceutical industry companies.
	Boehringer Ingelheim	consultancy				
	AstraZeneca	consultancy				
	Vifor	consultancy, travel to educational meeting				
Professor Theresa McDonagh	Novartis	Advisory Board Honoraria Speaker fees	None	None	No	None
	Vifor Pfizer	Speaker Fees				
Professor Pallav Shah	Olympus	Consultancy	ERBE, Medtronic, Olympus, PneumRX/BTG, Pulmonx, Boston Scientific, Nuvaria, Broncus	Sponsor Imperial College for bronchoscopy course	No	None

	Pulmonx	Consultancy/ lecture	Pulmonx	RCT with endobronchial valves Royal Brampton Hospital reimbursed for clinical trial expenses		
	CSA Medical	Consultancy/ lecture	PneumRX/BTG	RCT with endobronchial valves Royal Brompton Hospital and Chelsea & Westminster Hospital reimbursed for clinical trial expenses		
			Nuvaira	RCT with vagal nerve ablation Royal Brompton Hospital and Chelsea & Westminster Hospital reimbursed for clinical trial expenses		
			CSA	RCT with RejuvenAir Chelsea & Westminster Hospital reimbursed		
Dr Caroline Vaughan	None	None	None	None	No	None

Professor Sarah Wild	Novo Nordisk	Accommodation, subsistence and contribution to registration fees provided as part of unrestricted educational grant during attendance at biannual meetings of the Scottish Study Group for Care of Diabetes in the Young in role as member of Steering Group	None	None	Yes	None
Professor Ann Millar	None	None	None	None	No	None
Professor Hilary Pinnock	Teva	Fee for writing a piece on supported self-management for their website	None	None	No	Involved in several organisations, spoken at conferences/meetings which receive multi-company sponsorship. Specifically, ERS, PCRS-UK, IPCRG, Scottish Allergy and Respiratory Academy
	Medscape	chaired a discussion on primary care management of severe asthma - fee waived				

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

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Kevin Taylor	None	None	None	None	No	None
Professor Graham Buckton	Gilead Silvergate TEVA Lupin Mylan Apotex Genentech DRL Sigmapharm Zydus Aurobindo	Consultancy	None	None	Yes	None
Professor Brian John Clark	None	None	None	None	No	None
Professor Ruth Duncan	None	None	None	None	No	None
Mr V'lain Fenton-May	None	None	None	None	No	None
Professor Geoffrey William Hanlon	None	None	None	None	No	None
Dr Gillian Hawksworth	None	None	None	None	No	None

Miss Elizabeth Knott	Baxter Healthcare plc Windcliff Management Ltd	Shares obtained originally through company purchase scheme etc Carrying out project work for the NHS, private hospitals and the healthcare industry	None	None	Yes	None
Dr Majella Eileen Lane	None	None	none	None	No	Established a consultancy company called Melderm Ltd. The company provides expert witness services for patent litigation cases in the United States and Europe.
Professor Robert Lowe	None	None	none	None	No	None
Professor Yvonne Perrie	None	None	GSK	EU Grant to University of Strathclyde.	No	Controlled Release Society July 2018 - June 2020 President-elect (non-salary)
			AMRI Haver Pharmaceuticals Mologic Everna	Knowledge exchange research contracts from company to University of Strathclyde.	No	Controlled Release Society July 2018 - June 2020 President-elect (non-salary)
			Encap/Capsugel/ Lonza Lamellar Biomedical	KTP Grant to University of Strathclyde.		

Pfizer Inc, Astrazeneca, Precision Nanosystems, Centre for process innovation Ltd, Malvern instruments, Croda	Contract for grant signed in Dec 2017 (started March 2018) which includes contributions from listed companies to University of Strathclyde.
Microfluidics Precisions Nanosystems Inc	Equipment loan to University of Strathclyde.
Jansen	Writing a grant for a PhD – now funded.

