## Human Medicines Regulations 2012 Advisory Bodies

Annual Report 2022

**Commission on Human Medicines** 

**British Pharmacopoeia Commission** 

#### **Medicines and Healthcare products Regulatory Agency**

# HUMAN MEDICINES REGULATIONS 2012 ADVISORY BODIES ANNUAL REPORT 2022

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

Commission on Human Medicines

British Pharmacopoeia Commission



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Any enquiries regarding this publication should be sent to the Medicines and Healthcare products Regulatory Agency at:

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

Tel: 020 3080 6000

E-mail: info@mhra.gov.uk

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## FOREWORD BY THE MINISTER OF STATE FOR HEALTH AND SECONDARY CARE

It gives me great pleasure to present the annual reports for 2022 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 relevant industry as per the Conflicts of Interest 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 medicinal products we take continue to meet the highest standards of safety, quality and efficacy.

Will Quince MP

## COMMISSION ON HUMAN MEDICINES ANNUAL REPORT 2022

#### **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.

#### **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 wishes to record its gratitude and appreciation of the valuable work of its Expert Advisory Groups and Working Groups listed below. Members' details are listed at **Appendices II & III**.

#### **Expert Advisory Groups 2022**

Cardiovascular, Diabetes, Renal, Respiratory and Allergy (CDRRAEAG) Chaired by **Professor Amanda Adler** 

Chemistry, Pharmacy and Standards (CPSEAG)
Chaired by **Professor Yvonne Perrie** 

Clinical Trials, Biologicals & Vaccines (CTBVEAG)
Chaired by **Professor Marc Turner** 

Gastroenterology, Rheumatology, Immunology & Dermatology (GRIDEAG)

Chaired by Professor Anthony G Wilson

Infection (IEAG)

Chaired by Professor Jonathan S Friedland

Medicines for Women's Health (MWHEAG)
Chaired by **Professor Philip Hannaford** 

Neurology, Pain & Psychiatry (NPPEAG)
Chaired by **Professor Malcolm R Macleod** 

Oncology and Haematology (OHEAG)
Chaired by **Professor Poulam Patel** 

Paediatric Medicines (PMEAG)
Chaired by **Professor Steven Cunningham** 

Pharmacovigilance (PEAG)
Chaired by **Professor Jamie Coleman** 

#### **Working Groups 2022**

COVID-19 Therapeutic Expert Working Group Chaired by **Professor Jonathan S Friedland** 

COVID-19 Vaccines Benefit Risk Expert Working Group Chaired by **Professor Sir Munir Pirmohamed** 

Non-Medical Prescribing Expert Working Group Chaired by **Professor Sandosh Padmanabhan** 

Reclassification of a product for emergency contraception Ad Hoc Stakeholder Group Chaired by **Professor Kevin Taylor** 

Valproate Implementation Expert Working Group Chaired by **Professor David Hunt** 

#### **MEETINGS**

5. The Commission held 16 meetings during 2022 which included 4 adhoc/extra-ordinary meetings. Of these, 6 were two-day meetings. One-day meetings lasted an average of six hours. All meetings were held via videoconference.

#### SECRETARIAT

6. The Commission's secretariat is based at the MHRA. 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

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

#### FIRST CONSIDERATION BY THE COMMISSION

8. The Commission considered and advised on a total of 183 applications for marketing authorisations, of which final advice on grant was provided on 80 applications.

## **Commission Advice on Applications for National Marketing Authorisations and Centralised Applications**

	Grant advised	Grant not advised
New Active Substances	1	1
Abridged Applications	61	23

- 9. The Commission considered 4 papers under the Early Access to Medicines Scheme.
- 10. The Commission considered an average of 16 applications at each of its 12 meetings in 2022, in addition to clinical trial applications, appeals, reclassifications, pharmacovigilance issues and other matters.

#### **APPEALS**

- 11. The Commission considered two hearings and five pre-hearings covering 18 National applications and advised against the grant for 15 marketing authorisation applications.
- 12. The Commission considered a total of 9 written representations covering 64 applications. Of these, the Commission advised that marketing authorisations could be granted for 19, granted on conditions for 43 and

for the remaining 2, the Commission advised against the grant of marketing authorisations.

#### CO-OPTED MEMBERS KNOWN AS MEMBERS FOR THE DAY

#### Mrs Julia Cons

Lay Representative (June)

#### **Professor David Dockrell**

Professor of Infection Medicine, UoE Centre for Inflammation Research, The University of Edinburgh (June)

### **Professor Jonathan S Friedland** MA PhD FRCP FRCPE FRCPI FESCMID FMedSci

Deputy Principal, St. George's, University of London (April, May, June)

#### Professor Richard J C Gilson MD FRCP

Professor of Sexual Health & HIV Medicine, Director of the UCL Centre for Clinical Research in Infection & Sexual Health & Deputy Director of the UCL Institute for Global Health (December)

#### Ms Susan Hunneyball

Lay Member (June)

#### Professor David Hunt MB BChir FRCP PhD

Consultant Neurologist, NHS Lothian Professor of Neuroinflammatory Medicine, University of Edinburgh (June)

## 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 (April)

#### Professor David Moore MBChB MD MSc DTM&H

Professor of Infectious Diseases and Tropical Medicine, London School of Hygiene and Tropical Medicine and Consultant in Infectious Diseases and Tropical Medicine, Hospital for Tropical Diseases, University College London Hospital (August)

**Dr Gerri Mortimore** PhD; MSc Advanced Practice; PgCert (IPPE); BA (Hons) Health Studies; iLM. RGN; NMP; FHEA, Associate Professor in Advanced Practice; NICE Nurse Expert Advisor

(June)

## **Professor Shirley Price** MSc PhD FBTS FRSB ERT FHEA FRSC MBPharmacol Soc

Emerita Professor of Toxicology, University of Surrey Visiting Professor of Toxicology, University of Hertfordshire (April, May, June, August, September)

#### Professor Rui Providencia MD PhD

Institute of Health Informatics Research, University College London Consultant Cardiologist & Cardiac Electrophysiologist, Barts Health NHS Trust (June)

#### Dr Vanessa Raymont MBChB MSc MRCPsych

Senior Clinical Researcher, University of Oxford and Honorary Consultant Psychiatrist, Oxford Health NHS Foundation Trust (June)

#### Mrs Madeleine Wang

Lay Representative – Patient advocate (June)

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

#### **Professor Dominic Wilkinson**

Ethicist, Jesus College, Oxford (June)

#### **EXTERNAL EXPERTS AND STAKEHOLDERS**

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

#### Ms Gill Adams

Consultant Surgeon and specialist in Neuro-ophthalmology at Morefield's Eye Hospital (April)

#### **Dr Sharon Alroy-Preis** MD, MPH, MBA Deputy CEO at Carmel Medical Centre Head of Public Health Services in Israel (March)

#### **Dr Sarah Aylett**

BPNA, Epilepsy group

(June)

#### Ms Deborah Baidoo

Head of Programme - Sodium Valproate, Policy and Strategy Team, NHS England and NHS Improvement (January)

#### **Sandor Beukers**

Head of Pharmacy, DHSC (October)

#### Professor Judith Breuer MD FRCPath FmedSci

Professor of Virology, University College London (UCL), Division of Infection and Immunity, London (January, October)

#### Dr Rebecca Bromley ClinPsyD, PhD

Research Fellow & Neuropsychologist, University of Manchester & Royal Manchester Children's Hospital (October)

## **Professor Chris Butler** BA MBChB DCH CCH MD FRCGP (Hon)FFPH FMedSci

Professor of Primary Care, Nuffield Department of Primary Care Health Sciences, University of Oxford (March)

#### **Rheian Davies**

Head of Legal, Mind (January)

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

#### **Mr Andrew Evans**

Chief Pharmaceutical Officer, Wales (January)

#### Mr V'lain G Fenton-May BPharm MIPharm FRPharmS

Pharmaceutical Microbiologist (January)

#### **Professor Nicole Ferrier**

Emeritus Professor of Psychiatry, Newcastle University (January, June)

#### **Mrs Cathy Harrison**

Chief Pharmaceutical Officer, Northern Ireland (January)

## **Professor Simon Harding** MB ChB, FRCS, FRCOphth, MD Chair Professor of Clinical Ophthalmology, Head of Department (March)

#### Ms Sara Hartnell

Diabetes Educator/Diabetes Specialist Dietitian, Cambridge University Hospitals NHS Foundation Trust (January)

#### **Dr Dan Hawcutt**

Paediatric Consultant (June)

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

#### **Professor Peter Hindmarsh**

Professor of Paediatric Endocrinology, University College London (January, June)

#### **Susan Hopkins**

UKHSA (June)

#### Dr Kathryn Johnson MBChB FRCPCH

Consultant Neonatologist & Research Lead, Yorkshire & Humber CRN Children's Specialty Lead (April)

#### **Professor Keith Lloyd**

Pro Vice Chancellor / Executive Dean Medicine, Health & Life Science, Swansea University (January)

#### Professor Andrew Lotery MD FRCOphth

Professor of Ophthalmology (March)

#### Mr Robert Lowe BPharm FRPharmS

Practising Hospital Pharmacist, Specialist Pharmacy Services - East of England (January)

#### Professor Hamish McAllister-Williams PhD MD FRCPsych

Professor of Affective Disorders, Newcastle University (January)

#### **Professor Ron Milo**

Associate Professor, Weizmann Institute of Science, Department of Plant and Environmental Sciences (March)

#### Dr Siraj Misbah MBBS (Hons) MSc FRCP FRCPath

Consultant Clinical Immunologist, Lead for Clinical Immunology, Oxford University Hospitals (December)

#### Dr Rebecca Mann

Consultant Paediatrician, Taunton and Somerset NHS Foundation Trust (June)

#### **Professor Anthony Marson**

Professor of Neurology, University of Liverpool Director of Research Programmes, Liverpool Health Partners NIHR Senior Investigator (June)

#### Professor David Moore MBChB MD MSc DTM&H

Professor of Infectious Diseases and Tropical Medicine, London School of Hygiene and Tropical Medicine and Consultant in Infectious Diseases and Tropical Medicine, Hospital for Tropical Diseases, University College London Hospital (June)

#### **Ms Kim Morley**

Epilepsy Specialist Nurse (June)

#### Prof Finbar O'Callaghan

Professor of Paediatric Neuroscience, Developmental Neurosciences Dept, UCL GOS Institute of Child Health (June)

#### Professor David G C Owens MD (Hons) FRCP FRCPsych

Professor of Clinical Psychiatry, Edinburgh University (January, June)

#### Professor Sir Andrew Pollard PhD FRCPCH

Chair of the Joint Committee on Vaccination and Immunisation; Professor of Paediatric Infection and Immunity, University of Oxford (September)

## **Professor Shirley Price** MSc PhD FBTS FRSB ERT FHEA FRSC MBPharmacol Soc

Emerita Professor of Toxicology, University of Surrey Visiting Professor of Toxicology, University of Hertfordshire (October)

#### **Dr Mary Ramsay**

UKHSA (September)

#### **Professor Arjune Sen**

Consultant Neurologist BRC Senior Research Fellow (June)

#### Ms Hannah Sheridan

Lead Pharmacist – Emergency Department Blackpool Teaching Hospitals NHS Foundation Trust (October)

#### Professor Sanjay M Sisodiya

Institute Deputy Director Sustainability & Climate Change and Consultant Neurologist, Department of Clinical and Experimental Epilepsy, UCL Queen Square Institute of Neurology (June)

#### **Professor Philip Smith**

Consultant Neurologist, Cardiff University (June)

#### Josephine Tapper

Health advocate (January)

#### Professor Kevin M G Taylor BPharm PhD FRPharmS

Chair of the British Pharmacopoeia Commission and Professor of Clinical Pharmaceutics, UCL School of Pharmacy, London (January, October, December)

#### **Dr Robin Thorpe** BSc PhD FRCPath

Retired, Head, Division of Biotherapeutics, National Institute for Biological Standards and Control (NIBSC) & Member of the Clinical Trials, Biologicals & Vaccines Expert Advisory Group (CTBVEAG) (January, June, October)

#### Dr Naveen Vasudev

Associate Professor, Honorary Consultant in Medical Oncology Leeds Institute of Medical Research at St James's & St James's Institute of Oncology, St James's University Hospital, Leeds (January)

#### Professor Susannah Walsh BSc PhD MBA

Associate Head School of Pharmacy, Professor of Pharmaceutical Microbiology, Leicester School of Pharmacy, De Montfort University, Leicester

(January)

#### **Dr Bruce Warner**

Deputy Chief Pharmaceutical Officer for England (January, October)

#### **Ellen Williams**

Director of Regional Pharmacy Training, Pharmacy Workforce Development South (October)

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

#### **Dr Tom Caparrotta** BSc MBBCh MRCP(UK)

Diabetes UK 'Sir George Alberti' Clinical Research Fellow in Pharmacoepidemiology, Clinical Pharmacology, General (Internal) Medicine Trainee, University of Edinburgh, NHS Lothian (January)

#### Ms Jenna Dilkes

The National Institute for Health and Care Excellence (NICE) (March, April, October, November)

#### **Mr Andrew Evans**

Chief Pharmaceutical Officer of Wales (June, November)

#### **Mrs Cathy Harrison**

Chief Pharmaceutical Officer NI (November)

#### Zareef Khodabux

DHSC (June)

#### Claire Liew

DHSC (June)

#### **Professor Wei Shen Lim**

Chair of COVID-19 Immunisation on JCVI (September)

#### **Eric Power**

NICE (June)

#### **Ms Natalie Spray**

The National Institute for Health and Social Care Excellence (NICE) (January, May, June, August, September, October)

#### **Professor Alison Strath**

Chief Pharmaceutical Officer of Scotland (June)

#### **David Webb**

Chief Pharmaceutical Officer (June)

#### **DHSC Representatives**

(October)

#### **CONSIDERATION OF OTHER MATTERS**

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

#### SAFETY OF MARKETED MEDICINES

#### Valproate - Use during pregnancy; impaired fertility in males

16. In 2022, the Commission considered a review of safety data for valproate. This review included prescribing data showing continued use of valproate in female patients and also some use during pregnancy, as well as evolving information about potential risks in male patients. The Commission also considered the views of patients and other stakeholders on the current use of valproate and on how the risks of valproate are currently managed. The Commission advised that no patients (male or female) under the age of 55 years should be initiated on valproate unless two specialists independently consider and document that there is no other effective or tolerated treatment. For patients under 55 years currently receiving valproate, two specialists should independently consider and document that there is no other effective or tolerated treatment or the risks do not apply. The Commission advised that these measures should apply to people under the age of 55 because this is the age group most likely to be affected by the risks of valproate when taken during pregnancy and the possible risk of impaired fertility in males.

#### Valproate Implementation Group

- 17. In September 2022, the Commission agreed a proposal to convene the Valproate Implementation Expert Working Group with the following terms of reference:
- 18. To inform the Commission on Human Medicines on:

- Pathways and strategies for implementing the recommendations of the Commission on Human Medicines on valproate
- Communication and educational materials to support and record informed prescribing decisions
- Plans for measurement of compliance with the new regulatory requirements plans for determining the impact of the updated regulatory position and associated communications.

#### Topiramate – use during pregnancy

19. The Commission considered and advised on a review of the available data relating to the benefits and risks of use of topiramate in the treatment of women of childbearing potential and during pregnancy. This included a new study linking topiramate to an increased risk of neurodevelopmental disorders (attention deficit hyperactivity disorder and intellectual disability) in children of mothers who took topiramate during pregnancy. The initiation of this review along with a reminder of the current pregnancy prevention requirements were communicated to healthcare professionals and the public through Drug Safety Update<sup>1</sup> in July 2022. In October and December 2022, the Commission was asked to advise on the accumulating data and the need for additional risk minimisation measures to reduce the potential harms associated with the use of topiramate during pregnancy. Considerations and engagement with stakeholders are ongoing with regards to the most effective and consistent implementation of the advice across the UK healthcare system.

#### Isotretinoin

20. In August 2022, the Commission advised that to ensure the safe and effective introduction of the recommendations of the Isotretinoin Expert Working Group, an Implementation Working Group should be established with representation from the wider healthcare system in addition to relevant healthcare professionals.

### Antidepressants - Proposal to convene an expert working group to consider and advise on risk communication

21. In April 2022, the Commission endorsed the terms of reference and membership of an expert working group on the effectiveness of antidepressant risk communication.

## Pholcodine exposure and increased risk of anaphylaxis to neuromuscular blocking agents

22. The Commission considered and advised on a review of the available data relating to a possible increased risk of serious allergic reactions (anaphylaxis) to neuromuscular blocking agents (NMBAs) used during

<sup>&</sup>lt;sup>1</sup> Drug <u>Safety Update volume 15, issue 12: July 2022: 1.</u>

anaesthesia procedures, in patients who have previously taken the dry cough medicine pholcodine. The Commission considered this issue at its November and December meetings and advised that the potential risks of pholcodine outweighed the benefits and that pholcodine-containing products should be withdrawn from the UK market.

## NovoRapid PumpCart & Accu-Chek Insight insulin pumps – risk of leakage and inadequate supply of insulin

- 23. In January 2022, the Commission considered and advised on an assessment of the evidence on leakages, including cracked cartridges leading to serious medical problems associated with inadequate supply of insulin for the NovoRapid PumpCart insulin cartridge used with the Accu-Chek Insight insulin pump.
- 24. The safety measures implemented by the insulin pump and insulin cartridge manufacturers, including technical enhancements to the insulin pump and communicating safety notices to the public, were partially effective in reducing the risk, however based on continuing cases of leakages the Commission considered further safety measures were required to protect patients from unnecessary harm. The Commission's advice was sought at the March and April meetings on the accumulating data. This included information from a patient and public engagement session to gain insight into the patient's perspective of living with Type 1 diabetes and insulin pump therapy, as well as clinical advice from the NHS in relation to switching patients to alternative insulin pumps.
- 25. The Commission, with advice from the Devices Expert Advisory Committee (DEAC), recommended that patients using the Accu-Chek insulin pump should be encouraged to switch to alternative insulin pumps.
- 26. A National Patient Safety Alert was issued by the MHRA on 26 May 2022 to communicate the important safety message of leakages associated with use of the Accu-Chek Insight pump and NovoRapid PumpCart insulin cartridges leading to serious harm, and to advise health care professionals to move patients from Roche Accu-Chek pumps onto alternative pumps where possible. The advice was also communicated to healthcare professionals and the public through an article in Drug Safety Update<sup>2</sup>.

#### COVID-19 Vaccines

27. The Commission advised on the safety of COVID-19 vaccines based on reviews of suspected side-effects reported through the Yellow Card Scheme, epidemiological analyses, international safety data, non-clinical data and relevant clinical trial data. Major topics of vital clinical

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<sup>&</sup>lt;sup>2</sup> Drug Safety Update volume 15, issue 11: June 2022: 2.

importance considered and advised on by the Commission in 2022 included:

- The safety of the vaccines in pregnancy
- Changes to the recommended age groups for the authorisations of COVID-19 Pfizer/BioNTech and COVID-19 Vaccine Moderna vaccines
- Reviews of potential safety signals and advice on appropriate regulatory action where required, including: the risk of anaphylaxis in vaccine recipients aged under 18 years with the mRNA COVID-19 vaccines; menstrual disorders; and the risk of myocarditis and pericarditis with mRNA COVID-19 vaccines
- A review of the Office for National Statistics' (ONS) analysis of mortality data in those vaccinated against COVID-19
- 28. At its June meeting, the Commission also advised on and endorsed changes to MHRA's COVID-19 vaccines Safety Surveillance Strategy in line with the evolving vaccination programme.

#### Use of over-the-counter analgesics during pregnancy

- 29. In November 2022, the Commission advised on a review of the evidence on the effect of over-the-counter analgesics taken during pregnancy. The Commission noted that the use of non-prescription analgesics during pregnancy had increased over the past 10 years.
- 30. In addition, the Commission considered a review of the use of non-steroidal anti-inflammatory (NSAID) analgesics during late pregnancy. The Commission advised that warnings and reminders should be provided for healthcare professionals and patients, that NSAIDs should not be taken during the last trimester of pregnancy and should only be taken from week 20 of pregnancy if the benefits of treatment outweigh the risks of oligohydramnios and premature constriction of the ductus arteriosus.

#### Recreational use of codeine oral solution

31. In October 2022, the Commission reviewed the evidence for misuse and diversion of codeine oral solution and advised that regulatory steps should be taken to minimise the risk of misuse and diversion.

#### Risk of renal tubular acidosis and hypokalaemia with codeine/ibuprofen

32. In November 2022, the Commission considered and advised on a review of renal tubular acidosis and hypokalaemia with codeine/ibuprofen combination medicines, in Europe and in the UK following the overuse of these medicines or when taken at high doses. The Commission considered that further investigation was required in the UK for the potential reclassification of codeine/ibuprofen combination medicines. The Commission advised that the product information for healthcare

professionals and patients for all products containing ibuprofen should be updated to highlight these risks.

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

- 33. The remit and membership of the Expert Advisory Groups and Working Groups are listed in **Appendices II & III**.
- 34. Summary reports based on the minutes of each meeting are published on the GOV.UK website.

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

- 35. In 2022, the CDRRA EAG met remotely 3 times, in January, May and November, and provided advice in writing on an additional 2 occasions.
- 36. In January, the EAG met, discussed and made recommendations on:
  - a signal of transient blindness in association with use of a medicine indicated for prophylaxis of angina pectoris (chest pain), heart failure, control of hypertensive episodes, and for relief of pain associated with chronic anal fissures (tears or open sore of the anus).
- 37. In May, the EAG met, discussed and made recommendations on:
  - information relating to the manufacturer choosing to withdraw a medicine indicated for treating diabetes mellitus.
  - a published study of genital birth defects in male offspring associated with exposure before conception to a medicine used in the management of diabetes
  - information relating to the risk of liver injury while using medication indicated in the treatment of cystic fibrosis
- 38. In September, the EAG provided written comments on:
  - dosing issues and the potential for medication error with a medicine indicated for the treatment of mild and moderate hypertension; cardiac, renal and hepatic oedema; ascites or toxaemia of pregnancy
- 39. In November, the EAG met, discussed, and made recommendations on:
  - managing potential underdosing and maladministration of calcium gluconate which may lead to increased mortality from hyperkalaemia-induced cardiac arrest when given instead of calcium chloride
  - the risk of anaphylaxis to neuromuscular blocking agents used during surgery in patients who have taken the anti-tussive agent
- 40. In December the EAG provided written comments on:

 a medicine indicated for the treatment of asthma in adults and adolescents aged 12–17 years. It is also used to treat the symptoms of chronic obstructive pulmonary disease (COPD) in adults aged 18 years and older.