CLINICAL TRIALS, BIOLOGICALS & VACCINES EXPERT ADVISORY GROUP MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Dr Siraj Misbah	None	None	None	None	No	None
Professor Farzin Farzaneh	Cellectis, France	Consultancy, Contract Manufacture and R & D Collaborations	None	None	Yes	None
			Autolus Therapeutics	Shares, Consultancy Payments, Contract Manufacture and R&D Collaborations		
		Cell Vec Syncona Apterna	Consultancy			
		Servier Orchard Therapeutics	Contract Manufacture			
Professor Helen J Lachmann	Novartis	Consultancy	SOBI	Support for research nurse salary, support for national UK meetings ono autoinflammatory disorders	Yes	None
	SOBI	Consultancy (None in last 12 months)				

	UPTODATE	Editor fees				
Professor Kevin Park	EMD Serono	Consultancy	Janssen Pharmaceuticals (Belgium)	Mitochondrial toxicity research PI	Yes	None
			GlaxoSmithkline Research & Development Ltd (UK)	Quantitative assessment of drug-protein adduct formation and function PI		
			L'Institut de Recherches Internationales Servier (France)	Defining the molecular mechanisms underlying the complex role of mitochondrial dysfunction in the onset of drug-induced cholestatic injury CO-I		
			GlaxoSmithKline Research & Development Ltd (UK)	North West England MRC Fellowships in Clinical Pharmacology and Therapeutics CO-I		
			Wellcome Trust (UK)	Multi-modal high resolution preclinical PET+SPECT+CT scanner CO-I		
Professor Andrew	None	None	GSK and Gilead in	unrestricted grant	No	Chair of UK Dept. Health's

Pollard			July 2019	funding to Oxford University for a 3 day course on infectious disease in children		Joint Committee on Vaccination & Immunisation & the EMA vaccines SAG (until 31/1/2020), and a member of the WHO's SAGE.
Dr Robin Thorpe	None	None	None	None	No	None
Professor Marc Turner	Scottish National Blood Transfusion Service	Salary	None	None	Yes	None
	Cell and Gene Therapy Catapult	Non Executive Director				
Mrs Madeleine Wang	None	None	none	None	No	None
Professor Christopher Weir	AB Science	DSMB membership, resulting in personal income (no work done or payment received to date)	Eli Lilly	Research grant to institution, co-applicant	Yes	None
			Hasselt University	External expert on funding panel, resulting in income to my department		

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

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Anthony G Wilson	UCB	Advisory board meeting fee	Pfizer Biogen	Funding for a Public and Patient Involvement in research meeting	No	None
	Eli Lily Gilead	Advisory board meeting fee				
	Greenlight Medicines	Member of Scientific Advisory Committee				
Dr Michael Ardern-Jones	Sanofi-Genzyme	Conference attendance, speaker fees	Abbvie	UHS Commercial clinical trial	No	None
	Integritas communications	Conference attendance, speaker fees. Affiliated with Sanofi	Leo Pharma	UHS Commercial clinical trial		
	Jannsen	Conference attendance, Advisory board fees	AMGEN	UHS Commercial clinical trial		

	Leo Pharma	Conference attendance, Advisory board fees				
Professor Qasim Aziz	Allergan	Advisory board Review article Centre for phase III clinical trial	Alimentary Health	Conference support - national conference and departmental meeting	Yes	None
	Symprove	Research collaboration - no funding received				
Mr David Chandler	None	None	None	None	No	Employed by a patient charity, but the charity has a policy not to receive any funding or financial support whether monetary, in kind or via a third parties from pharmaceutical companies or other commercial organisations. Any events or meetings attended in relation to my work for the charity are funded by the charity, this includes: registration fees, travel, subsistence and accommodation. A family member also works for the same charity, and the above, applies to them. A family member works within the NHS as a diagnostic radiographer with nuclear medicine specialty, but has no personal or financial

						connections in the pharmaceutical industry. No other members of my immediate household have any financial interests in the pharmaceutical industry or associated organisations.
Professor Kevin Peter Moore	Servier	Consultancy	None	None	Yes	director of edgegilding Ltd, but this has no connection with the pharmaceutical industry, and is related to bookbinding.
	Mallinckrodt	Consultancy				
Professor Celia Moss	None	None	None	None	No	None
Dr Frances MK Williams	None	None	None	None	No	None

META-ANALYSIS OF ORAL HPTs EXPERT AD HOC GROUP MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Philip Hannaford	HRA Pharma	Received traveling expenses to attend an expert consultation for a proposed application to reclassify DSG-POP from POM to P in the UK. No other payments received	None	None	No	None
Professor Julian Higgins						None
Professor Ruth Newbury-Ecob	None	None	None	None	N/A	None
Jonathan Sterne	None	None	None	None	N/A	None