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

- 41. In 2022, the CPSEAG convened virtually 11 times and face-to-face once, and provided advice by written correspondence on 1 occasion.
- 42. In January, the EAG discussed and made recommendations on:
  - a medicine used to treat adults with Philadelphia chromosomepositive chronic myeloid leukaemia (Ph+ CML) in chronic phase who are no longer benefiting from previous treatments with two or more tyrosine kinase inhibitors.
  - a medicine used for the treatment of advanced breast cancer
  - a medicine for diagnostic use in adult patients to identify prostate cancer lesions that express a protein called prostate -specific membrane antigen.
  - a medicine used for the treatment of a certain type of advanced prostate cancer (called prostate-specific membrane antigenpositive metastatic castration-resistant prostate cancer [PSMApositive mCRPC]) that has spread to other parts of the body and that has already been treated with other anti-cancer therapies.
  - a medicine used in adult patients for the treatment of several forms of cancer of the stomach, kidney and pancreas where the cancer has spread to other parts of the body that cannot be removed by surgery.
  - a medicine used to replace the hormone thyroxine that the thyroid gland produces and prevents the symptoms of hypothyroidism. a condition in which the thyroid gland does not produce enough thyroxine for the body's needs.
  - five applications for a medicine used in adults adolescents and children aged 2 and older for the treatment of hereditary angioedema (HAE), a condition that may lead to symptoms like swelling, pain, nausea and diarrhoea.
  - an antibiotic used in adults and adolescents and children aged 3
    months and older to treat various serious bacterial infections such
    as pneumonia, bronchitis, urinary tract infections, infections in the
    abdomen, skin and soft tissue infections and bacterial infections of
    the lining surrounding the brain (meningitis)
- 43. In February, the EAG discussed and made recommendations on:
  - a medicine indicated for the treatment of adults with a type of lung cancer called 'non-small cell lung cancer' (NSCLC) that is caused by a specific change in the EGFR (epidermal growth factor receptor) gene.
  - a medicine indicated for the treatment of men with an enlarged prostate (benign prostatic hyperplasia) a non-cancerous growth of

- the prostate gland caused by producing too much of a hormone called dihydrotestosterone.
- a medicine indicated for the treatment of a bacterial infection of the vagina called bacterial vaginosis.
- a medicine indicated to help the body get rid of extra fluid which can stem from congestive heart failure, hepatic cirrhosis with ascites and oedema, malignant ascites, nephrotic syndrome and diagnosis and treatment of primary hyperaldosteronism.
- a medicine indicated in adults for the treatment of bacterial infections in the sinuses, lungs, urinary tract, prostate gland, skin and soft tissues.
- 44. In April, the EAG discussed and made recommendations on:
  - a medicine indicated for the treatment of Gastro-esophageal reflux disease' (GERD). This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn. Ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer).
  - a medicinal product for diagnostic use to image heart function and blood flow in adults with suspected or know coronary artery disease.
  - a medicine indicated for the treatment or prevention of a range of serious fungal infections.
  - a medicine indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and children from 3 years of age.
  - a medicine indicated for the treatment of a bacterial infection of the vagina called bacterial vaginosis.
- 45. In May, the EAG discussed and made recommendations on:
  - a medicine indicated for the treatment of insomnia (in adults and children), jet lag (in adults), single use short term sedation (in infants and children).
  - a medicine indicated for use of short-term management of mild to moderate acute pain which is not considered to be relieved by paracetamol or ibuprofen (alone) in children 2-aged 12 years of age.
  - a medicine indicated for the treatment of severe bacterial infections such as typhoid and meningitis (inflammation of the lining that covers the brain and spinal cord).
  - a medicine indicated for the treatment of asthma in adults.
- 46. In June, there were 2 meetings where the EAG discussed and made recommendations on:
  - a medicine indicated to prevent infection after cataract eye surgery.
  - a medicine indicated for the treatment of viral infections such as smallpox, monkeypox and cowpox.

- a medicine indicated for the treatment of migraines and cluster headache.
- medicines indicated for the treatment of life-threatening ventricular arrhythmias, such as sustained ventricular tachycardia.
- a medicine indicated for the treatment of severe depression in adult patients, often when treatment with other types of antidepressant medication has failed.
- a medicine indicated for the treatment of dizziness, ringing in ears and hearing loss associated with Meniere's syndrome.
- a medicine indicated for the symptomatic treatment of acute diarrhoea in adults and children aged 12 years and over. It is also indicated to treat acute episodes of diarrhoea associated with irritable bowel syndrome (IBS) in adults aged 18 years and over.
- a medicine indicated for the relief of mild to moderate pain, such as headache, backache, period pain, dental pain, neuralgia, rheumatic and muscular pain, migraine, cold and flu symptoms, and feverishness.
- a medicine indicated for the treatment of epileptic seizures.
- a medicine indicated for the treatment of type 2 diabetes mellitus, particularly in overweight patients, when dietary management and exercise alone does not result in adequate glycaemic control or as monotherapy or in combination with other oral anti-diabetic agents for adults or as a monotherapy with insulin for adults and children over 10 years.
- a medicine indicated for the treatment of vitamin D deficiency in adults and adolescents, with an identified risk.
- a medicine indicated for partial replacement therapy for primary and secondary adrenocortical insufficiency (the hormone producing gland (adrenal gland) is not working sufficiently) in Addison's disease and for the treatment of salt-losing adrenogenital syndrome. Short-term therapy of severe hypoadrenergic orthostatic hypotension (dysautonomia) requiring treatment.
- 47. In August, there were 2 meetings where the EAG discussed and made recommendations on:
  - a medicine indicated for the treatment of adult patients with a type of lung cancer called "small cell lung cancer".
  - medicines indicated for the treatment of anaemia (low amounts of red blood cells in the body) in adult patients with chronic kidney disease.
  - a medicine indicated for the treatment of moderate to severe depression in adults, when other antidepressants have not worked.
  - a medicine indicated for the treatment of a type of glaucoma called open angle glaucoma and a condition known as ocular hypertension in adults (including the elderly). Both of these conditions result from an increase in the pressure within your eye and eventually these conditions may affect your eyesight. The

- medicine works by lowering the pressure within your eye by increasing the natural outflow of fluid from inside the eye into the blood stream.
- a medicine indicated for the treatment of severe underactivity of the thyroid gland resulting in a severe complication of hypothyroidism (myxoedema coma). This medicine is also used for the treatment of hypothyroidism (a condition in which the thyroid gland does not make enough thyroxine for the body's needs) as a replacement for oral therapy in patients who cannot swallow or have trouble taking oral medicine.
- a medicine indicated for the symptomatic treatment of acute diarrhoea in adults and children aged 12 years and over. It is also indicated to treat acute episodes of diarrhoea associated with irritable bowel syndrome (IBS) in adults aged 18 years and over.
- a medicine used in infants and children to treat underactive thyroid conditions such as hypothyroidism (a condition in which the thyroid gland does not make enough thyroxine for the body's needs).
- a medicine indicated for the treatment of adult patients with types of lung cancer called "non-small cell lung cancer".
- a medicine indicated for the treatment of severe anxiety in adults and muscle spasms and convulsions (fits) in adults.
- a medicine indicated for the treatment of a bacterial infection of the vagina called bacterial vaginosis.
- 48. In September, the EAG met face-to-face and made recommendations on:
  - a medicine indicated for the prevention of migraine in adults who have at least 4 migraine days per month.
  - a medicine indicated for treatment of anaemia associated with chronic kidney disease in adults.
  - a radiopharmaceutical medicine for diagnostic use only.
  - a medicine indicated for the treatment of mild to moderate fungal infections of the nails without nail matrix/lunula (white half-moon of the nail) involvement in adults.
  - a medicine indicated for the treatment of eye infections caused by Herpes simplex virus.
  - a medicine indicated for the treatment of bacterial infections.
- 49. In October, the EAG discussed and made recommendations on:
  - a medicine indicated for the treatment of adults with a type of lung cancer called non-cell lung cancer (NSCLC), if the lung cancer is advanced or has spread to other parts of the body and is caused by a change in a gene that makes an enzyme call MET.
  - a medicine indicated for the treatment of moderate to severe depression in adults when other types of antidepressant medicines have not worked.
  - a medicine indicated to reduce the pressure in your eye if you have conditions known as open angle glaucoma or ocular hypertension.

- a medicine indicated to supress the immune system to treat diseases where the immune system is reacting against the body (autoimmune diseases) or to help the body accept an organ transplantation.
- a medicine indicated for the symptomatic treatment of acute diarrhoea in adults and children aged 12 years and over. It is also indicated to treat acute episodes of diarrhoea associated with irritable bowel syndrome (IBS) in adults aged 18 years and over.
- a medicine indicated for the treatment of a bacterial infection of the vagina called bacterial vaginosis.
- 50. In November, the EAG discussed and made recommendations on:
  - a medicine indicated for the treatment of serious fungal infections in tissues and organs (invasive candidiasis) in adults.
  - a medicine indicated for the treatment of a wide spectrum of diseases where corticosteroid therapy is required, such as asthma, inflammation of skin, joints or arteries in heart and to prevent rejection in organ transplants.
  - a medicinal product for diagnostic use to image heart function and blood flow in adults with suspected or know coronary artery disease.
  - medicines indicated for the treatment of high blood pressure ('hypertension') in adults and in children and adolescents aged 6 to 18 years.
  - the EAG considered the company's response to questions regarding a medicine indicated for the treatment of advanced breast cancer.
- 51. In December the EAG discussed and made recommendations on:
  - a medicine for the treatment of adult patients with advanced nonsmall cell lung cancer (NSCLC) when it has advanced or has spread to other parts of the body. This medicine is proposed to be used when the cancer cells have a genetic change that allows the cancer cells to produce an abnormal form of protein called KRAS G12C.
  - a medicine for the treatment of mild to moderate atopic dermatitis,
     a type of ezczema in children aged between 1 − 12 years.
  - a medicine to help increase the level of insulin produced by the body after meals and decrease the amount of sugar made by the body for the treatment of type 2 diabetes.
  - a medicine for the treatment or prevention of a range of serious fungal infections.
  - the EAG considered and advised on the company's response to questions regarding a medicine indicated for the treatment and prevention of vitamin D deficiency.

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

- 52. In 2022, the CTBVEAG convened virtually once and provided advice by written correspondence on 6 occasions.
- 53. In January, the EAG provided written comments on:
  - clinical trial application for Rifampicin in Healthy Volunteer Drug-Drug-Interaction studies
  - clinical trial application for the treatment of COVID-19
- 54. In March, the EAG provided written comments on clinical trial application for the treatment of COVID-19.
- 55. In June, the EAG provided written comments on a paper on the safety of albumin products derived from UK Plasma.
- 56. In August, the EAG discussed and made recommendations on a vaccine used to prevent poliomyelitis (polio).
- 57. In August, the EAG provided written comments on a clinical trial application for the treatment of monkey pox infection.
- 58. In October, the EAG provided written comments on a paper for advice on the use of UK-sourced plasma for the manufacture of human albumin in the context of vCJD risk.

#### **COVID-19 Therapeutics Expert Working Group**

- 59. The COVID-19 Therapeutics Expert Working Group was convened following the emergence of COVID-19 as a global pandemic. The primary aim of the group was to advise on the safety and efficacy of treatments and prophylaxis considered for use in COVID-19. The therapies and agents falling within the remit of the group include: candidate anti-viral agents, immune-based therapies and repurposed agents for the treatment and prevention of COVID-19 infection. The full terms of reference for the expert working group can be accessed <a href="here">here</a>.
- 60. The Expert Working Group brings together a range of formidable experts from the fields of infectious diseases, immunology, clinical pharmacology, genetics, paediatric infections, other relevant fields and inviting additional expertise as needed. Collective expertise enables the CHM to advise on a critical item on the public health agenda, that of regulating COVID-19 therapeutics.
- 61. Given the 16 COVID-19 therapeutics that were discussed by the group in 2021, it was only deemed necessary for the Expert Working Group to meet on two occasions in 2022.

- 62. Some of the more high-profile topics discussed at these meetings included: a COVID-19 antibody therapy. In considering this application the EWG recognised that further data in immuno-compromised patients as well as additional data that support a more comprehensive understanding of the potential risks associated with the therapy were required.
- 63. The group also considered increasing the recommended dose of an approved COVID-19 prophylactic antibody combination. However, the data considered were too limited to justify an increase in the dose. The Expert Working Group also considered the recommended dose of another antibody, that of Ronapreve.
- 64. The Expert Working Group continued to monitor data and pre-print papers emerging from clinical trials such as Panoramic and Clalit. The EWG also kept abreast of current NICE guidelines on the recommended therapies for COVID-19 in outpatient and inpatient settings. In particular, the Expert Working Group noted the results of Molnupiravir reported in the pre-print version of the Panoramic study and that the marketing authorisation holder is considering a submission of a variation application based on the final publication of the results.

#### **COVID-19 Vaccines Benefit Risk Expert Working Group**

- 65. The COVID-19 VBR EWG was convened following the emergence of SARS-CoV-2 (COVID-19) as a global pandemic.
- 66. The group's remit was primarily to advise the CHM on the quality, safety and efficacy of COVID-19 vaccines and on the balance of benefits and risks prior to and post authorisation. The complete list of the group's objectives can be found <a href="https://example.com/here/benefits/benefits/">https://example.com/here/benefits/</a>
- 67. The COVID-19 VBR EWG met on 18 occasions in 2022. The group advised on the safety of authorised COVID-19 vaccines following their administration, based on analyses of suspected side effects reported through the Yellow Card Scheme, epidemiological data and international safety data, as well as relevant clinical trial and non-clinical data.
- 68. Major topics of discussion and decisions reached by the group included:
  - Safety of the vaccines in pregnancy.
  - Changes to the recommended age groups for the authorisations of COVID-19 Pfizer/BioNTech and COVID-19 Vaccine Moderna vaccines.
  - Review of potential safety signals following administration of the vaccines and advice on appropriate regulatory action where required, including: the risk of anaphylaxis in under 18s with the mRNA COVID-19 vaccines, menstrual disorders, the risk of myocarditis and pericarditis with mRNA COVID-19 vaccines. The Expert Working Group's advice on these and other safety issues

- has been included in the COVID-19 vaccine Yellow Card report publication.
- Review and advice on authorisation of bivalent COVID-19 vaccines and new monovalent vaccines.
- Review of Office for National Statistics (ONS) analysis of mortality data following COVID-19 vaccination in the context of review of Yellow Card reports with a fatal outcome.
- 69. Experts from various public health organisations and academic institutions were invited to the Expert Working Group and presentations were heard from, the UK Health Security Agency (UKHSA), Office of National Statistics, and representatives from NHS England.

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

- 70. In 2022, the GRIDEAG convened once and provided advice by written correspondence on 2 occasions.
- 71. In February, the EAG provided written comments on:
  - an early access to medicines scheme (EAMS) which aims to give patients with life threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation when there is a clear unmet medical need. A treatment of patients 16 years and older with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant or contraindicated to tumour necrosis factor (TNF)-α antagonist therapies.
- 72. In May, the EAG discussed and made recommendations on:
  - an ongoing variation regarding the addition of dry eye as an adverse reaction in section 4.8 the Summary of Product Characteristics of a monoclonal antibody (a type of specialised protein) medicine used for the treatment of moderate to severe atopic dermatitis in adults and adolescents 12 years or older.
  - MHRA proposals for amendments to the Summary of Product Characteristics Section 4.4 and also the Patient information Leaflet with regard to this and other ocular side effects. The EAG further discussed the development of treatment pathways for ocular side effects with this medicine and options to communicate further information to prescribers.
- 73. In May, the EAG also provided written comments on:
  - The amendments to include a warning and the undesirable effect of dry eye to the Summary of Product Characteristics for a medicine indicated for the treatment of moderate to severe atopic dermatitis (also known as atopic dermatitis) in adults and adolescents 12 years or older. The relevant Drug Safety Article on this issue was published in November 2022 and is available via the link: <a href="https://www.gov.uk/drug-safety-update/dupilumab-">https://www.gov.uk/drug-safety-update/dupilumab-</a>

## <u>dupixentv-risk-of-ocular-adverse-reactions-and-need-for-prompt-management</u>

#### **Infection Expert Advisory Group (IEAG)**

- 74. In 2022, the IEAG did not convene, however it provided advice by written correspondence on seven occasions.
- 75. In January, the EAG provided written comments on a clinical trial application for the treatment of COVID-19.
- 76. In February, the EAG provided written comments on:
  - a medicine for the treatment of bacterial vaginosis, a bacterial infection of the vagina.
  - a medicine for the treatment of serious bacterial infections.
- 77. In March, the EAG provided written comments on:
  - a medicine for the pre-exposure prevention of HIV-1 infection in atrisk adult and adolescent males.
  - a clinical trial application for the treatment of COVID-19.
- 78. In August, the EAG provided written comments on a clinical trial application for the treatment of monkey pox infection.
- 79. In September, a member of the EAG provided written comments on a medicine for the treatment of multiple myeloma in patients with HIV.

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

- 80. The MWHEAG met on 6 occasions during the year and provided written comments on 3 occasions. Summary reports based on the minutes of each meeting are published on the GOV.UK website.
- 81. The MWHEAG considered the latest evidence and made recommendations on the following issues with marketed medicines:
  - Menstrual disorders reported following vaccination against COVID- 19
  - Amendments to the pregnancy prevention programmes for thalidomide, lenalidomide and pomalidomide to allow home pregnancy testing for women of childbearing potential during the pandemic.
- 82. The MWHEAG considered and made recommendations on applications related to duration of use of an existing long-acting contraceptive medicine, route of administration of a medicine used in the treatment of under active thyroid glands and legal status for supply of a contraceptive product.

- 83. The MWHEAG considered and made recommendations on a study to assess the effectiveness of materials to support pharmacy availability of desogestrel contraception.
- 84. The MWHEAG provided comments on the presentation of summary pharmacokinetic information for medicines used in pregnancy.

#### Safety of Medicines during pregnancy

- 85. During the year the MWHEAG monitored all reports of suspected ADRs associated with use of medicines and vaccines in pregnancy received by MHRA. The MWHEAG reviewed 1026 new reports of suspected ADRs associated with use of medicines in pregnancy received from October 2021 to November 2022. The majority of reports received during this period did not raise any new concerns. The EAG considered Yellow Card reports, including those received via the Yellow Card Vaccine Monitor and publications related to use of COVID-19 vaccines during pregnancy throughout the year and considered that these did not raise any safety concerns.
- 86. The MWHEAG reviewed potential safety signals following use of the following medicines during pregnancy and recommended that no regulatory action was warranted for: systemic corticosteroid use in pregnancy; exposure to paternal use of metformin during pregnancy.
- 87. The MWHEAG considered further review and/or regulatory action should be taken for NSAID analgesics use in later trimester pregnancy.

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

- 88. In 2022, the NPPEAG convened virtually once and provided advice by written correspondence on four occasions.
- 89. In February, the EAG provided written comments on a drug safety update regarding new advice to minimise risk of serious liver injury.
- 90. In March, the EAG discussed and made recommendations on an Early Access to Medicines (EAMS) procedure for a medicine to treat generalised myasthenia gravis, a chronic autoimmune neuromuscular disease that causes muscle weakness.
- 91. In April, the EAG provided written comments on a medicine for the treatment of status epilepticus, a type of epilepsy where a person has a seizure that last a long time, or a series of seizures and doesn't regain consciousness in between.
- 92. In September, the EAG provided written comments on a medicine for the prevention of migraines.

93. In November, the EAG provided written comments on a medicine for the short-term symptomatic treatment of anxiety in adults, when the disorder is severe, disabling or subjecting the individual to extreme distress.

#### **Oncology and Haematology Expert Advisory Group (OHEAG)**

- 94. In 2022, the OHEAG convened virtually seven times and provided advice by written correspondence on two occasions.
- 95. In January, the EAG discussed and made recommendations on:
  - a medicine indicated for the treatment of breast cancer that has spread to other parts of the body.
  - a medicinal product indicated for use in positron emission tomography (PET) scanning (a type of scan that is very sensitive and can detect abnormal activity) to detect a specific type of prostate cancer.
  - a medicine indicated for the treatment of patients with prostate cancer.
  - a medicine proposed for the treatment of children 12 years of age and older and adults with acute or chronic graft-versus-host disease (GvHD).
- 96. In February, the EAG discussed and made recommendations on:
  - a medicine indicated for the treatment of a type of lung cancer that has advanced or spread to other parts of the body and has a gene defect called EGFR Exon 20 insertion mutations in adults who have received platinum-based chemotherapy treatment.
  - a medicine indicated for the treatment of patients aged 12 years and older with chronic graft versus host disease who have received at least two prior treatments.
- 97. In April, the EAG discussed and made recommendations on a medicine indicated for the treatment of non-small cell lung cancer (a type of lung cancer), prior to surgical removal of the tumour.
- 98. In May, the EAG discussed and made recommendations on a medicine indicated for the treatment of prostate cancer that had spread to other parts of the body and was still responsive to hormone treatment.
- 99. In July, the EAG discussed and made recommendations on:
  - a medicine indicated for the treatment of adult patients with lung cancer.
  - a medicine indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma and primary mediastinal large B-cell lymphoma after two or more lines of systemic therapy.
- 100. In August, the EAG provided written comments on:
  - a medicine used to treat adults with non-small cell lung cancer.

- 101. In October, the EAG discussed and made recommendations on:
  - a medicine used to treat adults with non-small cell lung cancer.
  - a paper regarding the pregnancy prevention plan for thalidomide, lenalidomide and pomalidomide and noted that there had been no detrimental impact from the flexibilities introduced during the pandemic with regard to pregnancy testing and advised that the flexibilities can remain.
- 102. In November, the EAG discussed and made recommendations on:
  - a medicine indicated for the treatment of biliary tract cancer with local or distant spread.
  - a company's response to questions regarding a medicine indicated for the treatment of advanced breast cancer.
- 103. In December, the EAG provided written comments on:
  - a medicine for the treatment of a type of cancer of the bone marrow called multiple myeloma that has not responded to previous treatment with at least three different types of anti-cancer medicines. It was concluded that the submitted evidence was insufficient to confirm efficacy in the sought indication and that the proposed medicine did not show a major advantage over existing treatments in the UK. The discussion concluded with a negative preliminary opinion.
  - a medicine for the treatment of non-small cell lung cancer, when it is advanced, or has spread to other parts of the body.

#### Paediatric Medicines Expert Advisory Group (PMEAG)

- 104. 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 UK Paediatric Regulation.
- 105. The PMEAG met nine times in 2022 and provided advice through written correspondence for additional ten papers.

#### Paediatric Investigation Plans (PIPs)

106. The PMEAG advised on 8 PIP applications in a range of therapeutic areas including COVID-19 disease (prevention and treatment), diabetes, paediatric cancers and renal disease.

#### Marketing authorisation applications supported by paediatric data

107. The PMEAG advised on 4 applications to add paediatric indications to existing products. The products covered a range of indications in paediatric patients including high blood pressure and fluid volumes, eyesight defects, sleeping disorders and pain.

#### Safety of medicines in children

108. In 2022, 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 a number of

specific paediatric signals and paediatric safety reviews. They advised on a review of new evidence on the effect of over-the-counter analgesics, taken during pregnancy and on events of severe calcium disturbances associated with a drug used for treatment of osteoporosis in paediatric patients. The PMEAG advised on issues about the timing of the administration of live vaccination in infants exposed in utero and/or via breast feeding to an immunosuppressant medicine taken by mothers. The PMEAG also advised on the need for updated warnings to avoid children's accidental exposure to local hormonal products used by parents and on warnings about the correct use of devices for asthma treatment.

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

- 109. The PMEAG discussed a paper concerning a clinical trial to be conducted in infants with a skin condition and allergies.
- 110. The PMEAG advised on the clinical issues associated with prescribing different formulations of a drug for the treatment of attention deficit hyperactivity disorder (ADHD). They also advised on clinical issues associated with the use of medications for paediatric sleep disturbances.
- 111. The PMEAG advised on the clinical issues associated with the potential discontinuation of a medicine used for paediatric anaesthesia.