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

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Jonathan S Friedland	None	None	Astra Zeneca Chiesi Limited Edixomed Limited FairCourt Capital Fondazione PENTA ONLUS GSK Gilead Sciences Ltd HelperBy Therapeutics LDN Pharma Merck Serono Ltd McColl's Retail Group Pfizer QuantuMDX Group Becton Coulter Boston Scientific Celigene Jay Pharma Inc Merck Sharpe & Dohme Ltd Oxford Gene Technologies Shockwave Medical Incorporated SPD Development Co Ltd St Jude Medical, AFD Inc	The commercial company is a sponsor/funder of research at St Georges', University of London - not involved	Yes	None

Professor David Dockrell	None	None	Takeda UK Ltd VBI Vaccines None	None	No	Worked with ViiV healthcare to develop an educational programme on inflammation and HIV and delivered lectures to HIV centres based on this. Reimbursed by a payment to ViiV to my university department.
Dr Andrew Freedman	None	None	None	None	No	None
Dr Richard Gilson	None	None	ViiV	Department is a clinical site for trials sponsored by ViiV, who have provided research funds to the department (received by UCL and Central and North West London NHS Trust).	No	None
Dr Richard Hobson	None	None	None	None	No	None
Dr Susan Hopkins	None	None	None	None	No	None
Dr Katie Jeffery	None	None	None	None	No	None
Professor Martin Lombard	None	None	None	None	No	None
Dr Hermione Lyall	None	None	None	None	No	None
Professor Kevin Peter Moore	Servier	Consultancy	None	None	Yes	Director of Edgegilding Ltd, but this has no connection

						with the pharmaceutical industry, and is related to bookbinding.
Dr Matthias Schmid	None	None	None	None	No	The ID department has occasional support for meetings from various drug companies sponsoring a sandwich lunch. Have not had any personal gains or remuneration from any company.
Ms Hilary Anne 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 Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Dr Ailsa Gebbie	None	None	None	None	No	None
Professor Philip Hannaford	HRA Pharma	Received traveling expenses to attend an expert consultation for a proposed application to reclassify DSG-POP from POM to P in the UK. No other payments received	None	None	No	None
Ms Linda J Pepper	None	None	None	None	No	None
Professor Siobhan Quenby	None	None	None	None	No	None
Dr Clare Spencer	Mylan	Accepted speaker fee for speaking The 2019 Yorkshire Regional Family Planning & Reproductive Health Care Update	None	None	No	None

Ms Julia Tassano-Edgecombe	None	None	None	None	No	Occasionally our department has teaching/training sessions arranged and run by dwa reps. Do not participate in ant hospitality provided at the time (i.e. lunch/refreshments). Attend training/teaching sessions.
Professor Jonathan Tobias	UCB	Speaker fees	None	None	No	None
Dr Diana Wellesley	None	None	None	None	No	None

NEUROLOGY, PAIN & PSYCHIATRY EXPERT ADVISORY GROUP MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor David Griffith Cunningham Owens	None	None	None	None	No	Declared no interests under the MHRAs Code of Conduct for committee chairs and members. Hosted by the University of Edinburgh Division of Psychiatry, which has received monies from the Mortimer and Teresa Sackler Family Trust, an independent charitable trust which has disbursed funds to a number of academic departments around the world to support the study of the psychobiology of major psychiatric disorders, especially schizophrenia. The University of Edinburgh Division of Psychiatry has applied these grants independently and almost exclusively to analyse brain imaging data acquired in MRC or other non-industry funded projects. Played no role in administration, allocation or accounting for these funds and neither Purdue Pharma nor any

						member of the Sackler family has had any influence in determining their utilisation. These funds have not had any psychopharmacological utilisation and have not been used to generate/support/investigate any questions, clinical or theoretical, related to pharmaceutical products, whether manufactured by Purdue Pharma or other commercial companies. In relation to the Code of Conduct, can confirm that no member of the Sackler family nor representative of Purdue Pharma has sought to influence in any way advice that given to the Commission on Human Medicines.
Professor Thomas R. E. Barnes	None	None	None	None	No	None
Professor Naomi Fineberg	British Association for Psychopharmacology	Travel expenses for delivering educational masterclasses on treating anxiety	EU Horizon 2020	Grant supporting research into problematic internet usage	Yes	Medical lead of an NHS England service providing pharmalogical treatment for obsessive compulsive disorders. Act as an unpaid medical adviser and trustee to national consumer charities for OCD and related disorders. Chair the world psychiatric association scientific section on anxiety,