#### Pharmacovigilance Expert Advisory Group (PEAG)

- 112. In 2022, the Commission's Pharmacovigilance Expert Advisory Group (PEAG) met eight times by videoconference and provided advice by written comments on one further occasion. The PEAG considered the latest evidence and made recommendations on matters including:
  - Prenatal exposure to the antiepileptic and antimigraine medicine topiramate and risk of autism spectrum disorder and intellectual disability.
  - Increased risk of anaphylaxis to neuromuscular blocking agents (NMBAs) during anaesthesia in patients with prior exposure to the cough medicine pholcodine
  - Use of paracetamol for chronic pain and risk of increased blood pressure in people with pre-existing hypertension
  - The use of febuxostat, a treatment for hyperuricaemia and gout, in patients with pre-existing major cardiovascular disease
  - Prenatal exposure to systemic corticosteroids (medicines which are used to manage and treat a range of inflammatory and allergic disorders) and risk of oral clefts
  - Paternal exposure to metformin, a treatment for diabetes, and risk of genital birth defects in male offspring
  - Increased mortality and increased risk of respiratory failure in patients with hepatorenal syndrome type-1 treated with terlipressin

- Appropriate risk minimisation measures relating to the known risk of liver injury in patients with cystic fibrosis treated with Kaftrio-Kalydeco (ivacaftor, tezacaftor, elexacaftor)
- The risk of medication error with different preparations of metolazone, a diuretic used for the treatment of hypertension and oedema
- The risk of major adverse cardiovascular adverse events (MACE), malignancies, venous thromboembolism (VTE), serious infections and all-cause mortality with the janus kinase (JAK) inhibitor class of medicines.
- 113. The PEAG also considers matters raised by Coroners under Regulation 28 of the Coroners' (Investigations) Regulations 2013 to prevent future deaths. In 2022, the PEAG considered one Coroners Report relating to the risk of lung toxicity with the antibiotic nitrofurantoin.
- 114. The PEAG considered and gave pre-authorisation advice on Risk Management Plans (RMPs) for new medicines including Pluvicto, a radiopharmaceutical that contains the active substance lutetium (177Lu) vipivotide tetraxetan, and is now authorised for the treatment of metastatic, progressive, castration-resistant PSMA (prostate-specific membrane antigen) positive prostate cancer. The PEAG also advised on the RMP for Gallium (68Ga) gozetotide (PSMA-11), which is now authorised for use in PET imaging to identify PSMA-positive metastases in patients who are being considered for treatment with Pluvicto.
- 115. The EAG also gave pre-authorisation advice on the RMPs for a new medicine intended to treat multiple myeloma, and another for the treatment of metastatic breast cancer.
- 116. In accordance with its responsibility for oversight of the UK Yellow Card scheme, the PEAG considered UK Yellow Card reporting statistics, including reporting statistics for the COVID-19 vaccines at each of its meetings in 2022.
- 117. The PEAG also considered and made recommendations based on the results of the MHRA's investigation into the impact of the large proportion of COVID-19 vaccine reports in the Yellow Card database on disproportionality analyses and signal detection for both the COVID-19 vaccines and other vaccines.
- 118. The PEAG received an update on recent and planned developments to the Yellow Card System.
- 119. The Group also received an update on progress on the development of the Yellow Card Biobank and gave advice on proposals for a Pharmacogenomics Watchlist in relation to the Biobank work.

- 120. The PEAG's advice underpins key medicines safety advice provided to UK healthcare professionals in MHRA's monthly newsletter <a href="Drug Safety Update">Drug Safety Update</a>.
- 121. Summary reports based on the minutes of each meeting are published on the GOV.UK website.

## Reclassification of a product for emergency contraception Ad Hoc Stakeholder Group

- 122. Reclassification ad hoc stakeholder groups are established by the CHM to consider certain major applications to reclassify a medicine from a prescription only medicine (POM) to a pharmacy (P) medicine, or from a P medicine to a general sales list (GSL) medicine. The role of a stakeholder group is to consider the practical aspects of the supply and use of a proposed reclassified medicine. The views of the group are provided to the CHM when the MHRA seeks its advice on the reclassification application. The feedback from the stakeholder group is taken into account by the CHM when it considers all the evidence provided by the company and the MHRA's assessment of the application. A reclassification ad hoc stakeholder group meets on one occasion and usually comprises representatives from: the medical and pharmacy professional organisations, practising healthcare professionals, patients, and patient representatives.
- 123. In 2022, one reclassification ad hoc stakeholder group was established and met to consider a P to GSL reclassification application for a medicine indicated for emergency contraception.

#### **Valproate Implementation Group**

124. The Valproate Implementation Group was convened in September 2022 and met four times in 2022 to discuss the safe and effective implementation of the new safety measures. During discussions the group cautioned against an immediate implementation of the measures for all patients because of the large numbers of patients potentially affected, the complexity of implementation and the capacity of the healthcare system to safely manage the workload. The Group steered strongly towards a phased approach to implement the new safety measures over an extended period. An article to remind healthcare professionals of the existing safety measures in place for valproate and inform them of upcoming changes was published in the December edition of Drug Safety Update<sup>3</sup>.

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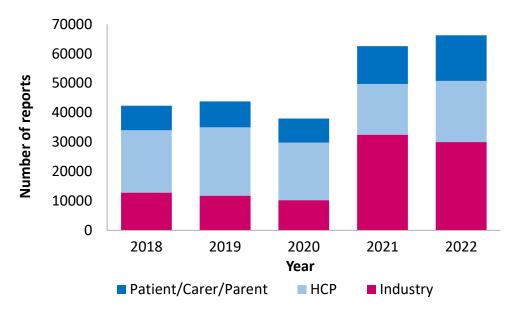
<sup>&</sup>lt;sup>3</sup> Drug Safety Update Volume 16, Issue 5: December 2022: 1

#### REPORTING OF SUSPECTED ADVERSE DRUG REACTIONS 2022

## **Yellow Card data (excluding for COVID-19 vaccines)**

- 125. Suspected Adverse Drug Reactions (ADRs) to medicinal products and vaccines are reported to the CHM and MHRA on a voluntary basis by healthcare professionals and members of the public through the Yellow Card scheme. Reports are also submitted as a legal requirement by pharmaceutical companies holding Marketing Authorisations. Information collected through the Yellow Card scheme is an important means of monitoring drug safety in clinical practice, acting as an early warning system for the identification of previously unrecognised adverse reactions and increasing clinical knowledge about known ADRs.
- 126. The average number of UK spontaneous suspected ADR reports received from all sources over the last five years is 50,465 reports annually. A breakdown of the total number of reports per year for the different reporter sources is shown in Figure 1. As expected with the introduction of social distancing measures across the UK in March 2020 due to the COVID-19 pandemic, total numbers of Yellow Card reports decreased by 13% in 2020 compared to 2019. This trend has reversed in the last two years with overall ADR reporting increasing in 2021 and 2022. The total number of suspected ADR reports received in 2022 is 66,159 which is a 6% increase overall (3,794 reports) compared to 2021, and a 51% (22,480 reports) increase compared to 2019 pre-pandemic reporting levels. This increase in 2022 compared to 2021 represents an increase in reporting from both healthcare professionals and members of the public.
- 127. Overall, direct Yellow Card reporting from healthcare professionals accounted for 31% (20,791 reports) of all suspected ADR reports received in 2022 and was an increase of 21% (3582 reports) compared to 2021. Reports from members of the public (including patients, parents and carers) accounted for 23% (15,470 reports) of all suspected ADR reports with an increase of 20% (2625 reports) compared to 2021.
- 128. In 2022, suspected ADR reports from the pharmaceutical industry accounted for 45% (29,993 reports) of all reports received by the MHRA. This represents a small decrease of 8% (2,504 reports) compared to 2021. The large increase in ADR reporting from industry since 2020 is linked to changes in the reporting from Marketing Authorisation Holders with the MHRA now receiving non-serious UK cases directly from Marketing Authorisation Holders, rather than through European systems since the UK's exit from the EU.

Figure 1 – Number of UK spontaneous suspected Adverse Drug Reaction reports received over the last 5 years broken down by reporter source.



Year	2018	2019	2020	2021	2022
Total number of UK					
spontaneous ADR	42259	43600	37941	62365	66159
reports					

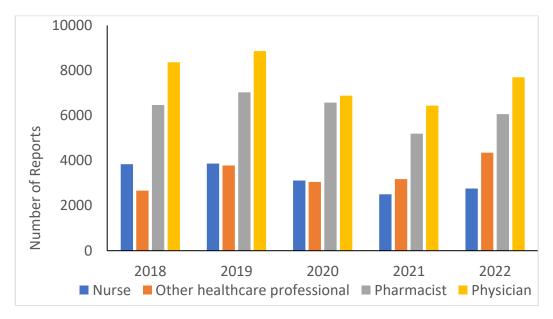
## **Patient ADR Reporting**

129. In 2022, the highest number of reports from members of the public (reports from patients, carers and parents) were received by the Yellow Card scheme to date with 15,470 suspected ADR reports received representing 23% of all reports received. Reports from members of the public increased by 86% (7,156 reports) over the average number received over the last five years. This in part results from the MHRA's Yellow Card strategy work, including campaign work, and its five Yellow Card Centres where efforts continue to proactively encourage reporting. The increase in 2021 (64%) for non-COVID-19 reporting is likely due to the increased awareness of the MHRA and the Yellow Card scheme due to significant media attention following the start of the COVID-19 vaccination campaign and MHRA campaign work.

#### Healthcare professional ADR reporting

130. Yellow Card reports received directly from healthcare professionals in 2022 increased by 21% (3,582 reports) compared to 2021 and 6% (1,239 reports) compared to 2020. However, in most reporter categories they remain lower than pre pandemic levels in 2019. A breakdown of direct healthcare professional reports by reporter category between 2018 and 2022 is shown in Figure 2.

Figure 2 – Number of spontaneous suspected Adverse Drug Reaction reports received directly from healthcare professionals over the last 5 years.



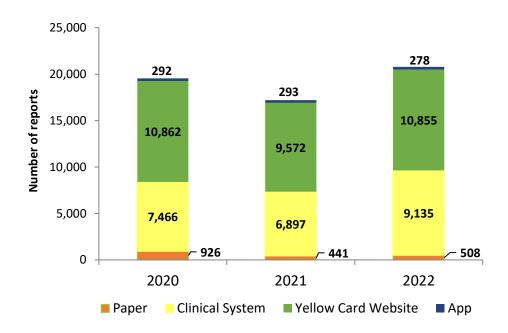
<sup>\*</sup>Other health professionals include dentists, optometrists, coroners, healthcare assistants, paramedics, chiropodists and other non-specified health professionals.

- 131. Reporting for all healthcare professional groups has increased from 2021 to 2022. Due to a process change implemented in 2021, reporter qualification is no longer routinely manually updated with more specific information. The reporter categories provided in Figure 2 are therefore less granular than provided in previous reports. This particularly affects reports received from clinical systems where reporter qualification remains at the default value.
- 132. Physicians (including GPs and hospital doctors) make up the largest reporter group accounting for 37% of all direct healthcare professional reports. Pharmacists are the second largerst reporting group (including community pharmacists, hospital pharmacists, pharmacy assistants and pharmacy technicians) with a 17% increase (894 reports) between 2021 and 2022.

#### **Electronic ADR Reporting**

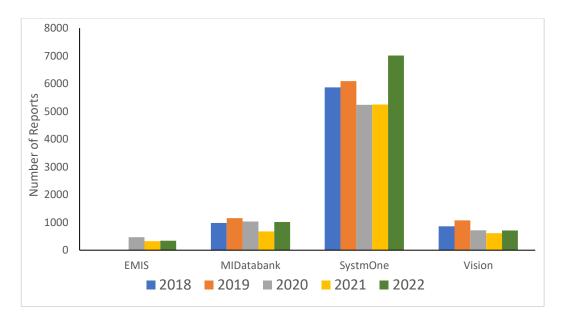
133. Nearly all reports from healthcare professionals and members of the public are received electronically either through the Yellow Card website, the Yellow Card App or directly from a clinical system. In 2022 96% (14,788 reports) of all ADR reports from the public were reported electronically, with a 19% (2,695 reports) increase in reports via the Yellow Card website compared to 2021. A breakdown of the main methods of reporting from healthcare professionals is shown in Figure 3.

Figure 3 - Yellow Card reporting methods for healthcare professionals reporting spontaneous suspected Adverse Drug Reaction reports between 2020 - 2022.



- 134. Reports from the Yellow Card Website make up 53% of all direct reports from healthcare professionals in 2022. The Yellow Card website was updated in 2022 to streamline the reporting site and deliver a number of improvements. A key improvement was enabling registered users to update their submitted ADR reports for medicines and vaccine directly in the website, allowing them to provide further information about their report in a simpler way. A further improvement was the ability to attach documents to a report, for instance pictures or test results.
- 135. Reports from Yellow Card forms integrated into Clinical IT systems make up 44% of the total in 2022, this is an increase of 32% (2238 reports) compared to 2021. Integrated Yellow card reporting is now available in 93% of GP practices in the UK and further work is underway to increase visibility of Yellow Card forms within those clinical systems to increase awareness and ease of reporting for clinicians.
- 136. Figure 4 below shows a breakdown of ADR reports received from healthcare professions through clinical systems over the past 5 years. In total 6 systems are integrated with Yellow Card however reports volumes from two of the systems are very low (<40 reports per year) and therefore have not been included on the graph.
- 137. Reports received from SystmOne make up the largest proportion of reports from clinical systems over the past 5 years, accounting for 77% (7014 reports) in 2022. This is an increase of 33% compared to 2021. The second largest contributor is MiDatabank accounting for 11% of reports in 2022 (1015 reports).

Figure 4 – Number of spontaneous suspected Adverse Drug Reaction reports received by the MHRA from clinical systems between 2018 – 2022



## The Yellow Card App

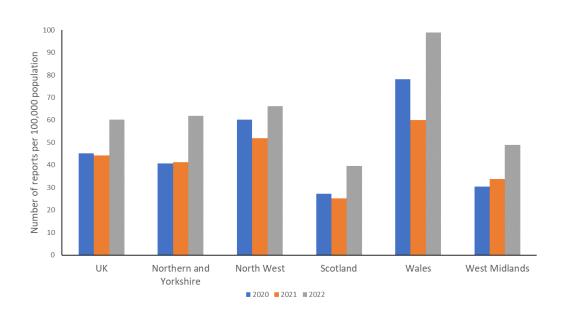
- 138. The Yellow Card App is targeted at both healthcare professionals and patients; reporting trends have shown that the app is particularly used by patients as a route of reporting. Suspected ADR reporting through the app decreased 21% in 2022 compared with 2021 with a total of 794 reports received. Of these reports, 65% (516 reports) were from members of the public. Reporting volumes through the app are low in comparison to other routes, feedback from users has suggested the app is mainly used as a source of information about the medicines they use rather than for reporting.
- 139. The technology which supports the Yellow Card website also supports the Yellow Card App and the App therefore also benefits from the enhancements delivered in 2022 including for reporters to update their reports and to be able to provide attachments with their reports. In 2023 a new release of the App will be launched which will allow reporters to be asked more bespoke questions based on the contents of their reports to improve the data collected. Further work is underway to increase reporting through the Yellow Card app including linkage to the NHS app.

#### **UK Yellow Card Centres**

140. The MHRA works with five Yellow Card Centres (YCCs) in Wales, Scotland, Northern & Yorkshire, North West and the West Midlands to increase awareness of the Yellow Card scheme and increase ADR

- reporting rates within their regions. The YCCs are also involved in various educational outreach programmes to encourage reporting.
- 141. In 2022 the YCCs continued to promote the Yellow Card scheme by delivering online virtual training sessions to healthcare students and qualified healthcare professionals. This has allowed training to be delivered with a wider national reach, for example educational training sessions on the Yellow Card scheme were provided to all pharmacy undergraduate teaching schools. The YCCs also play an important part in our social media campaigns, such as #MedSafetyWeek, through their YCC social media pages. Other activities of note include presentations and attendance at conferences, working with public and patient interest groups, digital enhancements to websites and IT platforms to access YCC services.
- 142. The YCCs dedication and continued support of the Yellow Card scheme has played an important role in ADR reporting. Figure 5 shows a breakdown of reporting between 2020 2022 for the UK and each of the five regional areas for non-COVID related ADR reports. Overall for 2022, reporting rates are higher than previous two years for all YCCs. In 2022 three YCCs had a higher reporting rate per 100,000 people than the UK average (60): Northern & Yorkshire (66) North West (62) and Wales (98).

Figure 5 – 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**

- 143. The MHRA signal<sup>4</sup> management system is designed to enable the timely detection of new or changing drug safety issues. Changes in the frequency of reporting ADRs that are 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.
- 144. In 2022, there was a total of 48 validated safety signals potential signals that have been identified by a statistical algorithm or from external sources which subsequently undergo 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 based on a number of different factors, a breakdown of the signals and assigned priorities is provided in Table 1.

Table 1: Number of signals requiring further investigation in 2022

	Signal Priority			
	Standard	Increased	Тор	
Number of				
signals	38	8	2	

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

- 145. These signals were identified from a range of sources including Yellow Card reports, medical literature, other international regulators and through communication received directly from marketing authorisation holders.
- 146. Patient reporting makes an important contribution to our signal detection activities. In 2022, 9 signals were identified for further investigation through reports to the scheme or via enquiries from members of the public.
- 147. Similarly, 12 signals were identified for further investigation from information received from healthcare professionals via Yellow Card reporting or enquiries.

<sup>4</sup> An alert from *any* available data source that a drug *may* be associated with a previously unrecognised hazard or that a known hazard is quantitatively or qualitatively different from existing expectations. (Davies's Textbook of ADRs – 5<sup>th</sup> edition).

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## Topical Testosterone and risk of accidental exposure signal

Topical testosterone and the risk of harm to children following accidental exposure is an example of a signal which stimulated regulatory action in 2022 and arose from a Yellow Card report from a parent. The risk was reviewed by the Paediatric Medicines Expert Advisory Group of the CHM, which recommended that a specific paediatric warning be added to the product information for topical testosterone products. The review found that premature puberty and genital enlargement have been reported in children who were in close physical contact with an adult using topical testosterone, and that were repeatedly accidentally exposed to this medicine. To reduce these risks, the MHRA requested updates to the product information to advise patients to wash their hands after application of topical testosterone, cover the application site with clothing once the product has dried, and wash the application site before physical contact with another adult or child. A <a href="Drug Safety Update">Drug Safety Update</a> was also published.

## Methylprednisolone and flushing signal

Another signal that stimulated regulatory action in 2022 concerned methylprednisolone and flushing and was prompted following receipt of a number of Yellow Card reports from both healthcare professionals and members of the public. Analysis concluded that there was significant evidence of a causal association between flushing and methylprednisolone. The MHRA requested the product information be updated for both healthcare professionals and patients regarding this potential adverse effect.

148. Any new signals reviewed by the European Pharmacovigilance Risk Assessment Committee (PRAC) and other international regulators, are also incorporated into the MHRA's routine signal detection activities. The MHRA assessed 49 signals that were also reviewed by the PRAC.

Table 2: Number of signals assessed in 2022 from other international regulators\*

	Signal Priority				
	Standard	Increased	Тор		
Number of					
signals	46	1	2		

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

\*The number of signals in this table will not equate to the total number of signals assessed by the PRAC, as if the signal was identified by other sources it will be included in Table 1.

149. In 2022, 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 Administration (TGA), Medsafe, Health Sciences Authority (HSA) and Swissmedic. Every two months, each agency can propose topics to the other agencies for discussion, the majority of which relate to drug safety issues. The MHRA have proposed a number of topics in 2022 through which further information and worldwide evidence has been obtained to aid the assessment of signals, such as the signal of topical testosterone and the risk of harm to children following accidental exposure discussed above.

## **E-Cigarette Reporting**

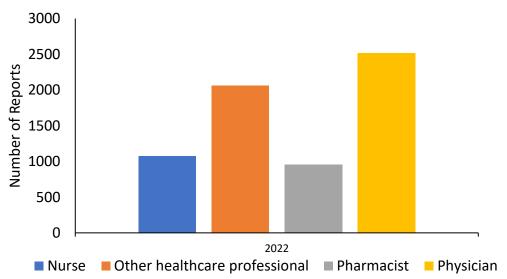
- 150. The MHRA is the competent authority for the UKs notification scheme for nicotine containing Vaping products (E-cigarettes and refill containers) in Great Britain and Northern Ireland and is responsible, working with other regulatory bodies, for implementing a number of provisions under Part 6 of the Tobacco and Related Products Regulations 2016 (TRPR), as amended.
- 151. In 2022, the MHRA received 40 adverse reaction reports associated with the use of a nicotine-containing e-cigarettes. This is an increase compared to 2021 where 24 ADR reports were received. The MHRA also received 4 reports of product quality concerns and continues to liaise closely with Trading Standards authorities to share information regarding product device-related safety and quality concerns.

## Yellow Card data for COVID-19 vaccines

- 152. In 2022 the MHRA received 46,551 spontaneous Yellow Card reports in association with the COVID-19 vaccines. The MHRA saw a decrease in the number of reports associated with COVID-19 vaccines throughout 2022 in line with the well-established safety profile. Overall, Yellow Card reports from the public accounted for 81% (37,871 reports) of all suspected spontaneous reports received for COVID-19 vaccines in 2022.
- 153. The vast majority of reporting for COVID-19 vaccines has been through the dedicated COVID-19 Yellow Card reporting site. Given the reduced scope and scale of the COVID-19 vaccination campaign and the stable safety profile of the vaccines, the MHRA is encouraging users of the scheme to transition to the use of the standard Yellow Card website for future suspected ADR reports for the COVID 19 vaccines. Robust safety monitoring and surveillance of any COVID-19 vaccines used in the UK will continue along with timely communication on any updated safety advice when needed.
- 154. Figure 6 provides a breakdown of suspected ADR reports for COVID-19 vaccines reported by healthcare professionals in 2022 by reporter

category. Similar to non-COVID-19 Yellow Card reporting, physicians are the highest reporting healthcare professional reporters for adverse reactions to COVID-19 vaccines, accounting for 38% (2515 reports) of all direct healthcare professional reports. Other healthcare professional group accounted for 31% (2064 reports) of all direct healthcare professional reports. The most frequently reported professions within this group were other healthcare professionals (59%) and healthcare assistants (16%).

Figure 6: Number of spontaneous suspected Adverse Drug Reaction reports in association with COVID-19 vaccines received in 2022 by reporter category.



<sup>\*</sup>Other health professionals include dentists, optometrists, coroners, healthcare assistants, paramedics, chiropodists and other non-specified health professionals.

155. In December 2022 the MHRA implemented a new enhanced format of data visualisations, starting with the publication of <u>COVID-19 vaccine</u> reports. This new format provides interactive graphs and tables displaying all UK spontaneous adverse reaction reports for COVID-19 vaccines used in the UK and delivers improvements in format and accessibility whilst allowing access to more data than has been published previously. Work is currently ongoing to include all routine vaccinations and extend to medicines in 2023 replacing the current <u>interactive Drug Analysis Profiles</u>.

#### COVID-19 vaccine signal detection

156. The MHRA has continued to adapt its signal management system in response to the COVID-19 pandemic. The <u>pharmacovigilance strategy</u> that was developed for medicines and vaccines, to manage the response to the COVID-19 pandemic continued to be followed in 2022.

- 157. The focus of the MHRA's pharmacovigilance activities were the COVID-19 vaccines being used in the UK as part of the national rollout of the vaccination programme and newly authorised COVID-19 therapeutics. The MHRA adapted their signal detection processes further following the Autumn 2022 booster campaign to include the reporting, assessment and evaluation of data concerning COVID-19 vaccines used in the campaign. Throughout each stage of the vaccination rollout and pandemic, the MHRA has assessed the COVID-19 vaccines and medicines continually and comprehensively. Further detail on the MHRA's response to the pandemic can be seen in the COVID-19 EWG section of the report.
- 158. In addition, until March 2023 the MHRA regularly published the <u>weekly</u> <u>summary of Yellow Card reporting</u> which summarised information received via the Yellow Card scheme as well as other safety investigations carried out under the COVID-19 Vaccine Surveillance Strategy.

## **Obituary**

Members were saddened to learn of the death of Dr Mark Glover who was a member of the Pharmacovigilance Expert Advisory Group from 2019 until early 2023.