				OCD and related disorders. Contributed to the British Association for Psychopharmacology (BAP) treatment guidelines for anxiety disorders (2014) and the NICE treatment guidelines including the most recent update (2013). No personal interests in the pharmaceutical industry are held by any adult members of my immediate household.
European College of Neuropsychopharma	Research meetings and symposia touching upon medication related to OCD and related psychiatric	NIHR	research grant, touching upon treatment of OCD	
Indian Association of Biological Psychiatry	Research meetings and symposia touching upon medication related to OCD and related psychiatric			
Royal College of Psychiatrists	Invited conference lecturer; travel expenses to attend meeting			

	Oxford University Press	Royalties for a book describing treatment for OCD				
	Elsevier	Personal fees for editorial duties				
	EU Horizon 2020	Travel expenses to attend meetings and symposia touching upon medication				
	World Psyciatric Association	Travel expenses to attend meetings and symposia touching upon medication				
Professor David Hunt	None	None	None	None	No	None
Professor Malcolm Macleod	None	None	The EQIPD IMI consortium	MM is academic coordinator of the consortium: details of consortium membership is given in the next section	Yes	I am academic coordinator of the EQIPD consortium, an IMI funded consortium which draws support from the European Union, and in-kind and cash support from 11 EFPIA members, Teva having joined in late 2020. UoE funding is derived from European Union funds, while 2 PhD studentships are shared with (and are partly funded by) Janssen Pharmaceutica NV. Details of

						the consortium are available at https://quality-preclinical-data.eu/about-eqipd/members/ Pharmaceutical industry project members are AbbVie Inc; Boehringer Ingelheim International GmbH; F. Hoffmann-La Roche AG; Institut de Recherches Servier; Janssen Pharmaceutica NV; Novartis Pharma AG; Orion Corporation; Pfizer Ltd.; Sanofi-Aventis Recherche & Dévelopement; Teva pharmaceuticals; Ucb Biopharma SPRL. For profit (SME) non pharmaceutical project members are Arlenda SA; concentris research management GmbH; Noldus Information Technology BV; PAASP GmbH; Porsolt SAS; PsychoGenics Inc.; Science Exchange Inc.; Synaptologics BV.
Dr Waqar Rashid	Roche	Consultancy	None	None	No	None
	Merck	Travel grant to attend meeting				
	Celgene	Consultancy				
Dr Fergus Rugg-	Livanova	Speaker fee for	None	None	No	None

Gunn		educational meeting sponsored by Livanova				
Dr Aditya Sharma	None	None	Lundbeck	Medical educational unrestricted grant	No	None
Dr Catherine Stannard	None	None	None	None	None	None
Professor Christopher Weir	AB Science	DSMB membership, resulting in personal income (no work done or payment received to date)	Eli Lilly	Research grant to institution, co-applicant	Yes	None

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

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Angela Thomas	Akari Therapeutics	Consultancy - advice on different routes to licensing	None	None	No	None
Professor David Bowen	None	None	None	None	No	None
Professor Stephen Devereux	None	None	None	None	No	None
Dr Hugo Ford	None	None	None	None	No	None
Dr Chris Gallagher	None	None	None	None	No	None
Dr Robert Marcus	Roche	Consultancy and lecture fees	None	None	No	None
Dr Geoff Shenton	None	None	None	None	No	None

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

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Dr Rebecca Mann	None	None	Sanofi	Unsalaried PI in multicentre trial evaluating conjugate menACYW vaccine in the UK infant schedule	Yes	None
Dr Eileen Baildam	None	None	None	None	No	None
Mrs Catrin Barker	None	None	None	None	No	None
Dr Helen Burdett	None	None	None	None	No	None
Professor Helen Cross	None	None	Zogenix	Investigator on clinical trials. Speaker at educational event Dec 2019	Yes	None
			GW Pharma	Investigator on clinical trials (remuneration to department). Guided expanded access programme (remunerated)		