## MEMBERSHIP OF THE COMMISSION ON HUMAN MEDICINES

#### 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

Vice Chair

## **Professor Jonathan S Friedland**<sup>1</sup> MA PhD FRCP FRCPE FRCPI FESCMID FMedSci

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

#### **Members**

## Professor Amanda Adler MD PhD FRCP

Professor of Diabetic Medicine and Health Policy, University of Oxford

#### Ms Susan Bradford

Lay Representative

#### Professor Jamie Coleman MD MA (Med Ed) FRCP FBPhS

Consultant Physician, University Hospitals Birmingham NHS Foundation Trust and Honorary Professor in Clinical Pharmacology and Medical Education, University of Birmingham

#### Mrs Julia Cons<sup>2</sup>

Lay Representative

#### Professor Steven Cunningham MBChB PhD FRCPCH

Professor of Paediatric Respiratory Medicine, University of Edinburgh and Honorary Consultant, Royal Hospital for Children and Young People, NHS Lothian, Edinburgh

**Professor Paul I Dargan<sup>3</sup> MB BS FRCP Edin FACMT FRCP ERT FAACT FEAPCCT FBPhS MAE** 

Consultant Physician and Professor of Clinical Toxicology, Guy's and St Thomas' NHS Foundation Trust, London

Professor of Clinical Toxicology, King's College London

<sup>&</sup>lt;sup>1</sup> End of appointment 31/03/2022

<sup>&</sup>lt;sup>2</sup> Appointed 01/07/2022

<sup>&</sup>lt;sup>3</sup> Appointed 01/07/2022

## Professor David Dockrell<sup>4</sup> MB BCh MD FRCPI FRCP (Glas) FACP

Professor of Infection Medicine, University of Edinburgh

## Dr Jamie Fraser<sup>5</sup> BSc (Hons) MBChB MRCGP

GP Partner, Southside Surgery, Inverness

#### Professor Richard J C Gilson<sup>6</sup> MD FRCP

Professor of Sexual Health & HIV Medicine, Director of the UCL Centre for Clinical Research in Infection & Sexual Health & Deputy Director of the UCL Institute for Global Health

### Professor David Hunt<sup>7</sup> MB BChir FRCP PhD

Consultant Neurologist, NHS Lothian

Professor of Neuroinflammatory Medicine, University of Edinburgh

## Professor Malcolm R Macleod<sup>8</sup> BSc MBChB MRCP PhD FRCP (Edin) FMedSci

Professor of Neurology and Translational Neurosciences, University of Edinburgh and Honorary Consultant Neurologist, NHS Forth Valley

## Dr Siraj Misbah<sup>9</sup> MBBS (Hons) MSc FRCP FRCPath

Consultant Clinical Immunologist, Lead for Clinical Immunology, Oxford University Hospitals

## Professor David Moore<sup>10</sup> MBChB MD MSc DTM&H

Professor of Infectious Diseases and Tropical Medicine, London School of Hygiene and Tropical Medicine and Consultant in Infectious Diseases and Tropical Medicine, Hospital for Tropical Diseases, University College London Hospital

**Dr Gerri Mortimore**<sup>11</sup> PhD; MSc Advanced Practice; PgCert (IPPE); BA(Hons) Health Studies; iLM. RGN; NMP; FHEA

Associate Professor in Advanced Clinical Practice; NICE Nurse Expert Advisor

## Professor Sandosh Padmanabhan MBBS MD PhD FRCP(Glasg)

FRCP(Edin) FBPhS FBIHS

Professor of Cardiovascular Genomics and Therapeutics, University of Glasgow

## Professor Poulam Patel PhD, MBBS, FRCP

Professor of Clinical Oncology, University of Nottingham

<sup>&</sup>lt;sup>4</sup> Appointed 01/07/2022

<sup>&</sup>lt;sup>5</sup> Reappointed 01/04/2022

<sup>&</sup>lt;sup>6</sup> End of appointment 14/12/2022

<sup>&</sup>lt;sup>7</sup> Appointed 01/07/2022

<sup>&</sup>lt;sup>8</sup> End of appointment 31/03/2022

<sup>&</sup>lt;sup>9</sup> End of appointment 30/06/2022

<sup>&</sup>lt;sup>10</sup> Appointed 15/12/2022

<sup>&</sup>lt;sup>11</sup> Appointed 01/07/2022

**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 Shirley Price<sup>12</sup>** MSc PhD FBTS FRSB ERT FHEA FRSC MBPharmacol Soc

Emerita Professor of Toxicology, University of Surrey Visiting Professor of Toxicology, University of Hertfordshire

## Professor Rui Providencia<sup>13</sup> MD PhD

Institute of Health Informatics Research, University College London Consultant Cardiologist & Cardiac Electrophysiologist, Barts Health NHS Trust

**Dr Vanessa Raymont**<sup>14</sup> MBChB MSc MRCPsych Senior Clinical Researcher, University of Oxford and Honorary Consultant Psychiatrist, Oxford Health NHS Foundation Trust

**Professor Marc Turner** MB ChB PhD MBA FRCP FRCPath FRSE Professor of Cellular Therapy; Director Scottish National Blood Transfusion Service (SNBTS)

**Professor Heather M Wallace** PhD FRCPath FRSC FRSB FBTS FBPhS ERT Professor Emerita of Biochemical Pharmacology and Toxicology, University of Aberdeen

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

**Professor Anthony Williams**<sup>15</sup> BSc MSc MRCP, FRCPath, PhD Professor of Translational Medicine and Honorary Consultant in Clinical Immunology and Allergy, University of Southampton and University Hospital Southampton NHS Trust

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

<sup>12</sup> End of appointment 31/03/2022

<sup>&</sup>lt;sup>13</sup> Appointed 01/07/2022

<sup>&</sup>lt;sup>14</sup> Appointed 01/07/2022

<sup>&</sup>lt;sup>15</sup> Appointed 01/07/2022

## Co-opted Members known as Members for the Day

#### Mrs Julia Cons

Lay Representative

## Professor David Dockrell MB BCh MD FRCPI FRCP (Glas) FACP

Professor of Infection Medicine, UoE Centre for Inflammation Research, The University of Edinburgh

## **Professor Jonathan S Friedland** MA PhD FRCP FRCPE FRCPI FESCMID FMedSci

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

#### Professor Richard J C Gilson MD FRCP

Professor of Sexual Health & HIV Medicine, Director of the UCL Centre for Clinical Research in Infection & Sexual Health & Deputy Director of the UCL Institute for Global Health

## Ms Susan Hunneyball

Lay Member

#### Professor David Hunt MB BChir FRCP PhD

Consultant Neurologist, NHS Lothian

Professor of Neuroinflammatory Medicine, University of Edinburgh

#### Professor Malcolm R Macleod BSc MBChB MRCP PhD FRCP (Edin)

Professor of Neurology and Translational Neurosciences, University of Edinburgh and Honorary Consultant Neurologist, NHS Forth Valley

#### Professor David Moore MBChB MD MSc DTM&H

Professor of Infectious Diseases and Tropical Medicine, London School of Hygiene and Tropical Medicine and Consultant in Infectious Diseases and Tropical Medicine, Hospital for Tropical Diseases, University College London Hospital

**Dr Gerri Mortimore** PhD; MSc Advanced Practice; PgCert (IPPE); BA (Hons) Health Studies; iLM. RGN; NMP; FHEA,

Associate Professor in Advanced Practice; NICE Nurse Expert Advisor

## Professor Shirley Price MSc PhD FBTS FRSB ERT FHEA FRSC

MBPharmacol Soc

Emerita Professor of Toxicology, University of Surrey

Visiting Professor of Toxicology, University of Hertfordshire

#### Professor Rui Providencia MD PhD

Institute of Health Informatics Research, University College London Consultant Cardiologist & Cardiac Electrophysiologist, Barts Health NHS Trust

## Dr Vanessa Raymont MBChB MSc MRCPsych

Senior Clinical Researcher, University of Oxford and Honorary Consultant Psychiatrist, Oxford Health NHS Foundation Trust

## Mrs Madeleine Wang

Lay Representative – Patient advocate

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

#### **Professor Dominic Wilkinson**

Ethicist, Jesus College, Oxford

## **Invited Experts to CHM Meetings**

#### Ms Gill Adams

Consultant Surgeon and specialist in Neuro-ophthalmology at Morefield's Eye Hospital

## Dr Sharon Alroy-Preis MD, MPH, MBA

Deputy CEO at Carmel Medical Centre Head of Public Health Services in Israel

#### Dr Sarah Aylett

BPNA, Epilepsy group

#### Ms Deborah Baidoo

Head of Programme - Sodium Valproate, Policy and Strategy Team, NHS England and NHS Improvement

#### Sandor Beukers

Head of Pharmacy, DHSC

#### Professor Judith Breuer MD FRCPath FmedSci

Professor of Virology, University College London (UCL), Division of Infection and Immunity, London

## Dr Rebecca Bromley ClinPsyD, PhD

Research Fellow & Neuropsychologist, University of Manchester & Royal Manchester Children's Hospital

## **Professor Chris Butler** BA MBChB DCH CCH MD FRCGP (Hon)FFPH FMedSci

Professor of Primary Care, Nuffield Department of Primary Care Health Sciences, University of Oxford

#### **Rheian Davies**

Head of Legal, Mind

## Professor David Dockrell MB BCh MD FRCPI FRCP (Glas) FACP

Professor of Infection Medicine, University of Edinburgh

#### Mr Andrew Evans

Chief Pharmaceutical Officer, Wales

## Mr V'lain G Fenton-May BPharm MIPharm FRPharmS

Pharmaceutical Microbiologist

#### **Professor Nicole Ferrier**

Emeritus Professor of Psychiatry, Newcastle University

#### **Mrs Cathy Harrison**

Chief Pharmaceutical Officer, Northern Ireland

## Professor Simon Harding MB ChB, FRCS, FRCOphth, MD

Chair Professor of Clinical Ophthalmology, Head of Department

#### Ms Sara Hartnell

Diabetes Educator/Diabetes Specialist Dietitian, Cambridge University Hospitals NHS Foundation Trust

#### **Dr Dan Hawcutt**

Paediatric Consultant

#### 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 Peter Hindmarsh**

Professor of Paediatric Endocrinology, University College London

#### **Susan Hopkins**

UKHSA

#### Dr Kathryn Johnson MBChB FRCPCH

Consultant Neonatologist & Research Lead, Yorkshire & Humber CRN Children's Specialty Lead

## **Professor Keith Lloyd**

Pro Vice Chancellor / Executive Dean Medicine, Health & Life Science, Swansea University

## Professor Andrew Lotery MD FRCOphth

Professor of Ophthalmology

#### Mr Robert Lowe BPharm FRPharmS

Practising Hospital Pharmacist, Specialist Pharmacy Services - East of England

## Professor Hamish McAllister-Williams PhD MD FRCPsych

Professor of Affective Disorders, Newcastle University

#### **Professor Ron Milo**

Associate Professor, Weizmann Institute of Science, Department of Plant and Environmental Sciences

## Dr Siraj Misbah MBBS (Hons) MSc FRCP FRCPath

Consultant Clinical Immunologist, Lead for Clinical Immunology, Oxford University Hospitals

#### Dr Rebecca Mann

Consultant Paediatrician, Taunton and Somerset NHS Foundation Trust

## **Professor Anthony Marson**

Professor of Neurology, University of Liverpool Director of Research Programmes, Liverpool Health Partners NIHR Senior Investigator

#### Professor David Moore MBChB MD MSc DTM&H

Professor of Infectious Diseases and Tropical Medicine, London School of Hygiene and Tropical Medicine and Consultant in Infectious Diseases and Tropical Medicine, Hospital for Tropical Diseases, University College London Hospital

#### **Ms Kim Morley**

**Epilepsy Specialist Nurse** 

## Prof Finbar O'Callaghan

Professor of Paediatric Neuroscience, Developmental Neurosciences Dept, UCL GOS Institute of Child Health

#### Professor David G C Owens MD (Hons) FRCP FRCPsych

Professor of Clinical Psychiatry, Edinburgh University

#### Professor Sir Andrew Pollard PhD FRCPCH

Chair of the Joint Committee on Vaccination and Immunisation; Professor of Paediatric Infection and Immunity, University of Oxford

## **Dr Mary Ramsay**

UKHSA

## **Professor Arjune Sen**

Consultant Neurologist
BRC Senior Research Fellow

#### Ms Hannah Sheridan

Lead Pharmacist – Emergency Department Blackpool Teaching Hospitals NHS Foundation Trust

## Professor Sanjay M Sisodiya

Institute Deputy Director Sustainability & Climate Change and Consultant Neurologist, Department of Clinical and Experimental Epilepsy, UCL Queen Square Institute of Neurology

## **Professor Philip Smith**

Consultant Neurologist, Cardiff University

## Josephine Tapper

Health advocate

## Professor Kevin M G Taylor BPharm PhD FRPharmS

Chair of the British Pharmacopoeia Commission and Professor of Clinical Pharmaceutics, UCL School of Pharmacy, London

## Dr Robin Thorpe BSc PhD FRCPath

Retired, Head, Division of Biotherapeutics, National Institute for Biological Standards and Control (NIBSC) & Member of the Clinical Trials, Biologicals & Vaccines Expert Advisory Group (CTBVEAG)

#### Dr Naveen Vasudev

Associate Professor, Honorary Consultant in Medical Oncology Leeds Institute of Medical Research at St James's & St James's Institute of Oncology, St James's University Hospital, Leeds

#### Professor Susannah Walsh BSc PhD MBA

Associate Head School of Pharmacy, Professor of Pharmaceutical Microbiology, Leicester School of Pharmacy, De Montfort University, Leicester

#### **Dr Bruce Warner**

Deputy Chief Pharmaceutical Officer for England

#### **Ellen Williams**

Director of Regional Pharmacy Training, Pharmacy Workforce Development South

## **Observers of CHM Meetings**

## **Dr Tom Caparrotta** BSc MBBCh MRCP(UK)

Diabetes UK 'Sir George Alberti' Clinical Research Fellow in Pharmacoepidemiology, Clinical Pharmacology, General (Internal) Medicine Trainee, University of Edinburgh, NHS Lothian

## Ms Jenna Dilkes

The National Institute for Health and Care Excellence (NICE)

#### **Mr Andrew Evans**

Chief Pharmaceutical Officer of Wales

## **Mrs Cathy Harrison**

Chief Pharmaceutical Officer NI

## **Zareef Khodabux**

**DHSC** 

#### **Claire Liew**

**DHSC** 

## **Professor Wei Shen Lim**

Chair of COVID-19 Immunisation on JCVI

#### **Olivia Moore**

Policy Advisor, Pharmacy, DHSC

## **Claire Potter**

Head of Prescribing Policy and Charges, DHSC

## **Eric Power**

NICE

## Ms Natalie Spray

The National Institute for Health and Social Care Excellence (NICE)

## **Professor Alison Strath**

Chief Pharmaceutical Officer of Scotland

#### **David Webb**

Chief Pharmaceutical Officer

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

#### Remit

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

#### Chair

#### Professor Amanda Adler MD PhD FRCP

Professor of Diabetic Medicine and Health Policy, University of Oxford

#### **Members**

**Dr Amine Boualem**<sup>16</sup> MD MRCGP PGDip(Diabetes) AHEA GP Partner, East Barnwell Health Centre, Cambridge

#### Professor Mark Evans<sup>17</sup> BSc MB BS MD FRCP

Professor of Diabetic Medicine, University of Cambridge and Consultant Physician, Cambridge University Hospitals

# **Associate Professor William G. Herrington**<sup>18</sup> MA(Cantab) MBBS(Lond) MD(Cantab) FRCP(London)

Medical Research Council-Population Health Research Unit at the University of Oxford; Honorary Consultant Nephrologist, Oxford Kidney Unit

# **Dr Patrick Holmes**<sup>19</sup> MB BS MSc MRCGP GP Partner St. George's Medical Practice, Darlington

**Dr Wajid Hussain<sup>20</sup>** BSc (Hons) MB ChB (Hons) MSc FRCP Consultant Cardiologist, Royal Brompton and Harefield Hospitals, Part of Guys and St Thomas' NHS Foundation Trust

# **Professor Sandosh Padmanabhan<sup>21</sup> MBBS MD PhD FRCP(Glasg)** FRCP(Edin) FBPhS FBIHS

Professor of Cardiovascular Genomics and Therapeutics, University of Glasgow

<sup>&</sup>lt;sup>16</sup> Appointed 07/04/2022

<sup>&</sup>lt;sup>17</sup> Appointed 07/04/2022

<sup>&</sup>lt;sup>18</sup> Appointed 07/04/2022

<sup>&</sup>lt;sup>19</sup> Appointed 07/04/2022

<sup>&</sup>lt;sup>20</sup> Appointed 07/04/2022

<sup>&</sup>lt;sup>21</sup> Appointed 07/04/2022

## 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

**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

## Dr Shuaib Nasser<sup>22</sup> MA MBBS MD FRCP

Consultant Allergist and Respiratory Physician, Head of Allergy Cambridge University Hospital NHS Foundation Trust, Cambridge

### Professor Pallav L Shah<sup>23</sup> MD MBBS FRCP

Consultant Physician, Royal Brompton Hospital and Chelsea & Westminster Hospital, Professor of Respiratory Medicine, Imperial College

## Professor Anita K Simonds<sup>24</sup> MD FRCP FERS

Professor Emeritus of Respiratory and Sleep Medicine, National Heart and Lung Institute, Imperial College, London & Honorary Consultant Respiratory and Sleep Physician, Royal Brompton & Harefield Hospital, Sydney Street, London

## Professor Michael Steiner<sup>25</sup> MB BS BSc MD FRCP

Professor in Respiratory Medicine and Honorary Consultant, Dept of Respiratory Science, University of Leicester

#### Professor Sarah Wild MB BChir MSc PhD FRCPE FFPH

Professor of Epidemiology, Honorary Consultant in Public Health, Usher Institute, University of Edinburgh

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<sup>&</sup>lt;sup>22</sup> Appointed 07/04/2022

<sup>&</sup>lt;sup>23</sup> End of appointment 06/09/2022

<sup>&</sup>lt;sup>24</sup> Appointed 07/04/2022

<sup>&</sup>lt;sup>25</sup> Appointed 07/04/2022

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

#### Remit

To advise the CHM 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 Yvonne Perrie BSc Hons MRPharmS FAPS FSB PhD Chair in Drug Delivery, Strathclyde Institute of Pharmacy and Biomedical Sciences, University of Strathclyde, Glasgow, Scotland

#### Members

#### Professor Hannah Batchelor BSc PhD

Professor of Pharmaceutics and Biopharmaceutics, Strathclyde Institute of Pharmaceutical and Biomedical Sciences, University of Strathclyde

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

Professor Barbara R Conway BSc (Pharm) PhD FRPharmS CMgr FCMI Head of Pharmacy and Professor of Pharmaceutics, University of Huddersfield, Huddersfield

## Professor Ben Forbes BPharm PhD

Professor of Pharmaceutics, Institute of Pharmaceutical Science, Kings College London

**Dr Majella Lane**<sup>26</sup> BSc PhD – (Vice Chair) Senior Lecturer in Pharmaceutics, UCL School of Pharmacy

Professor Christopher Marriott<sup>27</sup> PhD DSc Hon DSc FRPharmS CChem FRSC FRSM (Vice Chair)

Emeritus Professor of Pharmaceutics, King's College, London

### Professor Afzal R Mohammed BPharm PhD

Professor of Pharmaceutics, Aston Pharmacy School, Aston University

Professor Darragh Murnane PhD BSc (Pharm) PhD MRPharmS Professor of Pharmaceutics and Associate Dean (Enterprise), University of Hertfordshire

<sup>&</sup>lt;sup>26</sup> Reappointed 16/09/2022

<sup>&</sup>lt;sup>27</sup> End of appointment 16/09/2022

# **Mrs Ruth Paulin** BPharm MRPharmS Lay Member

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

**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 Susannah E Walsh PhD BSc MBA

Head of School, Professor of Pharmaceutical Microbiology, Pharmacy and Life Sciences, Robert Gordon University

**Mr Hadar Zaman** MPharm, MFRPSII, IPresc, FHEA Associate Professor in Pharmacy Practice and Head of School for Pharmacy and Medical Sciences, University of Bradford, , Associated Non-Executive Director Barnsley Hospital.

## MEMBERSHIP OF THE CLINICAL TRIALS, BIOLOGICALS AND VACCINES EXPERT ADVISORY GROUP

#### Remit

To advise the CHM on:

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

#### Chair

**Professor Marc Turner**<sup>28</sup> MB ChB PhD MBA FRCP FRCPath FRSE Professor of Cellular Therapy; Director Scottish National Blood Transfusion Service (SNBTS)

**Dr Siraj Misbah<sup>29</sup>** 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 Chris Goldring BSc PhD PGCert FBPhS

Professor of Pharmacology, Department of Pharmacology and Therapeutics, The University of Liverpool.