			Marinius	Investigator on clinical trials (remuneration to department)		
			Ovid	Investigator on study (remuneration to department)		
			Vitaflo	Investigator on clinical trial. Funded member of research staff (remuneration to department)		
			Nutricia	Lecturer on educational programme (remuneration to department)		
Professor Steve Cunningham	None	None	Ablynx	Consultancy with fees paid to the University of Edinburgh	Yes	Provided pharmacovigilance consultancy to the UK Cystic Fibrosis Trust Registry for an EMA requested PAES study of Ivacaftor in children. Fees are paid to the University of Edinburgh for the consultancy.
			Janssen	IDMC membership with fees paid to the University of Edinburgh		

			Galapagos Boehringer Ingelheim Boehringer Ingelheim	Consultancy with fees paid to the University of Edinburgh Grant to University of Edinburgh to support expenditure for hosting an international paediatric rare lung disease meeting.		
Professor Meriel Jenney	None	None	None	None	No	None
Dr Caroline Jones	None	None	BAPN National meeting in Winchester Alexion Epic Pharma Ireland	meeting was subsidized by several companies to reduce the cost of the meeting to all delegates - no direct funding received cannot recall all companies and products	No	None
Professor Nigel Klein	None	None	None	None	No	None
Dr Rubin Minhas	None	None	None	None	No	None
Professor Marie-Louise Newell	None	None	None	None	No	None

Professor Anthony Nunn	None	None	none	None	No	Registered scientific expert with EMA and a member of the EMA PDCO Formulation Working Group and the EMA excipients working group. BPC nominee to the EDQM advisory group on a pan European Paediatric Formulary. Member of the European Paediatric Formulations Initiative (EuPFI, www.eupfi.org). Member of a research steering group for a project funded by Wellcome Trust and UK Department of Health concerning reformulation of a medicine in children with cancer. Nova Laboratories is an industry partner in the project and administers the grant. Own company (Tony Nunn Consulting Ltd) involved in work with University of Liverpool (for coordination of research and advice to academic researchers about paediatric formulations) and Alder Hey Children's NHS Foundation Trust, Liverpool (research in paediatric medicines and pharmacology) - not product specific.

Ms Sara Louise Payne	PHG Foundation (Cambridge)	Associate (PT)	None	None	Yes	Family member is a barrister and acts in intellectual property cases concerning patents in many medical/medical devices.
Dr Guido Pieles	Canon Medical Systems Ltd.	Consultancy (lecturing, strategy of sports cardiology imaging)	None	None	Yes	None
	Cardiac Health & Performance Ltd.	Director (clinical sports cardiology and sports medicine consulting)				
Professor Heather M Wallace	None	None	Novabiotics	Shares (less than 0.1% of company)	No	President of EUROTOX. The Society recieves sponsorship from many sources for its annual congress. These funds go to the local organising committee (for 2019 Helsinki) who run the conference.
			CellProTx	Director		
			Antoxis	Shares (less than 0.1% of company)		
Dr Morris Zwi	None	None	None	None	No	None
Dr Mark Whiting	None	None	None	None	No	None

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

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Sir Munir Pirmohamed	None	None	Eli Lily Novartis Roche UCB Pharma	Research grant to UOL to support clinical training fellowships jointly with MRC	No	Academic research grants Research funding paid to the University of Liverpool from: - MRC, NIHR, Health Education England, EU Commission
			Astra-Zeneca/EPSRC	Research grant to UOL to support PHD in drug interactions		
			BMS (Bristol Myers Squibb)	Unrestricted educational grant to UOL to support UK pharmacogenentics and Stratified Medicine network open meeting		
			MC Diagnostics	Funding from NIHR i4i academic grant to UOL with MC Diagnostics to develop a HLA gene panel		

Professor Darren Ashcroft	None	None	AbbVie GSK Janssen LEO Becton Dickinson Pfizer Qiagen Celgene (Bristol Myer Squibb/Amgen) Eli Lilly Novartis Medimmune (since absorbed into AstraZeneca)	MRC Stratified Medicine Research Grant: Psoriasis Stratification to Optimise Relevant Therapy (PSORT).	No	None
			LEO Foundation Eli Lilly, Novartis, Abbvie, Almirall, Celgene, Janssen, UCB	Research grant to support the development of the Global Psoriasis Atlas.		
			Mundipharma	Research grant		
Professor Ann Daly	None	None	None	None	No	President, International Society for the Study of Xenobiotics (January 2020 to December 2021). Role involves regular interaction with members of the society who work for pharmaceutical companies.
Professor Ian Douglas	GSK	Shares	GSK	Research grant	Yes	None

	Bayer	Fee for delivering investigator training session				
Dr Mark Glover	None	None	None	None	No	None
Dr Daniel Hawcutt	None	None	None	None	No	None
Ms Susan Hunneyball	None	None	None	None	No	None
Dr Karen Isabel Miller	None	None	None	None	No	None
Dr Rupert Payne	None	None	None	None	No	I am consultant editor (remunerated position) for the journal Prescriber (John Wiley & Sons publishers) which carries advertising for the pharmaceutical industry. I am not involved in decisions around advertisements for the journal.
Ms Christine Randall	None	None	None	None	No	None
Dr Ruben Thanacoody	None	None	None	None	No	None
Mark Whiting	None	None	None	None	No	None
Professor Simon Maxwell	None	None	None	None	No	None

AVASTIN PEER REVIEW GROUP MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Kevin Taylor	None	None	None	None	No	None
Professor Paul Bishop	None	None	None	None	No	None
Mr Robert Lowe	None	None	none	None	No	None
Dr Siraj Misbah	None	None	None	None	No	None

E-CIGARETTES EXPERT WORKING GROUP MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Angela Thomas	Akari Therapeutics	Consultancy - advice on different routes to licensing	None	None	No	None
Professor Shirley Price	None	None	None	None	No	None
Professor Alan Raymond Boobis	None	None	None	None	No	Non-personal interests in e-cigarettes as follows: Chair of UK Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (2015-date) [currently reviewing the toxicity of e-cigarettes] Chair of ISO/TC126/Working Group 10: “Intense Smoking Regime” (nominated by UK Department of Health) (2007-date) [does not deal with e-cigarettes but declared for transparency] Member of the WHO Study Group on Tobacco Product Regulation (TobReg) (2012-date) [has reviewed various aspects of risk from of e-cigarettes]

Professor John Britton	None	None	None	None	No	None
Professor Steve Cunningham	None	None	Ablynx	Consultancy with fees paid to the University of Edinburgh	Yes	Provided pharmacovigilance consultancy to the UK Cystic Fibrosis Trust Registry for an EMA requested PAES study of Ivacaftor in children. Fees are paid to the University of Edinburgh for the consultancy.
Professor Pallav Shah	Olympus	Consultancy	ERBE, Medtronic, Olympus, PneumRX/BTG, Pulmonx, Boston Scientific, Nuvaria, Broncus	Sponsor Imperial College for bronchoscopy course	No	None
	Pulmonx	Consultancy/ lecture	Pulmonx	RCT with endobronchial valves Royal Brampton Hospital reimbursed for clinical trial expenses		
	CSA Medical	Consultancy/ lecture	PneumRX/BTG	RCT with endobronchial valves Royal Brompton Hospital and Chelsea & Westminster Hospital reimbursed for clinical trial expenses		
			Nuvaira	RCT with vagal nerve ablation Royal Brompton		

			CSA	Hospital and Chelsea & Westminster Hospital reimbursed for clinical trial expenses RCT with RejuvenAir Chelsea & Westminster Hospital reimbursed		
Professor Brian John Clark	None	None	None	None	No	None
Dr Gillian Hawksworth	None	None	None	None	No	None
Professor Christopher Marriott	Remedica Ltd Halation Ltd Vectura Ltd	Directorship, Fees Directorship, Shares, Fees Shares	None	None	No	Family member holds shares in Halation Ltd and Vectura Ltd.
Ms Deborah Arnott	None	None	None	None	No	None
Professor Paul Aveyard	None	None	None	None	No	Commented publicly and written about the safety and effectiveness of e-cigarettes for smoking cessation
Professor Ann McNeill	None	None	None	None	No	None

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

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Jamie Coleman	None	None	None	None	No	None
Dr Martin Allaby	None	None	None	None	No	None
Dr Helen Burdett	None	None	None	None	No	None
Professor Lesley A Colvin	None	None	None	None	No	Chaired the SIGN Guideline Development group for SIGN Guideline 136: Management of Chronic Pain, published Dec 2013. This included recommendations on opioid use. Worked with SIGN to update this section, published in Aug 2019. There is no involvement of any pharmaceutical industry, nor is it on one specific product.
Professor Peter Crome						None
Dr Richard J Davenport	None	None	None	None	No	None