<sup>&</sup>lt;sup>28</sup> Appointed as Chair 10/08/2022

<sup>&</sup>lt;sup>29</sup> End of appointment 30/06/2022

#### 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 Kirstie Shearman**<sup>30</sup> LLB MA PhD (Lay member)

Policy Manager, Health Research Authority

## **Dr Robin Thorpe** PhD FRCPath

Retired, Head, Division of Biotherapeutics, National Institute for Biological Standards and Control (NIBSC)

## Professor Marc Turner MB ChB PhD MBA FRCP FRCPath FRSE

Professor of Cellular Therapy; Director Scottish National Blood Transfusion Service (SNBTS)

## Professor Christina Yap MSci PhD Cstat

Professor of Clinical Trials Biostatistics, Team Leader in Early Phase and Adaptive Trials Team, ICR-Clinical Trials and Statistics Unit, The Institute of Cancer Research

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<sup>&</sup>lt;sup>30</sup> Appointed 15/06/2022

## MEMBERSHIP OF THE GASTROENTEROLOGY, RHEUMATOLOGY, IMMUNOLOGY AND DERMATOLOGY EXPERT ADVISORY GROUP

#### Remit

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

#### Chair

**Professor Anthony Williams**<sup>31</sup> BSc MSc MRCP FRCPath PhD Professor of Translational Medicine and Honorary Consultant in Clinical Immunology and Allergy, University of Southampton and University Hospital Southampton NHS Trust

**Professor Anthony G Wilson**<sup>32</sup> MB BCH BAO DCH PhD FRCP Professor of Rheumatology, Medical School, University of Sheffield

#### **Members**

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

#### Mr David Chandler

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

Professor Anjan Dhar<sup>33</sup> DM, MD (Medicine), FRCPE, AGAF, Cert. Med. Ed, FHEA

Professor of Medicine (Teesside University), Consultant Gastroenterologist, Clinical Lead for UGI Cancers, County Durham & Darlington NHS Foundation Trust

**Dr Shahida Din<sup>34</sup>** BMSc, MBChB, PhD, FRCP (Edin) Consultant Gastroenterologist & NHS Research Scotland Clinician, NHS Lothian; Honorary Senior Clinical Lecturer, University of Edinburgh

Professor Celia Moss<sup>35</sup> 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

<sup>&</sup>lt;sup>31</sup> Appointed in line with CHM 08/2022

<sup>32</sup> End of appointment 30/06/2022

<sup>33</sup> Reappointed 01/07/2022

<sup>34</sup> Reappointed 01/11/2022

<sup>35</sup> Reappointed 06/12/2022

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

**Dr Ravishankar Sargur** MD, FRCPath, FRCP, MBA Consultant Clinical Immunologist and Clinical Lead for Laboratory Immunology, Northern General Hospital, Sheffield

**Professor Nidhi Sofat** PhD MBBS FRCP PGCert FHEA Professor of Rheumatology, St Georges University London

#### MEMBERSHIP OF THE INFECTION EXPERT ADVISORY GROUP

#### Remit

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

#### Chair

**Professor David Dockrell**<sup>36</sup> MB BCh MD FRCPI FRCP (Glas) FACP Professor of Infection Medicine, University of Edinburgh

# **Professor Jonathan S Friedland**<sup>37</sup> MA PhD FRCP FRCPE FRCPI FESCMID FMedSci

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

#### **Members**

#### Dr Michael Brown BA BM BCh FRCP PhD DTM&H

Consultant Physician, Infectious Diseases & Acute Medicine, & Clinical Director, Division of Infection, University College London Hospitals NHS Foundation Trust & Honorary Associate Professor, Clinical Research Sept, London School of Hygiene & Tropical Medicine

#### Professor Geraint Rhys Davies BM DTM&H PhD FRCP

Professor of Infection Pharmacology, University of Liverpool, Honorary Consultant in Infectious Diseases, Liverpool University Hospitals Foundation Trust

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

## Professor Richard J C Gilson<sup>38</sup> MD FRCP

Professor of Sexual Health & HIV Medicine, Director of the UCL Centre for Clinical Research in Infection & Sexual Health & Deputy Director of the UCL Institute for Global Health

## Dr Louis Grandjean MBBS BSc MSc PhD MRCPCH

Associate Professor Paediatric Infectious Diseases Great Ormond Street Hospital and University College London

## Dr Susan Hopkins BA MB BCh BAO (Hons) FRCPI FCRP

Consultant in Infectious Diseases & Microbiology, Royal Free London NHS Foundation Trust, Healthcare Epidemiologist, Public Health England, Honorary Senior Lecturer, University College London

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<sup>&</sup>lt;sup>36</sup> Appointed in line with CHM post 04/08/2022

<sup>&</sup>lt;sup>37</sup> End of appointment 31/03/2022

<sup>38</sup> Reappointed 14/12/2022

## Dr Lim S Jones MBBCh, PhD, FRCPath

Consultant Microbiologist, Public Health Wales Microbiology, Cardiff; Clinical Lead Specialist Antimicrobial Chemotherapy Unit, Cardiff; Chair of the All Wales Medical Microbiology Development & Standardisation Group

## 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 CPFA

Lay Representative. Retired Secretary to the School of Medicine, University of Sheffield

## MEMBERSHIP OF THE MEDICINES FOR WOMEN'S HEALTH EXPERT ADVISORY GROUP

#### Remit

To advise the CHM 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

**Professor Philip Hannaford** MBChB, MD, FRCGP, FFPH, FFSRH, FRSE Emeritus Professor of Primary Care, University of Aberdeen

#### **Members**

**Dr Amparo Alvarez-Llobell** 

GP at Higherland Surgery GPwSI in Women's Health Speciality Dr in GUM

**Dr Caitlin Dean** RGN, MSc, PhD (Lay member) Chair Trustee, Pregnancy Sickness Support

**Dr Kenneth Hodson** MD MBChB MRCP(UK) MRCOG Head of UK Teratology Information Service UK Teratology Information Service

**Dr Lucy MacKillop**<sup>39</sup> BM BCh MA(Oxon.) FRCP FRCOG Ad Eundem Consultant Obstetric Physician and Honorary Senior Clinical Lecturer, Oxford University Hospitals NHS Foundation Trust, Oxford

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

Dr Julia Prague<sup>40</sup> MBBS PhD MRCP(UK) BSc

Consultant in Endocrinology, Diabetes, and General Internal Medicine, Royal Devon and Exeter NHS Foundation Trust, and Honorary Senior Clinical Lecturer, College of Medicine and Health, University of Exeter

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

<sup>&</sup>lt;sup>39</sup> Appointed 09/05/2022

<sup>&</sup>lt;sup>40</sup> Appointed 02/09/2022

## Mr Ertan Saridogan PhD MRCOG

Consultant in Gynaecology, Reproductive Medicine and Minimal Access Surgery, University College London Hospitals (UCLH) Elizabeth Garrett Anderson Wing

### Dr Laurie Tomlinson MBBS MSc PhD

Department of Non-communicable Disease Epidemiology Faculty of Epidemiology and Population Health London School of Hygiene & Tropical Medicine

Professor Rachel Tribe<sup>41</sup> BSc (Sp Dual Hons), PhD, FPhysiol Professor of Maternal and Perinatal Science, Department of Women and Children's Health, School of Life Course and Population Sciences, King's College London

## **Dr Diana Wellesley**<sup>42</sup> FRCP (Vice Chair)

Honorary Consultant and Honorary Senior Lecturer in Clinical Genetics, Wessex Clinical Genetics Service, Princess Anne Hospital Southampton

<sup>&</sup>lt;sup>41</sup> Appointed 09/05/2022

<sup>&</sup>lt;sup>42</sup> Reappointed 19/07/2022

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

#### Remit

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

#### Chair

#### Professor David Hunt<sup>43</sup> MB BChir FRCP PhD

Consultant Neurologist, NHS Lothian Professor of Neuroinflammatory Medicine, University of Edinburgh

# **Professor Malcolm R Macleod**<sup>44</sup> BSc MBChB MRCP PhD FRCP (Edin) FMedSci

Professor of Neurology and Translational Neurosciences, University of Edinburgh and Honorary Consultant Neurologist, NHS Forth Valley

#### **Members**

**Dr Lisa Brownell** BSc(Hons) MBChB PGCertMedEd FHEA FRCPsych Associate Medical Director, Birmingham and Solihull Mental Health NHS Foundation Trust

Chair of Area Prescribing Committee, Birmingham, Sandwell, Solihull and Environs

## **Professor Naomi Fineberg** BA Hons MB BS MA MRCPsych Consultant in General Psychiatry, Hertfordshire Partnership University NHS Foundation Trust.

#### Dr Barry Mark Miller MB ChB FRCA FFPMRCA

Consultant in Pain Medicine and Anaesthesia, Bolton NHS Foundation Trust. Board Member of the Faculty of Pain Medicine

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

## Dr Wagar Rashid MBBS BSc MRCP(UK) PhD

Consultant and Honorary Clinical Senior Lecturer in Neurology, Brighton and Sussex University Hospitals NHS Trust, member of the Multiple Sclerosis Society

<sup>&</sup>lt;sup>43</sup> Appointed to Chair 04/08/2022

<sup>44</sup> End of appointment 31/03/2022

**Professor Andrew Rice** MB BS, MD, FRCP, FRCA, FFPMRCA Professor of Pain Research, Imperial College London, United Kingdom Honorary Consultant in Pain Medicine, Chelsea and Westminster Hospital, London, England

## 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 and Cumbria, Northumberland Tyne and Wear NHS Foundation Trust

**Dr Hoo Kee Tsang** BSc(Hons) MB BCh FRCA FFPMRCA Consultant in Pain Medicine and Anaesthesia, Clinical Director of Pain Services, Liverpool University Hospitals NHS Foundation Trust, member of the Royal College of Anaesthetists and the Faculty of Pain Medicine training and assessment committees

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

## MEMBERSHIP OF THE ONCOLOGY AND HAEMATOLOGY EXPERT ADVISORY GROUP

#### Remit

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

#### Chair

#### Professor Poulam Patel PhD MBBS FRCP

Professor of Clinical Oncology, University of Nottingham

#### **Members**

## Professor David Bowen<sup>45</sup> MA MB BChir MD MRCP FRCPath

Consultant Haematologist, Leeds Teaching Hospitals and Honorary Professor of Myeloid Leukaemia Studies, University of Leeds

## Professor Janet E Brown FRCP MD MSc BMedSci MBBS

Academic Unit of Clinical Oncology, Department of Oncology and Metabolism, Weston Park Hospital, University of Sheffield.

## Professor Stephen Devereux<sup>46</sup> 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 Anjum Khan<sup>47</sup> PhD MBChB FRCPath MRCP

Consultant Haematologist, Leeds Teaching Hospitals NHS Trust

## Dr Rebecca Kristeleit BSc MBChB PhD FRCP FRSB

Consultant Medical Oncologist, Guy's and St Thomas' NHS Foundation Trust.

#### Professor Siow Ming Lee PhD FRCP

Professor of Medical Oncology, Consultant Medical Oncologist, University College London Hospital

#### Professor James Spicer FRCP PhD

Professor of Experimental Cancer Medicine, King's College London, Consultant in Medical Oncology, Guy's & St Thomas' NHS Foundation Trust

## Dr Ben Uttenthal MA MB BS PhD MRCP FRCPath

Consultant Haematologist, Cambridge University Hospitals

<sup>&</sup>lt;sup>45</sup> End of appointment 31/05/2022

<sup>&</sup>lt;sup>46</sup> Stepped down 20/10/2022

<sup>&</sup>lt;sup>47</sup> Appointed 01/09/2022

## MEMBERSHIP OF THE PAEDIATRIC MEDICINES EXPERT ADVISORY GROUP

#### Remit

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

## Chair

## Professor Steven Cunningham MBChB PhD FRCPCH

Professor of Paediatric Respiratory Medicine, University of Edinburgh and Honorary Consultant, Royal Hospital for Children and Young People, NHS Lothian, Edinburgh

#### **Members**

#### Mrs Catrin Barker

Pharmacist, NHS Professionals

**Dr Jayesh Mahendra Bhatt**<sup>48</sup> MBBS, MD, DCH, FRCPCH Consultant Respiratory Paediatrician, Nottingham Childrens Hospital

## Dr Benjamin Blaise<sup>49</sup> MD-PhD

Consultant Paediatric Anaesthetist, Evelina London Children's Hospital, Guy's and St Thomas' NHS Foundation Trust Honorary Senior Lecturer, Centre for the Developing Brain, King's College London

# **Dr Helen Burdett**<sup>50</sup> MB ChB MRCP FRCA Consultant Anaesthetist, Tunbridge Wells Hospital

## Miss Elinor Burrows<sup>51</sup> RGN RSCN MSc Respiratory Lead Nurse & Nurse Consultant Cystic Fibrosis

**Professor Helen Cross**<sup>52</sup> OBE MB ChB PhD FRCP FRCPCH The Prince of Wales's Chair of Childhood Epilepsy, Deputy Head of Developmental Neurosciences Programme, UCL Institute of Child Health

**Dr Simon B Drysdale**<sup>53</sup> BSc (Hons) MBBS FRCPCH PhD PgDip PID Consultant in Paediatric Infectious Diseases and Immunology, St George's University Hospital NHS Foundation Trust Honorary Senior Lecturer, St George's, University of London

<sup>50</sup> End of appointment 17/09/2022

<sup>&</sup>lt;sup>48</sup> End of appointment 01/07/2022

<sup>&</sup>lt;sup>49</sup> Appointed 05/08/2022

<sup>51</sup> Not active on the membership in 2022; Stepped down 01/09/2022

<sup>52</sup> Resigned 31/08/2022

<sup>53</sup> Appointed 17/10/2022

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

# Professor Meriel Jenney<sup>54</sup> MBChB MRCP MD FRCPCH

Deputy Medical Director, Cardiff and Vale University Health Board Consultant Paediatric Oncologist

# Dr Kathryn Johnson MBChB FRCPCH

Consultant Neonatologist & Research Lead Yorkshire & Humber CRN Children's Specialty Lead Clinical Lead, National Congenital Anomaly and Rare Disease Registration Service, NHSD, Leeds General Infirmary

# Dr Caroline Jones MB ChB FRCPCH MD

Consultant Paediatric Nephrologist, Alder Hey Children's NHS Foundation Trust

# Professor Nigel Klein<sup>55</sup> 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 Jacqueline McMurtrie<sup>56</sup> BSc (Hons), MSc, PhD

Lay Representative

# Dr Rubin Minhas<sup>57</sup> MB ChB MBA

**GP** Principal

# Dr Clare Pain BMBS, MSc, MRPCH

Consultant Paediatric Rheumatologist, Clinical Lead for Rheumatology Honorary Clinical Lecturer, University of Liverpool

Co-Chair of NIHR CRN: children/Versus Arthritis Paediatric Rheumatology Clinical Studies Group

Associate Director, UK Experimental Arthritis Treatment Centre for Children (Behcet's and scleroderma workstreams)

# Ms Sara Payne<sup>58</sup> MA (Oxon), MA Kings

Lay Representative. Solicitor

# Dr Guido Pieles<sup>59</sup> PhD MD

Consultant Congenital Cardiologist Congenital Hear Unit, Bristol Heart Institute

<sup>&</sup>lt;sup>54</sup> Resigned 31/08/2022

<sup>55</sup> End of appointment 13/09/2022

<sup>&</sup>lt;sup>56</sup> Appointed 28/01/2022

<sup>&</sup>lt;sup>57</sup> Reappointed 15/07/2022

<sup>&</sup>lt;sup>58</sup> End of appointment 30/02/2022

<sup>&</sup>lt;sup>59</sup> Reappointed 15/03/2022

# Mrs Rhian Thomas-Turner<sup>60</sup> LLM, PG Dip Legal Practice

Lay Representative. Research and Development Lead, Noah's Ark Children's Hospital for Wales, Cardiff and Vale University Health Board

# **Professor Heather M Wallace<sup>61</sup> PhD FRCPath FRSC FRSB FBTS FBPhS ERT**

Professor Emeritus of Biochemical Pharmacology and Toxicology, University of Aberdeen

# Dr William John Watkins BSc PhD

Senior Statistician/Lecturer, College of Biomedical & Life Sciences, Cardiff University

# Dr Morris Zwi MBBCh, FRCPsych

Consultant Child & Adolescent Psychiatrist, Whittington Health, Child & Adolescent Mental Health Services

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<sup>&</sup>lt;sup>60</sup> Appointed 28/01/2022

<sup>61</sup> End of appointment 11/11/2022

# MEMBERSHIP OF THE PHARMACOVIGILANCE EXPERT ADVISORY GROUP

#### Remit

To advise the CHM 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 Jamie Coleman<sup>62</sup> MD MA (Med Ed) FRCP FBPhS

Consultant Physician, University Hospitals Birmingham NHS Foundation Trust and Honorary Professor in Clinical Pharmacology and Medical Education, University of Birmingham

#### **Members**

# Mrs Alana Adams BPharm (Hons) MSc IP MRPharmS

Principal Pharmacist Medicines Information, advice and Safety, University of Cardiff

# Professor Darren Ashcroft BPharm MSc PhD FRPharmS

Professor of Pharmacoepidemiology, Head, Drug Usage and Pharmacy Practice Group, University of Manchester & Member of the Pharmacovigilance Expert Advisory Group (PEAG)

# Professor Ann Daly BA PhD FBPhS

Professor of Pharmacogenetics, Faculty of Medical Sciences, Newcastle University

# Professor Ian J Douglas BSc MSc PhD

Professor of Pharmacoepidemiology, London School of Hygiene & Tropical Medicine

# Dr Richard FitzGerald MD MBChB PhD FRC

CRF Director, NIHR Royal Liverpool and Broadgreen CRF

# Dr Mark Glover BA MA MB BChir MRCP PhD

Associate Professor and Honorary Consultant Physician, Clinical Pharmacology and General Medicine, University of Nottingham

<sup>62</sup> Reappointed in line with CHM post 01/09/2022

**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 (Vice Chair)

# Ms Susan Hunneyball BSc (Hons)

Lay Member

**Dr Patricia McGettigan** BSc (Pharm) MD FRCPI FRACP SFHEA FBPhS Reader in Clinical Pharmacology and Medical Education, Queen Mary University of London, Consultant Physician, Barts Health NHS Trust

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

**Professor Rupert Payne** MB ChB PhD MRCGP FRCPE FBPhS FHEA Professor of Primary Care & Clinical Pharmacology University of Exeter

# Professor Reecha Sofat<sup>63</sup> MBBS, FRCP, PhD

Breckenridge Chair of Clinical Pharmacology and Therapeutics, University of Liverpool.

# **Dr Ruben Thanacoody** 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, UK Health Security Agency Director National Poisons Information Service (Newcastle unit)

# Mrs Madeleine Wang

Lay Representative – Patient advocate

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<sup>63</sup> Appointed 08/04/2022

# MEMBERSHIP OF AD HOC STAKEHOLDER GROUP FOR RECLASSIFICATION OF A PRODUCT FOR EMERGENCY CONTRACEPTIVE\*

Chair

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

Lay Representatives

Ms Tamanna Miah Ms Aurora Todisco Ms Sophie Kemball Lay member (anonymous)

Medical Bodies/Royal College Representatives

#### Portia Jackson

Faculty of Sexual & Reproductive Healthcare - Lead Pharmacist for the integrated Contraception and Sexual Health (iCaSH) service across the East of England

**Pharmacists** 

# Philip Boyle

Pharmacy manager and Pharmacy lead in Down area integrated care partnership, Northern Ireland. Board member in Pharmacy forum NI.

# **Sharon Dickson**

Locum Pharmacist serving Independent and chain Pharmacies across Central Scotland.

# Rebecca Shepherd

Patient Safety and Experience Pharmacist at Well Pharmacy, Manchester

# Wing Tang

Interim Associate Director, Royal Pharmaceutical Society

# **Rhys Williams**

Independent Prescriber and Superintendent Pharmacist at Woodville Road Pharmacy, Cardiff

<sup>\*</sup> Members were asked to complete their declaration of interest form at the start of the EWG in all relevant pharmaceutical industry.

# **Safeguarding Nurses**

# **Anne-Marie Gallogly**

Complex Safeguarding Nurse and Lead on Sexual Health for the School Nursing service in Stockport (Stockport NHS Foundation Trust)

# Alison McClean

Safeguarding Champion and Domestic Abuse Change Champion (integrated Contraception and Sexual Health (iCaSH) Norfolk)

**Sexual Health Specialists** 

# **Dr Kate Campbell**

Community Sexual and Reproductive Health doctor (Umbrella Sexual Health, University Hospitals Birmingham NHS Foundation Trust)

# Karen Provan

Senior charge nurse for sexual health and Lead nurse of the Ayrshire and Arran's Sexual Health Services

# MEMBERSHIP OF THE COVID-19 THERAPEUTIC EXPERT WORKING GROUP

#### Chair

# **Professor Jonathan S Friedland** MA PhD FRCP FRCPE FRCPI FESCMID FMedSci

Deputy Prinicipal, St. George's, University of London

#### Members

**Professor Kenneth Baillie** BSc(Hons) MBChB PhD FRCA FRCP FFICM Professor of Experimental Medicine, Roslin Institute, University of Edinburgh

# Ms Susan Bradford

Lay Representative

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

# Professor Richard J C Gilson MD FRCP

Professor of Sexual Health & HIV Medicine, Director of the UCL Centre for Clinical Research in Infection & Sexual Health & Deputy Director of the UCL Institute for Global Health

**Sir Michael Jacobs** MA PhD MB BS FRCP FRCP Edin DTM&H Consultant in Infectious Diseases, Royal Free London NHS Foundation Trust; Hon. Senior Lecturer, University College London and Liverpool School of Tropical Medicine

# 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 Siraj Misbah MBBS (Hons) MSc FRCP FRCPath

Consultant Clinical Immunologist, Lead for Clinical Immunology, Oxford University Hospitals

**Professor B Kevin Park** BSc PhD FMedSci HonFRCP FBTS HonFBPhs Professor of Pharmacology, University of Liverpool

# **Professor Deenan Pillay**

Professor of Virology, UCL Pro-Vice-Provost International

**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 Centre for Drug Safety Science

**Professor Shirley Price** MSc, PhD, FBTS, FRSB, ERT, FHEA ,FRSC, MBPharmacolSoc Emerita Professor of Toxicology, University of Surrey Visiting Profesor of Toxicology, University of Hertfordshire

# MEMBERSHIP OF THE COVID-19 VACCINES BENEFIT RISK EXPERT WORKING GROUP

#### 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 Centre for Drug Safety Science

#### **Members**

# Professor Judith Breuer MD FRCPath FmedSci

Professor of Virology, University College London (UCL), Division of Infection and Immunity, London

# **Professor Gordon Dougan FRS**

Department of Medicine, Cambridge Infectious Diseases, University of Cambridge

# Mr V'lain G Fenton-May BPharm MIPharm FRPharmS

Pharmaceutical Microbiologist

# Professor Neil French MB ChB FRCP PhD

Head Department of Clinical Infection Microbiology and Immunology, Chair of Infectious Diseases & Global Health, Hon Consultant Infectious Diseases, Royal Liverpool & Broadgreen University Hospitals Trust

# Professor David Goldblatt MB ChB FRCPCH FRCP PhD

Professor of Vaccinology and Immunology, Consultant in Paediatric Immunology, NIHR Senior Investigator, Great Ormond Street Hospital & University College London

# Ms Susan Hunneyball BSc(Hons)

Lay Member, Member of the Pharmacovigilance Expert Advisory Group (PEAG) and Advisory Board on the Registration of Homeopathic Products (ABRHP)

**Professor Kimme Hyrich** MD PhD FRCPC Professor of Epidemiology and Honorary Consultant in Rheumatology, Centre for Musculoskeletal Research, Faculty of Biology Medicine and Health, University of Manchester and Kellgren Centre for Rheumatology, Manchester University NHS Foundation Trust

Professor Helen J Lachmann MA MB BChir MD FRCP FRCPath Professor of Medicine & Honorary Consultant Nephrologist Clinical Director UCL Division of Medicine & Clinical Lead for National Amyloidosis Centre, University College London & Royal Free Hospital London NHS Foundation Trust

# Professor Paul J Lehner PhD FRCP FMedSci FRS

Professor of Immunology and Medicine, Wellcome Trust Principal Research Fellow

Honorary Consultant Infectious Diseases, Cambridge Institute of Therapeutic Immunology and Infectious Disease (CITIID), Jeffrey Cheah Biomedical Centre, Cambridge Biomedical Campus

# Mr Robert Lowe BPharm FRPharmS -

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

**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 Shirley Price** MSc, PhD, FBTS, FRSB, ERT, FHEA, FRSC, MBPharmacolSoc

Emerita Professor of Toxicology, University of Surrey, Visiting Professor of Toxicology, University of Hertfordshire

# Dr Andrew Riordan MD FRCPCH DTM&H

Consultant in Paediatric Infectious Diseases and Immunology, Honorary Clinical Lecturer, University of Liverpool, Alder Hey Children's NHS Foundation Trust, Liverpool

# Professor Chris Robertson PhD MSc BSc

Professor of Public Health Epidemiology, University of Strathclyde

# Professor Kevin M G Taylor BPharm PhD FRPharmS

Chair of the British Pharmacopoeia Commission and Emeritus Professor of Clinical Pharmaceutics, UCL School of Pharmacy, London

# **Dr Robin Thorpe** BSc PhD FRCPath

Retired, Head, Division of Biotherapeutics, National Institute for Biological Standards and Control (NIBSC) & Member of the Clinical Trials, Biologicals & Vaccines Expert Advisory Group (CTBVEAG)

# Professor Marc Turner MB ChB PhD MBA FRCP FRCPath FRSE

Professor of Cellular Therapy; Director Scottish National Blood Transfusion Service (SNBTS)

# Professor Susannah E Walsh PhD BSc MBA

Head of School, Professor of Pharmaceutical Microbiology, Pharmacy and Life Sciences, Robert Gordon University

# Mrs Madeleine Wang BA (Hons)

Lay Member

**Professor Christopher Weir** BSc MSc PhD FRSS Cstat Professor of Medical Statistics & Clinical Trials, Edinburgh Clinical Trials Unit, Usher Institute, University of Edinburgh & Member of Commission on Human Medicines (CHM)

# MEMBERSHIP OF THE COMMISSION ON HUMAN MEDICINES VALPROATE IMPLEMENTATION EXPERT WORKING GROUP\*

#### Chair

# Professor David Hunt MB BChir FRCP PhD

Consultant Neurologist, NHS Lothian Professor of Neuroinflammatory Medicine, University of Edinburgh

# **Members**

#### Professor Helen Cross OBE MB ChB PhD FRCP FRCPCH

The Prince of Wales's Chair of Childhood Epilepsy, Deputy Head of Developmental Neurosciences Programme, UCL Institute of Child Health

# Dr Sofia Eriksson

Consultant neurologist and honorary associate Professor at The National Hospital for Neurology and Neurosurgery at Queen Square and University College London Hospitals NHS Foundation Trust

# **Dr Lucy Kinton**

Consultant Neurologist, University Hospital Southampton NHS Foundation Trust, Department of Neurosurgery

# **Professor Naomi Fineberg**

Consultant Adult Psychiatrist and Professor of Psychiatry at University of Hertfordshire

# **Dr Dan Hawcutt**

Senior Lecturer Paediatric Clinical Pharmacology Women's & Children's Health, University of Liverpool. Consultant Paediatrician

# **Professor Anthony Marson**

Professor of Neurology, University of Liverpool, Director of Research Programmes, Liverpool Health Partners, NIHR Senior Investigator

# **Dr Teial Mitchell**

Consultant Neurologist at Peterborough City Hospital Northwest Anglia NHS Foundation Trust

# Ms Kim Morley

Advanced Clinical Practitioner Epilepsy Specialist Nurse and Midwife

# **Professor Finbar O'Callaghan**

Professor of Paediatric Neuroscience, Developmental Neurosciences Dept UCL GOS Institute of Child Health

<sup>\*</sup> Members were asked to complete their declaration of interest form at the start of the EWG in all relevant pharmaceutical industry.