Dr Jamie Fraser	None	None	None	None	No	None
Professor Philip Hannaford	HRA Pharma	Received traveling expenses to attend an expert consultation for a proposed application to reclassify DSG-POP from POM to P in the UK. No other payments received	None	None	No	None
Dr Meghna Jani	None	None	None	None	No	None
Dr Karen Isabel Miller	None	None	None	None	No	
Professor Ashok Soni	None	None	None	None	No	None
Mrs Helen Ward	None	None	None	None	No	None
Mrs Madeleine Wang	None	None	none	None	No	None
Professor Christopher Weir	AB Science	DSMB membership, resulting in personal income (no work done or payment received to date)	Eli Lilly	Research grant to institution, co-applicant	Yes	None
			Hasselt University	External expert on funding panel, resulting in income to my department		

OPTIMISING DATA ON MEDICINES USED IN PREGNANCY WORKING GROUP MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Jane Elizabeth Norman	None	None	None	None		Received fees from the Wellcome Trust for being Chair of one of their Science Interview Panels. Had renumeration from Research England for participation in a REF panel. Chief Investigator of the NIHR funded STOPPIT 2 study which investigated the effectiveness of Arabin pessary to prevent preterm birth in women with twin pregnancy. Funding for this project was received by the University of Edinburgh (former employer) in the form of research grant from NIHR.
Professor Peter Brocklehurst	Biotest AG	Consultancy	None	None	No	None
Mr Paul Brown	None	None	None	None		None
Ms Caroline Cake	None	None	None	None		None
Dr Rachel Charlton	GSK	Small number of shares	University of Bath - funded by pharmaceutical	Worked for a group which held research grants	Yes	None

			companies	from pharmaceutical companies for research on topics outside of those covered by this working group		
Dr Llion Davies	None	None	None	None	No	None
Mr Chris Dickson	None	None	None	None	No	None
Professor Helen Dolk	None	None	None	None	No	Work within an EU Innovative Medicines Initiative funded project CONCEPTION, which involves collaboration between public and industry
Professor Elizabeth S Draper	None	None	None	None	No	None
Ms Adele Graham	None	None	None	None	No	None
Dr Kenneth Hodson	UCB Pharma	Received honoraria with regard to giving two lectures in the treatment of rheumatological and dermatological conditions in pregnancy respectively	UCB Pharma	Sponsored UKTIS to produce a monograph on Cetrolizumab	No	None

Matthew Jolly	None	None	None	None	No	None
Alison Little	None	None	None	None	No	None
Neena Modi	Shire	Travel and accommodation expenses	Medical Research Council	Research grants	Yes	None
Joan Morris	GSK	Family member is an employee	None	None	Yes	None
Dr Puja Myles	None	None	None	None		None
Ms Katharine Robbins	None	None	None	None	No	None
Mr. David Roberts	None	None	None	None	No	None
Dr Sarah Stevens	None	None	None	None		None
Dr Sarah Stock	None	None	None	None		None
Mrs Madeleine Wang	None	None	none	None	No	None
Dr Rachael Wood	None	None	None	None	No	None

YELLOW FEVER EXPERT WORKING GROUP MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Sir Munir Pirmohamed	None	None	Eli Lily Novartis Roche UCB Pharma	Research grant to UOL to support clinical training fellowships jointly with MRC	No	Academic research grants Research funding paid to the University of Liverpool from: - MRC, NIHR, Health Education England, EU Commission
			Astra-Zeneca/ EPSRC	Research grant to UOL to support PHD in drug interactions		
			BMS (Bristol Myers Squibb)	Unrestricted educational grant to UOL to support UK pharmacogenentics and Stratified Medicine network open meeting		
			MC Diagnostics	Funding from NIHR i4i academic grant to UOL with MC Diagnostics to develop a HLA gene panel		
Professor Guruprasad P Aithal	None	None	None	None	No	None

Professor David Gunnell	None	None	None	None	No	None
Sir Michael Jacobs	None	None	None	None	No	None
Professor Paul Klenerman	None	None	None	None	No	None
Dr Donald Palmer	None	None	None	None	No	None
Mrs Madeleine Wang	None	None	none	None	No	None
Ms Annelies Wilder-Smith	None	None	None	None	No	None
Professor David Hunt	None	None	None	None	No	None
Professor Alan Barrett	None	None	None	None	No	Member of WHO yellow fever committees and write articles/commentaries in peer reviews journals. There is no change from last year. This has been ongoing for over 20 years.
Dr Lance Turtle	None	None	None	None	No	None
Professor Simon Kroll	None	None	None	None	No	None
Dr Richard Dawood	None	None	None	None	No	None