# **Professor David G C Owens**

Professor of Clinical Psychiatry, Edinburgh University

# Dr Vanessa Raymont MBChB MSc MRCPsych

Senior Clinical Researcher, University of Oxford and Honorary Consultant Psychiatrist, Oxford Health NHS Foundation Trust

# **Professor David Taylor**

Director of Pharmacy and Pathology at Maudsley and Professor of Psychopharmacology at King's College London

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

**Co-opted Member** 

Ms Donna Beddard

**NHS** Digital

# MEMBERSHIP OF THE NON MEDICAL PRESCRIBING EXPERT WORKING GROUP

#### Chair

# **Professor Sandosh Padmanabhan** MBBS MD PhD FRCP(Glasg) FRCP(Edin) FBPhS FBIHS

Professor of Cardiovascular Genomics and Therapeutics, University of Glasgow & Member of Commission on Human Medicines (CHM) & Member of the Cardiovascular, Diabetes, Renal, Respiratory & Allergy Expert Advisory Group (CDRRA)

#### Members

# Dr Richard FitzGerald MD MBChB PhD FRC

CRF Director, NIHR Royal Liverpool and Broadgreen CRF & member of the Pharmacovigilance Expert Advisory Group (PEAG)

# Dr Jamie Fraser BSc (Hons) MBChB MRCGP

GP Partner, Southside Surgery, Inverness & Member of Commission on Human Medicines (CHM)

# Dr Seán MacBride-Stewart PhD FRPharmS GPhC(IP)

Lead Pharmacist Medicines Management Resources, Pharmacy Services, NHSGGC

**Dr Patricia McGettigan** BSc (Pharm) MD FRCPI FRACP SFHEA FBPhS Reader in Clinical Pharmacology and Medical Education, Queen Mary University of London, Consultant Physician, Barts Health NHS Trust & member of the Pharmacovigilance Expert Advisory Group (PEAG)

# **Dr Karen Miller** BSc MBBS DRCOG DCH DFFP FRCGP GP Partner, Adelaide Medical Centre, London and member of the Sodium Valproate Expert Working Group & member of the Pharmacovigilance Expert Advisory Group (PEAG)

**Dr Gerri Mortimore** PhD; MSc (Advanced Practice); PgCert (IPPE); BA(Hons) Health Studies; iLM; RGN; NMP; FHEA Associate Professor in Advanced Practice; NICE Nurse Expert Advisor & Member of Commission on Human Medicines (CHM)

**Dr Martin Wilson** MB ChB, MPhil (Glasgow), FRCP(Edin) Consultant Physician in Care of the Elderly, Raigmore Hospital, Inverness & Member of Commission on Human Medicines (CHM)

# **Glossary of Acronyms and Abbreviations**

ADR	An adverse drug reaction
BPC	British Pharmacopoeia Commission
CDRRA / CDRRA EAG	Cardiovascular, Diabetes, Renal, Respiratory and Allergy
СНМ	Commission on Human Medicines
COM	The UK Committee on Mutagenicity
COPD	chronic obstructive pulmonary disease
CPS / CPSEAG	Chemistry, Pharmacy and Standards
CTBV / CTBVEAG	Clinical Trials, Biologicals & Vaccines
DEAC	Devices Expert Advisory Committee
DHSC	Department of Health and Social Care
DSU	Drug Safety Update
EAG	Expert Advisory Group
EAMS	Early Access to Medicines Scheme
EGFR	epidermal growth factor receptor (gene)
(gene)	
EWG	Expert Working Group
GMP	Good Manufacturing Practice
GRID /	Gastroenterology, Rheumatology, Immunology &
GRIDEAG	Dermatology
GSL	General Sales
GVHD	graft-versus-host disease
HAE	hereditary angioedema
HSA	Health Sciences Authority
IBS	irritable bowel syndrome
IEAG	Infection Expert Advisory Group
IEWG	Isotretinoin Expert Working Group
ILAP	Innovative Licensing Access Pathway
JCVI	Joint Committee on Vaccination & Immunisation
LA	Licensing Authority
MHRA	The Medicines and Healthcare products Regulatory Agency
MWH / MWHEAG	Medicines for Women's Health
NIBSC	National Institute of Biological Standard and Control
NICE	National Institute for Health and Care Excellence
NMBA	neuromuscular blocking agent
NPP / NPPEAG	Neurology, Pain & Psychiatry
NSAID(s)	Nonsteroidal Anti-inflammatory Drug(s)

NSCLC	non-small cell lung cancer
OH / OHEAG	Oncology and Haematology
ONS	Office for National Statistics
P (medicine)	Pharmacy Only (medicine)
PEAG	Pharmacovigilance Expert Advisory Group
Ph+ CML	Philadelphia chromosome-positive chronic myeloid leukaemia
PHE	Public Health England
PIP	Paediatric Investigation Plans
PMEAG	Paediatric Medicines Expert Advisory Group
POC	point of care
POM	Prescription Only Medicine
PRAC	Pharmacovigilance Risk Assessment Committee
PSMA	prostate-specific membrane antigen
YCC	Yellow Card Centre

# BRITISH PHARMACOPOEIA COMMISSION ANNUAL REPORT FOR 2022

# INTRODUCTION

- 1. The British Pharmacopoeia Commission, appointed under Part 2 of the Human Medicines Regulations 2012 (the 2012 Regulations), is responsible under regulation 317 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). 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.
- 2. It is of paramount importance that the medicines received by patients are safe, effective and of a suitable quality. The British Pharmacopoeia and British Pharmacopoeia (Veterinary) contribute significantly to the quality of medicines for human use and for animal use by providing publicly available, legally enforceable standards which are part of the overall system for safeguarding the health of patients in the UK. The British Pharmacopoeia is also important internationally, being used across the globe and referenced in the legislation of several countries.

# THE BRITISH PHARMACOPOEIA AND COVID-19

3. Throughout the COVID-19 pandemic, the British Pharmacopoeia has worked at both national and international levels to support the public health response to the pandemic. This has included: (i) ensuring that BP standards (both monographs and their supporting reference materials) remained available; (ii) working with the European Pharmacopoeia to provide free access to supportive pharmacopoeial text; (iii) providing additional access to the online BP for NHS users; (iv) enhanced monitoring and supply management of British Pharmacopoeia Chemical Reference Substances (BPCRS); (v) working with other pharmacopoeias across the globe through the World Health Organization's International Meeting of World Pharmacopoeias; (vi) providing updates via the dedicated COVID-19 page on the BP website.

# **MEMBERSHIP**

4. A list of members of the British Pharmacopoeia Commission during 2022 is shown in **Appendix I**.

- 5. Professor Kevin Taylor retired at the end of September, after having served for two terms as Chair. Following a successful campaign carried out in collaboration with the Department of Health and Social Care Appointments Team, Dr Anna-Maria Brady was appointed as the new Chair for a four-year period with effect from 1<sup>st</sup> October 2022. Dr Brady is the first female Chair to be appointed to the British Pharmacopoeia Commission.
- 6. Four new members were appointed to the Commission for a period of four years with effect from 1<sup>st</sup> May 2022.
- 7. The second term of office for three members was due to end on 31<sup>st</sup> December 2022. Two members had their term of office extended for one year with effect from 1st January 2023 and one member retired at the end of the year.
- 8. A list of members of the supporting Expert Advisory Groups, Panels of Experts and Working Parties for 2022 is given in Appendix II. The term of office for all members was extended for one year until 31<sup>st</sup> December 2023 and a comprehensive membership review will be carried out in 2023. The remit of the Expert Advisory Group on Antibiotics was expanded during the year and the name of the group was changed to Anti-Infective Medicines to better reflect the range of monographs covered.

# **CODE OF PRACTICE**

9. Members of the British Pharmacopoeia Commission are required to comply with the MHRA Code of Practice on Identifying, Declaring and Managing Interests. This new Code of Practice was launched on 8<sup>th</sup> September 2022 and replaced the former BPC Code of Practice. Members of the Expert Advisory Groups, Panels of Experts and Working Parties are also required to comply with the new Code of Practice. With the exception of the Chair of the BP Commission, members of the Commission and the supporting Expert Advisory Groups, Panels of Experts and Working Parties are permitted to hold personal interests in the pharmaceutical industry.

#### **MEETINGS**

- 10. The British Pharmacopoeia Commission met three times during 2022. Thirteen meetings of the Expert Advisory Groups, Panels of Experts and Working Parties were also held during the year, together with several meetings of the four sub-groups of the Working Party on Advanced Therapy Medicinal Products. All meetings were held remotely.
- 11. 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

12. The British Pharmacopoeia Secretariat is based at the headquarters of the Medicines and Healthcare products Regulatory Agency, 10 South Colonnade, Canary Wharf, London E14 4PU. Staff continued to work at home for most of the year.

# **LABORATORY**

13. The Laboratory is based at the Laboratory of the Government Chemist (LGC) (Teddington) and is managed under a collaboration agreement with LGC.

# **COSTS**

14. 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 costs are also payable within MHRA guidelines.

#### PROGRESS AND PUBLICATIONS

# **British Pharmacopoeia 2022**

15. Following publication of the British Pharmacopoeia 2022, three online updates were issued providing users with the text of Supplements 10.6, 10.7 and 10.8 of the 10<sup>th</sup> Edition of the European Pharmacopoeia.

# **British Pharmacopoeia 2023**

- 16. The British Pharmacopoeia 2023 was published in August 2022. This new edition is available as a package containing the five volumes of the British Pharmacopoeia 2023, the one volume of the British Pharmacopoeia (Veterinary) 2023 and access to the electronic versions of both publications (online BP and offline download format).
- 17. 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 2023 is 1st January 2023.
- 18. All monographs published within the 10th Edition of the European Pharmacopoeia, as amended by Supplements 10.1 to 10.8, 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.

- 19. The British Pharmacopoeia 2023 contains 23 new monographs of national origin which were not published in previous editions, including two new monographs for unlicensed formulations. A significant number of monographs were amended in respect of technical or editorial content (142 in total) and the titles of 8 national monographs were amended in this edition.
- 20. Four new Appendices were added to harmonise with the European Pharmacopoeia: Appendix V S Balances for Analytical Purposes; Appendix VIII V N-Nitrosamines in Active Substances; Appendix XI X Contaminant Pyrrolizidine Alkaloids; Appendix XIII C Particulate Contamination: Sub-Visible Particles in Non-Injectable Liquid Preparations.
- 21. Two new Supplementary Chapters were added by means of this edition. Information on Monograph Development for Unlicensed Medicines was included in Supplementary Chapter V A2 and information relating to Monographs on Essential Oils, harmonised with the European Pharmacopoeia, was included in Supplementary Chapter VII F.
- 22. Nine national monographs were omitted from the British Pharmacopoeia 2023 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) 2023

- 23. The British Pharmacopoeia (Veterinary) 2023 was published as a companion volume to the British Pharmacopoeia 2023 in August 2022. 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) 2023 is 1st January 2023.
- 24. Nine monographs of national origin were amended in respect of technical or editorial content and the title of one monograph was amended in this edition.
- 25. A new Supplementary Chapter on Inactivated Autogenous Veterinary Vaccines was added by means of this edition.
- 26. Three national monographs were omitted from the British Pharmacopoeia (Veterinary) 2023, following consultation.

# **British Approved Names 2022**

27. British Approved Names 2022 (Supplement No.1) was published in August 2022. This Supplement defines 49 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 not previously been marketed in the UK.

# **Digital Publications**

- 28. The BP 2023 publications can be accessed through the online version (<a href="pharmacopoeia.com">pharmacopoeia.com</a>) and the offline download edition. Both formats have been updated to include the European Pharmacopoeia 11<sup>th</sup> edition in its entirety.
- 29. The branding of the BP website was updated to harmonise with other MHRA and gov.uk websites during the year.
- 30. Following the regular public consultation schedule for new and revised monographs, four three-month consultation periods were held during 2022. This continues to provide users with the opportunity to contribute to the monograph development and revision process, thereby helping to ensure that published monographs are relevant and robust.
- 31. A response to the consultation on Guidance on the Application of Vector Copy Number Quantification for the ATMP Community was published on the BP website in March and a new consultation on Guidance on the Characterisation of the Particle Population in AAV (Adeno-Associated Virus) Products was launched in November.
- 32. As a result of the positive responses received to the consultation undertaken in 2020, numerical limits have started to be included in Related substances tests in the BP 2023 and this approach will be increased in future publications. This change will ensure that BP methods are more closely aligned with registered methods and the approach used in other pharmacopoeias.
- 33. The introduction of the Revision History feature in the online BP 2022 helped users to understand why individual monographs had been updated. Over time this feature will provide a full history of a monograph from initial publication through to major and minor revisions.

# **Prices and Availability**

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

35. 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**

- 36. By the end of 2022 work was progressing on the preparation of the next editions of the British Pharmacopoeia and British Pharmacopoeia (Veterinary). These will be published during 2023 and will have an effective date of 1st January 2024.
- 37. A digital update to the British Pharmacopoeia 2023 was issued in November 2022, providing users with the text of the 11<sup>th</sup> Edition of the European Pharmacopoeia, two months ahead of its implementation on 1<sup>st</sup> January 2023. A further update was issued in December providing users with the text of Supplement 11.1, which will come into effect on 1<sup>st</sup> April 2023. Supplement 11.2 will be available in advance of its implementation on 1<sup>st</sup> July 2023. These updates will only be available via the online BP and the offline download. The texts will subsequently be included in the BP 2024 publications as appropriate.

#### OTHER PHARMACOPOEIAL MATTERS

# **Biological Medicines**

- 38. While continuing to maintain quality standard monographs for Biological products, the main focus during the year has been the continued development of non-mandatory guidance for the analysis of cell and gene therapy products as well as the continued exploration and assessment of innovative approaches for monoclonal antibody standards.
- 39. The Advanced Therapy Medicinal Products (ATMP) Working Party continues to develop non-mandatory guidance documents that support quality and innovation in these medicines. The Application of Flow Cytometry and the Vector Copy Number guidance documents were made freely available on the British Pharmacopoeia website (<a href="mailto:pharmacopoeia.com/atmpguidance">pharmacopoeia.com/atmpguidance</a>) in early 2022. The published guidance was developed and approved by the BP, as part of the MHRA, in partnership with experts from the cell and gene therapy community including representatives from industry, the NHS and academia. In December a further draft guidance document was published for public consultation, focussing on empty capsids and the characterisation of the particle population for adeno-associated virus (AAV) products.
- 40. The importance of stakeholder contributions and systems wide approaches is recognised, and the Working Party includes representatives from the NHS, academia, industry and the UK Catapult network. In addition, a secondment programme between the MHRA and the Cell and Gene Therapy Catapult has been extended and continues to support the work and

- continued staff development in both organisations. The Working Party continues to focus on horizon scanning and identifying new topics and is working to produce further non-mandatory guidance documents for the ATMP community.
- 41. The BIO-DPS Working Party (Alternative Approaches for Documentary and Physical Standards for Biotechnological Products) has continued to explore the potential of performance and class-based standards for biotechnological products. An international multi-laboratory study has been completed involving the analysis of a monoclonal antibody. The results of the study will be used to assess the value of alternative standards, including advantages and disadvantages when compared to the traditional pharmacopoeial approach.
- 42. In addition to the work related to standards development, the Agency has also recognised and continued to support broader engagement across the biopharmaceutical and ATMP landscape. The Agency and BP remains active within the regulatory and pharmacopoeial community, for example through continued engagement with colleagues in the US Standards Coordinating Body for Regenerative Medicines (SCB), BioPhorum and the Centre for Process Innovation.

#### **Unlicensed Medicines**

- 43. Monographs that have been developed to cover unlicensed formulations are identified as such in the British Pharmacopoeia. These monographs provide legally enforceable standards for unlicensed formulations which may be widely used or are required for certain patient populations. The BP is also continuing to develop further guidance for prescribers, manufacturers and suppliers of unlicensed medicines which will be included in future publications.
- 44. A number of monographs for unlicensed formulations are being developed as part of a series of family monographs alongside those for licensed products containing the same active ingredient. This initiative will make the most efficient use of Laboratory resources and will provide assurance that the methods for the unlicensed formulations are suitable.

# **Herbal and Complementary Medicines**

45. Following the previous year's strategic review and endorsement by the BP Commission, the Expert Advisory Group on Herbal and Complementary Medicines implemented a work programme to develop monographs for herbal extracts. Laboratory assessment was initiated on the first two candidate monographs (Juniper Tincture and Green Tea Extract) during the year.

46. In parallel, work to maintain and update the existing monographs for herbal medicines which are still used and would benefit from modernisation has been undertaken and will continue in the coming year.

# **Nomenclature**

- 47. 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 INN Consultations during the year and contributed to the evaluation of INN requests and the development of WHO policies on drug nomenclature. Two rINN Lists (87 and 88) were published by WHO during the year.
- 48. The BP Secretariat is also responsible for advising the MHRA on the acceptability of proposed invented names for medicines in the UK. BP staff also continue to provide advice to manufacturers on the acceptability of invented names and remain the experts on the acceptability of invented names within the MHRA.

# **Analytical Quality by Design**

- 49. Following publication of the "Supplementary Chapter on the use of Analytical Quality by Design Concepts for Analytical Procedures" in the BP 2022, the Analytical Quality by Design (AQbD) Working Party achieved another key milestone through the publication of the "Atorvastatin Tablets" monograph in the BP 2023. The Assay in this monograph is the first to have been practically assessed in the laboratory using AQbD principles and was accompanied by the publication of an additional information document containing the method understanding built up throughout this process.
- 50. The Working Party are working on drafting additional content for a future revision of the Supplementary Chapter to further aid users as well as reflecting on the development of ICH Guidelines Q2 and Q14 (Validation of Analytical Procedures and Analytical Procedure Development) in order to reflect current regulatory thinking.
- 51. Following on from the laboratory project on the application of AQbD principles to a pharmacopoeial Assay procedure, a subsequent laboratory project on the application of the principles to a Related substances test procedure was completed in 2022. The outcomes of this project are currently being considered by the Working Party for publication in a future edition of the BP.

# **Liaison with Other UK Organisations**

- 52. The BP has continued to collaborate with academic institutions throughout the year. Several projects are in progress with the Robert Gordon University and with the University of Sunderland and future projects are under consideration. This work will be reflected in future revisions to BP monographs.
- 53. The BP and Veterinary Medicines Directorate (VMD), an executive agency of the Department for Environment, Food and Rural Affairs, continue to collaborate closely on the development of monographs for veterinary medicines through representation from the VMD on Expert Advisory Groups.

# Laboratory

- 54. The Laboratory has continued to support the work of the British Pharmacopoeia Commission and the wider MHRA remit relating to public health throughout 2022.
- 55. As pandemic restrictions were relaxed, the Laboratory returned to normal operations by implementing social distancing and by adjustments to working arrangements including enhanced cleaning and laboratory protocols.
- 56. During the year laboratory work on 33 new and revised BP monographs was undertaken for inclusion in future publications. The Laboratory also provided data to support several regulatory investigations during the year.

# **BP Reference Materials**

- 57. Thirteen new British Pharmacopoeia Chemical Reference Substances (BPCRS) were established to support the British Pharmacopoeia and British Pharmacopoeia (Veterinary) publications, sixty-three were replaced and two hundred and thirteen were re-tested to ascertain their continued stability.
- 58. All new BPCRS that were introduced into the BP 2023 and BP (Vet) 2023 were made available by November 2022. Five of these were available to coincide with publication in August 2022, but the remainder were delayed due to logistical challenges in obtaining materials, in part due to continuing lockdowns in some parts of the world. Making the materials available as early as possible ensures that users are ready to comply with the new and revised monographs before they come into force.
- 59. The demand for these reference materials remained high throughout the year. 35,381 vials were sold within the UK and to countries worldwide, representing an increase of about 3% from the previous year.

# **European Pharmacopoeia**

- 60. The 11<sup>th</sup> Edition of the European Pharmacopoeia and its first Supplement (Supplement 11.1) were published in July 2022 and October 2022 respectively. The 11<sup>th</sup> Edition came into effect on 1<sup>st</sup> January 2023 and Supplement 11.1 will come into effect on 1<sup>st</sup> April 2023. The second Supplement (11.2) was published in January 2023 and will come into effect on 1<sup>st</sup> July 2023. The text of these publications will be included in the online BP in advance of their effective date and will be published in the next editions of the British Pharmacopoeia or British Pharmacopoeia (Veterinary), as appropriate.
- 61. 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, providing Chairs to two Expert Groups and experts to those groups that are most relevant to the UK market. 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.
- 62. 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.
- 63. 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 2022, is included in **Appendix IV**.

# **International Liaison and Collaboration**

- 64. 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 United States Pharmacopeia (USP) and the United States Adopted Names (USAN) Council.
- 65. Due to on-going travel restrictions imposed by the COVID-19 pandemic the majority of international meetings were held remotely, with a few meetings being held in person or in a hybrid format. BP staff and experts participated in many meetings either as attendees or participants.
- 66. BP Staff attended the thirteenth International Meeting of World Pharmacopoeias (IMWP) which was co-hosted by the World Health Organization and the Pharmacopoeia of the United Mexican States in September. These annual meetings provide an opportunity for the major pharmacopoeial authorities to discuss models of collaboration and how pharmacopoeias add value to standards in public health. The participants

- discussed many issues including the ongoing pharmacopoeial activities in response to the COVID-19 pandemic.
- 67. Throughout the year BP Secretariat staff provided feedback to WHO on draft monographs for the International Pharmacopoeia, which was greatly appreciated. Many of the standards included in the International Pharmacopoeia, and the policies employed, are consistent with those in the British Pharmacopoeia.
- 68. The BP attended the WHO Expert Committee meeting on Specifications for Pharmaceutical Preparations in April during which monographs and reference materials for the International Pharmacopoeia were discussed.
- 69. BP staff attended the 74<sup>th</sup> and 75<sup>th</sup> WHO Consultations on International Non-proprietary Names (INN) in April and October. In addition to discussing a significant number of names for new chemical and biological substances at both meetings, the INN Committee also discussed names for many new drugs that are being evaluated through an expedited procedure for potential use in the treatment of COVID-related diseases.
- 70. BP staff held regular discussions with the United States Pharmacopeia throughout the year to discuss areas of mutual interest. These included joint collaboration on informal harmonisation projects for finished product monographs, Analytical Quality by Design and Monograph Lifecycle, together with BP and USP investigations into standards for digital therapeutics. Criteria for the prioritisation of monograph development and targets for harmonisation of monographs were agreed. Following the success of the two joint webinars on Analytical Quality by Design held in 2021, the potential for future joint webinars in this area was also discussed.
- 71. A successful in-person meeting between BP staff and USP representatives was held in London during October which provided the opportunity to progress discussions in key areas including the global harmonisation of standards to remove regulatory burden, digital therapeutics, environmental sustainability and pharmacopoeias, guidance and standards for biological medicines and AQbD.
- 72. BP staff also met with representatives from the Compendial Policy, Process and Quality Stakeholder Organisation Discussion Group (CPPQ) (which consists of several pharmaceutical industry groups within the USA) to discuss the potential for a future joint BP/CPPQ symposium on the BP.
- 73. A joint webinar, organised by the Foreign, Commonwealth and Development Office (FCDO), between the BP and the Chinese Pharmacopoeia was held in March as part of an initiative by the FCDO to work with the Chinese authorities to provide information on global requirements for medicines. This provided the opportunity for both organisations to discuss how standards are produced, potential areas for collaboration and future developments including standards for modern medicines.

- 74. BP staff held a teleconference with the Indian Pharmacopoeia in February to discuss areas of mutual interest and share experiences relating to the joint development of finished product monographs, the development of reference standards, the development of digital pharmacopoeias and the potential to hold joint webinars on specific topics. The first candidate monograph to be developed jointly was proposed and further candidate monographs would be identified as part of a future work programme.
- 75. The BP was represented at a conference held in India in June to celebrate the publication of the 2022 edition of the Indian Pharmacopoeia. Productive meetings were held with staff from the Indian Pharmacopoeia, with Indian Health Ministers and with the Central Drugs Standard Control Organisation and the Drugs Controller General of India.
- 76. The Memorandum of Understanding between the BP and the State Pharmacopoeia of Ukraine was renewed during the year. This agreement allowed the publication of an agreed number of BP monographs in the Ukraine Pharmacopoeia, helping to increase the number of their national standards and ensuring the quality of medicines across the global supply chain.

# **ACKNOWLEDGEMENTS**

- 77. The Commission wishes to place on record its heartfelt thanks to Professor Kevin Taylor who retired at the end of September after serving for nine years as Chair. Throughout his exemplary Chairmanship the British Pharmacopoeia had significantly evolved and had become more useful to its users. Professor Taylor had been a highly engaged Chair, encouraging contributions from all members, and had championed new areas of work that would ensure the British Pharmacopoeia was in a good place for the future. In addition to his work at national level, he had played a leading role in representing the UK at European level through his position as Chair of the UK delegation to the European Pharmacopoeia Commission, defending the interests of the MHRA and the UK during many challenging discussions.
- 78. The Commission also wished to thank Dr Jon Beaman who retired from the Commission at the end of the year after seven years of service.
- 79. 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.
- 80. In particular, members, wished to record their thanks and appreciation to Professor Alastair Davidson (former Vice-Chair of the Commission) who retired at the end of the year after having provided an incredible 50 years of

- public service through his work on the British Pharmacopoeia Commission, Expert Advisory Groups and the European Pharmacopoeia Commission.
- 81. 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. Significant input to the work of the British Pharmacopoeia Commission continued to be received from members of staff from the following Groups of the MHRA: Healthcare, Quality & Access; Scientific Research & Innovation (encompassing staff from the National Institute for Biological Standards and Control site at South Mimms); Communications and Engagement. Significant input has also been received from the BP and MHRA Laboratories, from the Department of Health and Social Care, from the Cell and Gene Therapy Catapult and from the Veterinary Medicines Directorate.
- 82. The Commission wishes to acknowledge the advice of the publishing team at The Stationery Office in the production of the British Pharmacopoeia 2023, the British Pharmacopoeia (Veterinary) 2023 and Supplement No.1 to British Approved Names 2022.

#### **OBITUARIES**

83. Members were saddened to learn of the deaths of Professor Anthony Fell, Professor David Ganderton and Professor John Midgley. Professor Ganderton had been Chair of the British Pharmacopoeia Commission between 1990 and 1997. Professor Fell had been a member of the BP Commission between 1984 and 2002 and Professor Midgley had been a member of the BP Commission between 1986 and 2005.

# MEMBERSHIP OF THE BRITISH PHARMACOPOEIA COMMISSION DURING 2022

# Chair

**Professor Kevin M G Taylor**<sup>1</sup> BPharm PhD FRPharmS (*until 30<sup>th</sup> September*) Professor of Clinical Pharmaceutics, UCL School of Pharmacy

**Dr Anna-Maria Brady** BSc PhD (*Vice-Chair; Chair from 1st October*) Former Head of Biologicals and Administration, Veterinary Medicines Directorate

# **Members**

# Dr Emre Amirak BSc MBBS MRCS

Country Medical Director UK & Ireland, Orphazyme A/S; President & Chief Medical Director, Vionelix Therapeutics

#### Dr Andrew Barnes BSc PhD FRSC

Quality Assurance Pharmacist, Pharmacy Manufacturing Unit, East Suffolk and North Essex NHS Trust

**Dr Jon Beaman**<sup>2</sup> BSc PhD MBA CChem MRSC Head of Development Analytical Group, Pfizer UK

# Dr Edward Bush BSc PhD

Principal Scientist – Pharmacopoeia Specialist, Chemical Development, AstraZeneca

# Mr Carlo Emanuele Giartosio MSc

Former Regulatory Coordination & Scientific Support Manager, Merck Serono

# **Dr Alison Gleadle** BSc PhD (*Lay member*)

Former Group Product Risk Director, Tesco Stores Ltd.

**Dr Vikas Jaitely** BPharm MPharm PhD MRPharmS GPhC MTOPRA Director (EU Digital Healthcare & Devices), Global Regulatory Affairs, Merck

# Mr Sean Jones BSc MSc MRPharmS

Former Expert Quality Assessor, MHRA; former Trust Quality Controller, Guy's and St. Thomas' NHS Foundation Trust

**Mr Robert Lowe** BPharm FRPharmS (*Vice-Chair from 1st January 2023*) Director of Pharmacy Quality Assurance Specialist Services, NHS East of England & Northamptonshire

# **Dr Paul Marshall** BPharm PhD MRPharmS MAPS FTOPRA Director, Global Regulatory Affairs, Jazz Pharmaceuticals

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

# Mr James Rickard MPharm MRPharmS

Chief Scientific & Regulatory Officer, Biotherapy Services; Visiting Senior Lecturer, Kings College, London

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

**Secretary and Scientific Director** 

# Mr James Pound BSc

Deputy Director, Standards and Compliance – Healthcare, Quality & Access, MHRA

<sup>&</sup>lt;sup>1</sup>Retired, 30<sup>th</sup> September 2022.

<sup>&</sup>lt;sup>2</sup>Retired, 31<sup>st</sup> December 2022.

# MEMBERSHIP OF EXPERT ADVISORY GROUPS, PANELS OF EXPERTS AND WORKING PARTIES OF THE BRITISH PHARMACOPOEIA COMMISSION DURING 2022

#### **EXPERT ADVISORY GROUPS**

AIM: Anti-Infective Medicines (formerly ABS: Antibiotics)

R L Horder (Chair), G D Cook (Vice Chair),

G Blake,

G Clarke,

E Flahive.

V Jaitely.

S Jones,

W Mann,

J Miller,

M Pires<sup>1</sup>,

J Sumal,

I R Williams

BIO: Biological and Biotechnological Products

A-M Brady (Chair), E Amirak (Vice-Chair),

Diagott\*

L Bissett\*,

C Braxton\*,

C Burns,

K Chidwick\*,

B Cowper,

S Gill,

C Jones\*,

A Kippen,

V Loh,

K Nordgren\*,

B Patel\*,

L Randon,

I Rees\*,

S Schepelmann\*,

P Stickings\*,

R Thorpe,

L Tsang,

P Varley,

M Wadhwa\*,

W Zunic

Complementary Medicines R Middleton (Vice-Chair), A Booker, C Etheridge, C Leon, B Moore, M Pires<sup>1</sup>, E Reich, M Rowan, A Slater. K Strohfeldt-Venables, J Sumal\*, C Welham, E Williamson, K Zhao (Corresponding members SS Handa, Z-T Wang) MC1: Medicinal Chemicals A G Davidson (Chair), P Marshall (Vice-Chair), H Batchelor. J C Berridge, E Bush, D Cairns. A J Caws, P Fleming, E Gray<sup>1</sup>, G L Lee, W J Lough, D J Malpas, S Nolan, F Pina MC2: Medicinal Chemicals G Cook (Chair), C T Goddard (Vice-Chair), J Birchall, K Boon, J Cowie, K Foster. E Hook, J Lim<sup>1</sup>, J Miller, J Rickard, A Ruggiero, N Wynne

M Simmonds (Chair),

HCM: Herbal and

(Corresponding member M Brits)

MC3: Medicinal Chemicals M Almond<sup>1</sup> (Chair), J Beach (Vice-Chair), J Beaman<sup>1</sup>, K Foster, C T Goddard, P Hampshire, V Ibekwe. W K L Pugh<sup>1</sup>, B Rackstraw<sup>1</sup>, R Torano. I R Williams PCN: Pharmacy and Nomenclature J K Aronson (Chair), R A Lowe (Vice-Chair), M Ahmed\*, E Baker<sup>1</sup>, J Beach. D Elder. E Gray<sup>1</sup>, R L Horder, J Lim<sup>1</sup>, J MacDonald<sup>1</sup>, A McFarlane, J F McGuire, G P Moss, K M G Taylor, R Thorpe (Corresponding member R G Balocco Mattavelli) **ULM: Unlicensed Medicines** M G Lee (Chair), V Fenton-May (Vice-Chair), A Barnes, A Bosley, M Godber, W Goddard, S Hartley, D Kirby, J Ramada-Magalhaes,

> P Weir<sup>1</sup>, M Westwood

M Santillo, J Smith, A Sully,

# **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, G Inwards

IGC: Inorganic and General Chemicals C T Goddard (Chair),

M Almond<sup>1</sup>, S Boland, P Henrys, G Inwards

MIC: Microbiology V Fenton-May (Chair),

B Alexander, C Iverson, V Jaitely, J Silva

RAD: Radioactive Materials I Boros,

J Brain, D Graham, G Inwards, R D Pickett

VET: Veterinary Medicines E Williamson (Chair),

A Cairns, S Cockbill, D Evans, E Flahive, B Ward

VIP: Veterinary A-M Brady (Chair),

Immunological Products R Banks,

R Cooney, M Ilott, C Stirling, R Woodland

#### **WORKING PARTIES**

AQbD: Analytical Quality by Design

G Cook (**Chair**),
P Borman,
C Burwood,
M Chatfield<sup>1</sup>,
S Ellison,
P Hamilton,
M Hanna-Brown,
S Jones,
A Kettle,
W J Lough,
P Nethercote,
E Razzano<sup>1</sup>,
M Zaman<sup>1</sup>

(Corresponding members K Barnett, B Harrington, R LoBrutto, T Morris)

ATMP: Advanced Therapy Medicinal Products (incorporating the sub-groups on (i) Flow Cytometry, (ii) Vector Copy Number, (iii) Empty Capsids for AAV Products and (iv) T Cell and NK Cell Characterisation Assays)

J Barry (Chair), I Anderson, L Bisset. C Blue, G Bou-Assaf, C Burns, J Campbell, D Caulfield, M Collis, P Getty, K Gilmour, J Glassford. D Grandolfo. Z Hannoun, T Kanwarjit, L Li, A Lovatt, M Lowdell, J McIntosh, J Nieto, A Niewiarowska, J Nilsson, R Nordstrom, J Norton, A Nowocin,

L Pattenden, J Rattu, E Razzano<sup>1</sup>,

I Rees, R Rego, ATMP: Advanced Therapy Medicinal Products (incorporating the sub-groups on (i) Flow Cytometry, (ii) Vector Copy Number, (iii) Empty Capsids for AAV Products and (iv) T Cell and NK Cell Characterisation Assays)

I Santeramo, F Schnetzinger, I Searing, V Smith, B Surmacz-Cordle, H Tao, V Vanhoutte,

S Vinter, P Wang

BIO-DPS: Alternative Approaches for Documentary and Physical Standards for Biotechnological Products

P Varley (Chair),
A-M Brady (Vice-Chair),
C Burns,
B Cowper,
L Duhau,
V Ganeva,
C E Giartosio,
F Plath,
A Ramzan,
B Rellahan,

#### **AD-HOC GROUP**

**New Analytical Technologies** 

J Beaman<sup>1</sup>, G Cook, J Miller, M Simmonds, R Torano

<sup>&</sup>lt;sup>1</sup> Retired during the year.

<sup>\*</sup> Specialist member.

#### BRITISH PHARMACOPOEIA COMMISSION PUBLICATIONS DURING 2022

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

British Pharmacopoeia 2023 package

Consisting of:-

British Pharmacopoeia 2023

British Pharmacopoeia (Veterinary) 2023

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 2022: Supplement No.1

(Price £20)

#### **EUROPEAN PHARMACOPOEIA COMMISSION**

#### MEMBERS OF THE UNITED KINGDOM DELEGATION DURING 2022

Main: A-M Brady, A G Davidson<sup>1</sup>, J Pound, K M G Taylor<sup>1</sup>

Alternates: R L Horder, S Young

## MEMBERS OF GROUPS OF EXPERTS FROM THE UNITED KINGDOM DURING 2022

Group 1	Microbiology	M Whaley
Group 6	Biological Substances	B Cowper
Group 6B	Human Blood and Blood Products	C Thelwell
Group 7	Antibiotics	J Sumal
Group 9G	Medicinal Gases	P Henrys ( <i>Chair</i> )
Group 10A	Organic Chemistry (Synthetic Products)	D J Malpas
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)	H Corns
Group 12	Dosage Forms and Methods	R L Horder ( <i>Chair</i> ), E Gray <sup>1</sup>
Group 13B	Phytochemistry (B)	P Anderson
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 17	Medicinal Products Containing Chemically Defined Active Substances	S Young
Group P4	Procedure 4	A Evans

## MEMBERS OF WORKING PARTIES FROM THE UNITED KINGDOM DURING 2022:

Bacterial Endotoxins Test S Diebold

Cell Therapy Products K Cornish

Chromatographic Separation Techniques S Young

Extracts M Pires<sup>1</sup>, L Anderson

Gene Therapy Products Y Zhao<sup>1</sup>, C Kerridge

General Methods E Gray<sup>1</sup>,

O McPolin<sup>1</sup> (Specialist)

Host-cell Proteins A Kippen

Inhalanda K M G Taylor<sup>1</sup>, O N Ogian

Monoclonal Antibodies P Varley, S Prior,

M Wadhwa

L Bisset

Mycoplasmas R Hawkins<sup>1</sup>

Paediatric Formulary K Boon

Procedure 4 for Biologicals M Wadhwa, L Both

Pyrrolizidine Alkaloids S MacDonald

Raw Materials for the Preparation of Cellular and Gene

Therapy Products

Rules of Procedure H Corns

Special Revision Programme A Evans

Standard Terms M Ahmed

Statistics R Gaines Das

<sup>&</sup>lt;sup>1</sup>Retired during the year.

# PREVIOUS CODE OF PRACTICE FOR CHAIRMEN AND MEMBERS OF THE COMMISSION ON HUMAN MEDICINES, CERTAIN COMMITTEES AND EXPERT ADVISORY GROUPS IN USE UNTIL SEPTEMBER 2022

#### INTRODUCTION

#### **Purpose of the Code**

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

#### Importance of impartiality

- 1.2 Ministers expect the advice they receive on matters relating to the regulation of medicines to be impartial. Ministers also expect to be able to seek such advice from a wide range of highly skilled professionals who are senior and well regarded in their respective fields. Many experts in the field of medicines have, or have had, connections with the pharmaceutical industry and other commercial organisations whose business may be considered relevant to their work on the advisory bodies but may have an impact on their impartiality. For example, the University department for which an individual is responsible may have received a research grant from industry, or the individual may have shareholdings from previous industry employment.
- 1.3 To reassure Ministers and the public that the advice on which decisions about medicines is based is impartial, it is important to have in place a robust policy governing the declaration and management of relevant interests. In the interests of transparency and accountability, this Code of Practice, the declarations made by chairmen and members of the various committees, and the actions taken to manage potential conflicts of interest are made public. In addition, where an individual has declared in advance of a meeting an interest that would exclude him or her from the relevant discussions, this information will be used by the secretariat to ensure that, wherever possible, the relevant committee papers are not sent to that individual.

#### SCOPE

#### Committees and groups to which this Code applies

- 2.1 The Code of Practice applies to the chairmen and members of the following committees and groups:
  - Commission on Human Medicines (CHM)
  - The following committees ("the Committees"):
    - Herbal Medicines Advisory Committee (HMAC);
    - The Advisory Board on the Registration of Homeopathic Products (ABRHP)
  - The Expert Advisory Groups (EAGs) established by the CHM and/or the Committees.
- 2.2 This Code of Practice does not apply to the British Pharmacopoeia Commission (BPC), which does not advise Ministers directly. A separate Code has been developed for the BPC to take account of their different role and remit.

#### **DEFINITIONS**

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

#### Pharmaceutical Industry

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

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

#### **Immediate family**

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

#### INTERESTS WHICH NEED TO BE DECLARED

#### Summary of interests that need to be declared

- 4.1 It is the responsibility of each individual to identify and to declare all relevant interests. The following types of interest must be declared by the chairmen and members of all committees and groups:
  - Their own financial interests in the pharmaceutical industry; (financial interests are either personal or non-personal, and either specific to the product being discussed, or non-specific);
  - Financial interests in the pharmaceutical industry held by members of their immediate family;
  - Any other matter that could affect their impartiality, or that could reasonably be perceived as affecting their impartiality. Some examples of interests that are relevant in the context of this Code of Practice, not all associated with the pharmaceutical industry, are set out in section 4.7 below.
- 4.2 The following paragraphs describe in more detail the types of interests that must be declared. The procedures for handling interests that have been declared are described in Section 7.

#### Personal interests

4.3 A personal interest in the context of this Code, involves the payment, in any form, to an individual personally, by a pharmaceutical company whose business may be directly affected by the advice of the advisory body. At a meeting, personal interests must be declared as specific (that is, payment relates to a particular product under consideration), or as non-specific (that is, not related to the particular product under discussion). The following main examples of interests to be declared should not be regarded as a definitive list, and the Medicines and Healthcare products Regulatory Agency (MHRA) secretariat to each committee will advise if a chairmen 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 chairmen and members and/or their immediate family have no financial control (such as holdings in a wide share portfolio -Unit Trust or similar - where the Fund Manager has full discretion over the composition of the portfolio) do not need to be declared. However, funds held in a portfolio in which the chairmen and members and/or their immediate family have the ability to instruct the Fund Manager as to the composition of the fund must be declared.

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

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

- 4.4 The chairmen and members of the CHM, HMAC and ABRHP serve on the committees that provide advice direct to the Licensing Authority. For this reason, they are not permitted to hold any current personal interests in the pharmaceutical industry. This policy also applies to the chairmen of the Pharmacy and Standards EAG, the Pharmacovigilance EAG and the Biologicals and Vaccines EAG by virtue of their membership of the CHM. The chairmen and members of the CHM and the chairmen and members of the HMAC and ABRHP, and the chairmen of the three EAGs specified are required to make a declaration on appointment that they are disposing /have disposed of any such current personal interests.
- 4.5 The chairmen and members of these committees have three months from the date of appointment to dispose of any current personal interests in the pharmaceutical industry. During this period, they are required to declare any relevant current personal interests at meetings and to exclude themselves from discussion on the relevant product(s) and abstain from any vote.

#### **Non-personal interests**

4.6 A non-personal interest in the context of this Code, involves payment that benefits a department for which an individual is responsible, but is not received by the member personally. As with personal interests, non-personal interests at a meeting must be specific or non-specific. The main examples that follow should not be regarded as a definitive list, and the advice of the committee secretariat provided by the MHRA should be sought if a chairmen 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 chairmen and members of the CHM, HMAC and ABRHP (including the chairperson of the Pharmacy and Standards EAG, the Pharmacovigilance EAG and the Biologicals and Vaccines EAG) who, as set out above, are not permitted to hold personal interests in the pharmaceutical industry.
- 4.9 The nature of the events that fall within the scope of this Code of Practice and the industry sponsorship received can vary widely from, at one extreme, a conference sponsored by a single company to launch a product to, at the other extreme, a scientific meeting organised by a learned society that has received some financial support from a number of companies paid into a dedicated meeting fund. Between these extremes there are many variations in events and funding that may occur.
- 4.10 In order that the chairmen and members of CHM, HMAC, ABRHP and the three EAG chairmen specified in paragraph 4.8 above should be able to attend appropriate scientific events to keep their knowledge up to date, the MHRA has established a discretionary fund to meet the reasonable expenses (e.g. travel and accommodation costs) incurred in their attendance. The relevant MHRA committee secretariat will administer the fund, and chairmen and members wishing to claim the costs of attendance at such events must make an application in good time to enable appropriate travel and other arrangements to be made. The fund will cover educational events that are relevant to maintaining the expertise of

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

- 4.11 In some cases it will permissible for members of CHM, HMAC, ABRHP or the EAG chairmen to attend events sponsored by the pharmaceutical industry (and accept the payment of their expenses) without recourse to the MHRA discretionary fund. For example, where a learned society holds an international conference that is sponsored by a number of different pharmaceutical companies, it will generally be acceptable for the member to accept such an invitation and to receive payment of expenses, although in such instances declaration of attendance and receipt of funding must be declared in the normal way.
- 4.12 If funding and/or expenses are paid specifically for an individual's attendance but nevertheless paid to his department rather than the individual himself, it will not normally be acceptable for the individual to attend.
- 4.13 Benefits of this nature paid to an immediate family member that also benefit the committee chairman or member (e.g. a company pays his or her flight costs so that the he or she can attend a conference with a family member) must be declared as the individual's own interest. However, there is no requirement to declare educational conferences and similar events attended by immediate family members.
- 4.14 If an individual attends an educational conference or similar, he or she should avoid participation in, for example, "satellite" meetings sponsored and arranged by specific companies or focusing on specific products where involvement in discussions might reasonably be perceived as affecting his or her impartiality. If in doubt, this must be raised with the MHRA Secretariat at the earliest possible opportunity, who will be able to provide further guidance.
- 4.15 The rules for holding personal interest in the pharmaceutical industry do not apply to the chairmen and members of EAGs, apart from the chairmen 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 Chairmen and members are required to make a full declaration of interests on appointment and annually. They must also inform the MHRA secretariat promptly of any changes or updates to the terms of their declaration during the year. This includes reporting promptly attendance at events described in paragraphs 4.8 – 4.17. If an individual is uncertain as to whether or not an interest should be declared, he or she must seek guidance from the MHRA secretariat. Chairmen and members are also required to make further declarations of relevant interests at meetings when they will be advised as to the procedure that will apply.

#### **Annual declaration**

- 6.2 The annual declaration must include all the financial (personal and non-personal) interests in the pharmaceutical industry of the chairmen and members currently held or held in the last 12 months and financial interests in the pharmaceutical industry that they know of that are held by their immediate family. Members and chairmen are also required to include in the annual declaration details of any other matter which could reasonably be regarded as affecting their impartiality.
- 6.3 The declaration of certain interests will not be restricted to the last 12 months. For example, an individual's significant involvement in the development of a particular product will need to be declared each year as well as at relevant meetings, and may restrict that individual's participation in some discussions.
- 6.4 The chairmen and members' declaration of their own interests will identify them with the interests declared, but the interests declared do not need to be quantified. For example, in declaring a grant received by a department

for which the individual is responsible, only the company name is required, not the value of the grant.