Alisdair MacConnachie	None	None	None	None	No	None
Professor Andrew Pollard	None	None	GSK and Gilead in July 2019	unrestricted grant funding to Oxford University for a 3 day course on infectious disease in children	No	Chair of UK Dept. Health's Joint Committee on Vaccination & Immunisation & the EMA vaccines SAG (until 31/1/2020), and a member of the WHO's SAGE.
Dr Joachim Hombach	None	None	None	None	No	None
Ms Margaret Umeed	None	None	None	None	No	None
Dr Shirley Marshall	None	None	None	None	No	None
Dr Dipti Patel	None	None	None	None	No	Member of the NaTHNaC team. Asked to talk at conferences/study days on yellow fever (along with other travel health related issues) and provide guidance for YFVC. Also a member of the travel sub-committee of JCVI
Dr Kali Perrow	None	None	None	None	No	None
Ms Hilary Simons	None	None	None	None	No	Member of the NaTHNaC team. Asked to talk at conferences/study days on yellow fever (along with other travel health related issues) and provide guidance for YFVC

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

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Sajjad Ahmad	Santen	Speaker fees	Akari Therapeutics	Funding for Clinical Trial	No	None
Bruce Allan	Private Medical and NHS medical practice	salary income	Alcon	Unrestricted grant part funding for a development of a novel PROM in refractive surgery	Yes	None
Mr Ejaz Ansari	Thea	Fees	None	None	None	None
Professor Paul Bishop	None	None	None	None	No	None
Professor Baljean Dhillon						
Ms Cecelia Fenerty	None	None	None	None	No	none
Mr Teifion Emlyn James						
Professor Sir Peng T Khaw	Santen	Speaker fee, advisory board	None	None	No	None
	National Medical Research Council Singapore	Grant panel				

	Novartis	Advisory board & fees				
	Alcon	Scientific selection panel				
	Valid Insight Interview	Honorarium				
	Aerie Pharmaceuticals	Advisory Board				
	Radiance Therapeutics	Founder				
	Optceutics	Founder				
Mr Anthony J King						
Mr Martin McKibbin						
Professor David O'Brart	Rayner Ltd	Non-commercial research grant	None	None	Yes	None
Professor Sunil Shah	Presbyopia Treatments Ltd	Shares	None	None		None
Miss Laura Steeples	Alimera Sciences	Travel expenses, Honorarium for participation in advisory board meetings	None	None	No	None

BRITISH PHARMACOPOEIA COMMISSION HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Prof K Taylor (Chair)	None		None			
Prof M Almond	GlaxoSmithKline	Shares (immediate family member)	None			
Dr J Beaman						
Dr A-M Brady	AstraZeneca	Shares (immediate family member)	Biologicals (journal)	Section Editor (unpaid)	Yes	
	GlaxoSmithKline	Shares (immediate family member)	VAC2VAC Working Party	Member (unpaid)	Yes	
	Vernalis	Shares (immediate family member)				
Dr G D Cook	Pfizer	Salary, Shares	None			
Prof A G Davidson (Vice-Chair)	None		None			
Dr A Gleadle	Tesco PLC	Shares	None			
	AstraZeneca (Medimmune)	Salary (other person)				

Dr M G Lee	None		None		
Mr R Lowe	None		None		
Prof J Miller	None		None		
Ms S Palser	None		None		
Prof M Simmonds	Pharmakos Ltd	Director	College of Medicine	Member	Yes
			DEFRA Darwin Initiative Advisory Committee	Member	Yes
			Hong Kong Department of Health, Pharmacopoeia International Advisory Committee	Member	Yes
Dr R Torano	GlaxoSmithKline	Salary, Shares	None		
Dr P Varley	Kymab Ltd	Salary, Shares	None		
	Astra Zeneca PLC	Shares			

Contact for information about these reports:
Expert Committee Support
10 South Colonnade Canary Wharf
London E14 4PU
020 3080 6060

Published by the Medicine & Healthcare products Regulatory Agency

ISBN 978-1-900731-19-5