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

#### **Declarations at meetings**

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

## PARTICIPATION IN DISCUSSIONS WHEN AN INTEREST HAS BEEN DECLARED

- 7.1 "Taking part in discussions" means speaking at meetings or voting. Where an individual is not to take part in a discussion, he or she should leave the room before the discussion commences and return only when that agenda item is complete.
- 7.2 The following paragraphs describe, for each category of interests declared, the actions to be taken.

#### **Personal Interests**

- 7.3 A personal specific interest will have been declared if an individual has worked on the product under consideration and is receiving or has received payment for that work. As a general rule, the individual will normally not be allowed to take part in discussions as they relate to that product, except where the Chairman exercises his discretion (which will be rarely exercised) to answer questions from other members. A significant involvement in the development of a product will usually debar an individual from ever participating in discussion on that product. A less significant involvement, or less specific work with or on a product, may not permanently debar an individual, but such decisions will need to be taken on a case by case basis, taking account of the nature of the involvement, its specificity and when the work was undertaken.
- 7.4 If an individual has declared a personal non-specific interest the individual must take no part in discussions on that agenda item, except at the Chairman's discretion to answer questions from other members. If the personal non-specific interest relates to shares that have been disposed of, the individual will generally be permitted to take part in discussions once three months have elapsed from the date of the disposal of them If the personal non-specific interest relates to other matters, such as a payment received from a pharmaceutical company, the individual will generally be permitted to take part in discussions once 12 months has elapsed from the date of receipt of payment. However, in some cases it will not be appropriate for the individual to take part even though 12 months have elapsed for example, where he has an ongoing consultancy or other financial relationship with the pharmaceutical company.
- 7.5 If the individual has declared a personal interest in relation to a member of his or her immediate family, he or she should similarly take no part in discussions except at the Chairman's discretion to answer questions from other members. Such interests may range from a family member's major role in the development of a product under consideration to a family member's shareholdings.

#### **Non-Personal Interests**

- 7.6 A non-personal specific interest will have been declared if the department for which the individual is responsible is currently receiving payment in respect of work done on the product. The individual will generally not be able to take part in proceedings where a department for which he has responsibility has carried out specific work on the product under discussion.
- 7.7 A non-personal, non-specific interest will not normally debar an individual from taking part in discussions, unless exceptional circumstances arise in which it is not appropriate for them to do so.

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

#### **Other Interests**

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

#### **Rival Products**

- 7.10 It is important to remember that not only the company whose application is being considered will be affected by the advice that is given by advisory bodies companies who make competitor products may also be affected.
- 7.11 If a product is being discussed and an individual is aware that he or she has an interest in a company which markets a rival product, the business of which will directly benefit or suffer as a result of the advice that is given, the individual must declare that interest at the meeting. An example might be where an application for a generic product is being considered and the individual holds an interest in the current brand-leader, or where a new active substance is under consideration that will directly affect the market of another company for a similar product in which an individual has an interest. Whether the individual will be permitted to take part in discussions will depend upon the circumstances and the extent to which the business of the competitor is likely to be affected.
- 7.12 There is no requirement to carry out specific research to identify issues such as these individuals need only to declare interests of which they are aware.

#### **Consideration of Classes of Products**

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

#### RECORD OF INTERESTS

- 8.1 A record is kept in the MHRA of:
  - names of chairmen and members who have declared interests on appointment, when an interest first arises or through the annual declaration, and the nature of the interest;
  - names of chairmen and members who have declared interests at meetings of the CHM, the Committees and EAGs, giving dates, names of relevant products and companies, details of the interest declared and whether the individual took part in the proceedings.

#### **PUBLICATION**

- 9.1 Interests declared to the MHRA by chairmen and members of all committees, including EAGs, will be published each year in the Annual Reports of the CHM and the Committees (normally published in July).
- 9.2 Interests of immediate family and other closely connected people declared by chairmen and members will be included in the Annual Reports. This information will provide only the name of the committee chairman or member, the source of the interest (e.g. the company name), will not provide any financial information nor numbers (e.g. for shares) nor identify the family member or other holding the interest by name.

#### **NEW CODE OF PRACTICE FOR EXPERT COMMITTEES**

In 2022, the MHRA led a public consultation exercise on a set of proposals to improve and strengthen the Code of Practice on conflicts of interest for experts who provide advice on which decisions about the regulation of medicines and medical devices may be based, or provide advice on standards used in the British Pharmacopeia.

In response to the public consultation, a new Code of Practice was drafted to clarify the ways that chairs, members, co-opted members, invited and patient experts and the public can participate in meetings and discussions of the advisory committees and working groups.

The new Code has now replaced the version shown above. It is published alongside the consultation response document and is available via the link: <a href="https://www.gov.uk/government/consultations/consultation-on-a-new-code-of-practice-for-the-expert-advisory-committees">https://www.gov.uk/government/consultations/consultation-on-a-new-code-of-practice-for-the-expert-advisory-committees</a>

## COMMISSION ON HUMAN MEDICINES, COMMISSION'S EXPERT ADVISORY GROUPS, EXPERT WORKING GROUPS AND AD HOC GROUPS MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

Member	Committee(s)	Interest Type	Company/Organisation /Sponsor	Nature of Interest	Current	Additional Information
Aditya Sharma	NPPEAG	Personal	NIL	N/A	N/A	
Aditya Sharma	NPPEAG	Non- Personal	Lundbeck	Unrestricted medical educational grant towards a study	No	
Afzal Mohammed	CPSEAG	Personal	Aston Particle Technologies	shares, consultancy	Yes	
Afzal Mohammed	CPSEAG	Non- Personal	Catalent Pharma	Research Grant	Yes	
Afzal Mohammed	CPSEAG	Non- Personal	Colorcon Ltd	Research Grant	Yes	
Afzal Mohammed	CPSEAG	Non- Personal	MaxBiotech Ltd	Research Grant	Yes	
Afzal Mohammed	CPSEAG	Non- Personal	Proveca Ltd	Research Grant	Yes	
Afzal Mohammed	CPSEAG	Non- Personal	Quest Healthcare	Research Grant	Yes	
Alana Adams	PEAG	Personal	Pfizer	Fees for educational session	No	

Alana Adams	PEAG	Non- Personal	NIL	N/A	N/A
Alison McClean	Emergency Contraception Ad Hoc Stakeholder Group	Personal	NIL	N/A	N/A
Alison McClean	Emergency Contraception Ad Hoc Stakeholder Group	Non- Personal	NIL	N/A	N/A
Amanda Adler	CHM, CDRRA EAG	Personal	NIL	N/A	N/A
Amanda Adler	CHM, CDRRA EAG	Non- Personal	Novo Nordisk	Grant - Diabetes Trials Unit to conduct the ISAP trial	Yes
Amanda Adler	CHM, CDRRA EAG	Non- Personal	Bayer	Oxford University Innovations	No
Amine Boualem	CDRRA EAG	Personal	NIL	N/A	N/A
Amine Boualem	CDRRA EAG	Non- Personal	NIL	N/A	N/A
Amparo Alvarez-Llobell	MWHEAG	Personal	NIL	N/A	N/A
Amparo Alvarez-Llobell	MWHEAG	Non- Personal	NIL	N/A	N/A
Andrew Freedman	IEAG	Personal	NIL	N/A	N/A

Andrew Freedman	IEAG	Non- Personal	NIL	N/A	N/A
Andrew Pollard	CTBVEAG	Personal	Shionogi	consultancy	No
Andrew Pollard	CTBVEAG	Non- Personal	Sequirus, Sanofi	Unrestricted grant for 3- day educational course paid to Oxford University	No
Andrew Pollard	CTBVEAG	Non- Personal	Astra Zeneca	Partnership between Oxford University and AZ for development of a Covid19 vaccine.	Yes
Andrew Pollard	CTBVEAG	Non- Personal	Johnson and Johnson	I have irrevocably waived any personal rights under this agreement	Yes
Andrew Pollard	CTBVEAG	Non- Personal	NIHR/UKRI	Grant to Oxford University	Yes
Andrew Pollard	CTBVEAG	Non- Personal	Serum Institute of India	Grant to Oxford University	Yes
Andrew Pollard	CTBVEAG	Additional			

Non-commercial: Grants from Wellcome and Bill & Melinda Gates Found'n on typhoid vaccines (Tybar-CV, Bharat Biotech, 2013-current); from MRC on paratyphoid vaccine (U. Maryland; from 2018-); Grant from the Gavi on

CTBVEAG	Additional	
CTBVEAG	Additional	Innovate UK
CTBVEAG	Additional	CEPI
CTBVEAG	Additional	Meningitis Res Found'n
	CTBVEAG	CTBVEAG Additional  CTBVEAG Additional

pneumococcal vaccines in Nepal (2013-current).

**European Commission** (EC): EC IMI grants (EBOVAC), on Ebola vaccine (Janssen; 2015current); (PERISCOPE) on pertussis vaccines (2016current); (RESCEU and PROMISE) on RSV biomarkers (2016-Current). EC H2020 grant (PERFORM/DIAMONDS) on fever in children and pneumonia (2016-current); EC grant (Innovac4) to develop a CDiff challenge model (2021-current);

Grants from Innovate UK to develop plague, zika, Q fever vaccines (2016-current).

Grants from CEPI on COVID19 vaccines (2021-current)

Grant from Meningitis Res Found'n on a booster of Bexsero in teens (2018current), and MRC on novel meningococcal vaccine; Grant from Bill & Melinda Gates Found'n on

Andrew Pollard	CTBVEAG	Additional			
Andrew Pollard	CTBVEAG	Additional			
Andrew Pollard	CTBVEAG	Additional			
Andrew Rice	NPPEAG	Personal	Imperial College Consultants	Fee remunerated consultancy work	Yes
Andrew Rice	NPPEAG	Personal	Imperial College London	Salary - Full time employee	Yes
Andrew Rice	NPPEAG	Non- Personal	NIL	N/A	N/A
Andrew Riordan	COVID-19 VBREWG	Personal	NIL	N/A	N/A
Andrew Riordan	COVID-19 VBREWG	Non- Personal	NIL	N/A	N/A
Anita Simonds	CDRRA EAG	Personal	NIL	N/A	N/A

evaluating infant schedules (2019 – current)

I have a patent pending on a meningococcal vaccine.

I chaired the scientific advisory group on vaccines for the European Medicines Agency until March 2020 and I am a member of the World Health Organization's SAGE until 31/12/21.

I am the chair of DHSC's JCVI

Anita Simonds	CDRRA EAG	Conference /Scientific Meetings	ResMed	World Sleep Congress- Fee for lecture on Real World Sleep, fee for lecture	No
Anita Simonds	CDRRA EAG	Conference /Scientific Meetings	ACI clinical	End Point committee BioALS trial - Member of committee analysing, fee paid for trial endpoints analysed	No
Anita Simonds	CDRRA EAG	Conference /Scientific Meetings	European Medicines Agency (EMA)	Membership of EMA Task Force – I offer advice but do not make decisions on vaccines and drug regulation	No
Anita Simonds	CDRRA EAG	Non- Personal	NIL	N/A	N/A
Anjan Dhar	GRIDEAG	Personal	Takeda UK	Consultancy and Advisory Role, speaker fees	No
Anjan Dhar	GRIDEAG	Personal	Janssen UK	Consultancy, advisory and speaker fees	No
Anjan Dhar	GRIDEAG	Personal	Dr Falk Pharma UK	Consultancy, advisory and speaker fees	No
Anjan Dhar	GRIDEAG	Personal	Galapagos	Advisory role, speaker fees	No
Anjan Dhar	GRIDEAG	Personal	Abbvie UK	Speaker Fees and Chair	No
Anjan Dhar	GRIDEAG	Personal	BMS	Speaker fees	No

Anjan Dhar	GRIDEAG	Personal	Health Beacon	Speaker fees	No
Anjan Dhar	GRIDEAG	Personal	Tillotts UK	Speaker Fees and Chair	No
Anjan Dhar	GRIDEAG	Conference /Scientific Meetings	Dr Falk Pharma UK	Full registration, travel and accommodation	No
Anjan Dhar	GRIDEAG	Non- Personal	NIL	N/A	N/A
Anjum Khan	OHEAG	Personal	Jazz	Speaker's fee	No
Anjum Khan	OHEAG	Personal	Pfizer	Speaker's fee	No
Anjum Khan	OHEAG	Personal	Astellas	Speaker's fee	No
Anjum Khan	OHEAG	Personal	Novartis	Consultancy	No
Anjum Khan	OHEAG	Conference /Scientific Meetings	American Society of Haematology	Conference attendance and flights, accommodation	No
Anjum Khan	OHEAG	Non- Personal	NIL	N/A	N/A
Ann Daly	PEAG	Personal	NIL	N/A	N/A
Ann Daly	PEAG	Non- Personal	Sanofi	Consultancy via Newcastle University. No personal payment.	Yes

Ann Daly	PEAG	Non- Personal	Daiichi-Sankyo	Consultancy via Newcastle University. No personal payment.	No
Anne-Marie Gallogly	Emergency Contraception Ad Hoc Stakeholder Group	Personal	NIL	N/A	N/A
Anne-Marie Gallogly	Emergency Contraception Ad Hoc Stakeholder Group	Non- Personal	NIL	N/A	N/A
Anthony Marson	Valproate Implementation EWG	Personal	NIL	N/A	N/A
Anthony Marson	Valproate Implementation EWG	Non- Personal	UCB	Grant paid to University of Liverpool for National Audit of Seizure Management in Hospitals	Yes
Anthony Marson	Valproate Implementation EWG	Non- Personal	GSK	Fee for recording a lecture, paid to University of Liverpool	No
Anthony Marson	Valproate Implementation EWG	Non- Personal	Equity Pharmaceuticals	Fee for recording a lecture, paid to University of Liverpool	No
Anthony Williams	CHM, GRID EAG	Personal	NIL	N/A	N/A

Anthony Williams	CHM, GRID EAG	Non- Personal	NIL	N/A	N/A
Anthony G Wilson	GRIDEAG	Personal	NIL	N/A	N/A
Anthony G Wilson	GRIDEAG	Non- Personal	NIL	N/A	N/A
Aurora Todisco	Emergency Contraception Ad Hoc Stakeholder Group	Personal	NIL	N/A	N/A
Aurora Todisco	Emergency Contraception Ad Hoc Stakeholder Group	Non- Personal	NIL	N/A	N/A
Barbara Conway	CPSEAG	Personal	NIL	N/A	N/A
Barbara Conway	CPSEAG	Conference /Scientific Meetings	Journal of Woundcare	Wounds Week - Honorarium	No
Barbara Conway	CPSEAG	Non- Personal	Paxman Coolers	Research grant	No
Barry Miller	NPPEAG	Personal	NIL	N/A	N/A
Barry Miller	NPPEAG	Non- Personal	NIL	N/A	N/A

Benjamin Blaise	PMEAG	Personal	NIL	N/A	N/A
Benjamin Blaise	PMEAG	Non- Personal	NIL	N/A	N/A
Ben Forbes	CPSEAG	Personal	NIL	N/A	N/A
Ben Forbes	CPSEAG	Non- Personal	Astrazeneca	Grant	Yes
Ben Uttenthal	OHEAG	Personal	NIL	N/A	N/A
Ben Uttenthal	OHEAG	Conference /Scientific Meetings	Gilead	Sponsorship to attend American Society of Hematology annual scientific meeting	No
Ben Uttenthal	OHEAG	Non- Personal	NIL	N/A	N/A
Caitlin Dean	MWHEAG	Personal	NIL	N/A	N/A
Caitlin Dean	MWHEAG	Non- Personal	NIL	N/A	N/A
Caroline Jones	PMEAG	Personal	NIL	N/A	N/A
Caroline Jones	PMEAG	Non- Personal	NIL	N/A	N/A
Caroline Jones	PMEAG	Additional			

Currently in the process of setting up an industry sponsored study and will be PI at Alder Hey

Childrens Hospital for a multicentre study for an erythropoietin stimulating agent from GSK with Syneos Health acting as the organisation for research contracts I will receive no personal or non-personal benefit but the research department at Alder Hey Childrens Hospital will receive funding to support the trial costs

Catrin Barker	PMEAG	Personal	NIL	N/A	N/A
Catrin Barker	PMEAG	Non- Personal	NIL	N/A	N/A
Celia Moss	GRIDEAG	Personal	NIL	N/A	N/A
Celia Moss	GRIDEAG	Non- Personal	NIL	N/A	N/A
Celia Moss	GRIDEAG	Additional			
Chris Goldring	CTBVEAG	Personal	NIL	N/A	N/A
Chris Goldring	CTBVEAG	Non- Personal	Pfizer, MSD, Roche, Eli Lilly, Novartis, Janssen, Sanofi-Aventis	Grant for Innovative Medicines Initiative project	Yes
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Trustee and Chair of the Medical Advisory Board for the National Eczema Society (charity)

Chris Goldring	CTBVEAG	Non- Personal	Eli Lilly, Abbvie, Servier, Sanofi-Aventis, AZ, GSK, Janssen, Orion, B.I.	Grant for Innovative Medicines Initiative project	Yes	
Chris Goldring	CTBVEAG	Non- Personal	Merck	Grant	Yes	
Chris Goldring	CTBVEAG	Additional				On the organising committee for a scientific meeting in June 2023. a joint meeting of the International Society for the Study of Xenobiotics (ISSX) and the Drug Metabolism Discussion Group (DMDG). There are many Pharmaceutical Industry members of both of these societies. I receive no financial gain from my role on the committee, which is comprised of a mixture of academic and Industry scientists.
Chris Robertson	COVID-19 VBREWG	Personal	NIL	N/A	N/A	
Chris Robertson	COVID-19 VBREWG	Non- Personal	NIL	N/A	N/A	
Chris Robertson	COVID-19 VBREWG	Additional				Research Grants to Strathclyde University to carry out work on vaccine effect, uptake and safety funded by Public Health

Scotland, MRC, CSO, NIHR. Member of SPI-M and Scottish Government Covid 19 Scientific Advisory Committee

						Committee
Christina Yap	CTBVEAG	Personal	Faron Pharmaceuicals	Independent Statistical Consultant	Yes	
Christina Yap	CTBVEAG	Personal	Bayer	Honorarium for educational workshop presentation	No	
Christina Yap	CTBVEAG	Non- Personal	Astrazeneca	Trial grant (where I am a co-investigator)	Yes	
Christina Yap	CTBVEAG	Non- Personal	Plexxikon	Trial grant (where I am a co-investigator)	No	
Christopher Marriott	CPSEAG	Personal	Halation Ltd	Company Secretary, Directorship, Fees, Shares.	Yes	
Christopher Marriott	CPSEAG	Personal	Vectura Ltd	Shares - sold on 18th October 2021	No	
Christopher Marriott	CPSEAG	Non- Personal	NIL	N/A	N/A	
Christopher Marriott	CPSEAG	Additional				Immediate family member holds shares in Halation Ltd and Vectura Ltd. The shares in Vectura Ltd were sold on 18 October 2021.
Christopher Weir	CHM, COVID- 19 VBREWG, NPPEAG	Personal	NIL	N/A	N/A	
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Christopher Weir	CHM, COVID- 19 VBREWG, NPPEAG	Non- Personal	AB Science	DSMB membership for three trials (in ALS, mastocytosis and progressive MS), with income to my department	Yes
Clare Pain	PMEAG	Personal	Amgen	UK CI fee for BEAN study of apremilast in paediatric Behcet's.	Yes
Clare Pain	PMEAG	Non- Personal	NIL	N/A	N/A
Daniel Hawcutt	PEAG, PMEAG, Valproate Implementation EWG	Personal	NIL	N/A	N/A
Daniel Hawcutt	PEAG, PMEAG, Valproate Implementation EWG	Non- Personal	Various	I am the Director of the NIHR Alder Hey Clinical Research Facility – we have over 60 studies open at any one time, and I am a named investigator or PI on many of them. I do not get paid for my time, it is recycled into the finances of the CRF, and nothing comes to me personally. I report any product specific COIs during a meeting where it is listed on the agenda	Yes

				specific for the chair to consider.	
Darragh Murnane	CPSEAG	Personal	Adare Pharmaceuticals Inc. (New Jersey, USA)	Consultancy	No
Darragh Murnane	CPSEAG	Conference /Scientific Meetings	RDD Online	RDD Europe 2023 - Speakers Fees	No
Darragh Murnane	CPSEAG	Conference /Scientific Meetings	Zeiss	Hospitality at RDD Europe 2023 conference	No
Darragh Murnane	CPSEAG	Conference /Scientific Meetings	Merxin Ltd	RDD Europe 2023 - Hospitality	No
Darragh Murnane	CPSEAG	Conference /Scientific Meetings	Zeiss	Zeiss User Meeting - Travel expenses and accommodation	Yes
Darragh Murnane	CPSEAG	Non- Personal	Chiesi Ltd	Sponsored PhD student at University of Hertfordshire	Yes
Darragh Murnane	CPSEAG	Non- Personal	GlaxoSmithKline	In-kind support for research project and sponsored PhD studentship at University of Hertfordshire	No
Darragh Murnane	CPSEAG	Non- Personal	AstraZeneca	In-kind support for research project at University of Hertfordshire	Yes

as non-personal non-

Darragh Murnane	CPSEAG	Non- Personal	Kindeva Drug Delivery Ltd.	In-kind support for research project at University of Hertfordshire	No
Darragh Murnane	CPSEAG	Non- Personal	Philips Respironics	Sponsored PhD Studentship at University of Hertfordshire	No
Darragh Murnane	CPSEAG	Non- Personal	Philips Respironics	Loaned Equipment at University of Hertfordshire	Yes
Darragh Murnane	CPSEAG	Non- Personal	Clement Clarke International	Funded contract research at University of Hertfordshire, provision of respiratory devices for research	Yes
Darragh Murnane	CPSEAG	Non- Personal	Bespak Recipharm	Funding for collaborative research project, cofunded by Innovate UK. Consultancy and contract research at University of Hertfordshire	Yes
Darragh Murnane	CPSEAG	Non- Personal	Merxin Ltd.	Sponsored PhD Studentship at University of Hertfordshire	Yes
Darragh Murnane	CPSEAG	Non- Personal	Capitainer Ab	Sponsored PhD Studentship at University of Hertfordshire	Yes
Darragh Murnane	CPSEAG	Non- Personal	Fluid Pharma Ltd.	University Director and no personal benefit	Yes

Darragh Murnane	CPSEAG	Additional			
Darragh Murnane	CPSEAG	Additional			
Darragh Murnane	CPSEAG	Additional			
Darren Ashcroft	PEAG, IEWG	Personal	NIL	N/A	N/A
Darren Ashcroft	PEAG, IEWG	Non- Personal	Abbvie, Amgen (was Celgene), Janssen, Eli Lilly, Novartis (Sandoz), UCB, LEO Foundation	Research grant to support the development of the Global Psoriasis Atlas	Yes
David Bowen	OHEAG	Personal	Abbvie	Consultancy	No
David Bowen	OHEAG	Personal	Janssen	Consultancy	No

Organization: Glatt – Current - Collaborator of Fluid Pharma (company of which I hold a Directorship) to develop novel paediatric therapies

Reviral - Research Collaboration between Fluid Pharma (company of which I hold a Directorship) to develop novel paediatric therapies

David Bowen	OHEAG	Non- Personal	NIL	N/A	N/A
David Bowen	OHEAG	Additional			F
					<i>a</i>
David Chandler	GRIDEAG	Personal	NIL	N/A	N/A
David Chandler	GRIDEAG	Non- Personal	NIL	N/A	N/A
David Chandler	GRIDEAG	Additional			l C
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David	GRIDEAG	Additional			Ä
Chandler					V
					C

Patent for Siglec-9 binding agents: WO 2007/049044 A1

I'm employed by a patient charity, but the charity has a policy not to receive any funding or financial support whether monetary, in kind or via a third parties from pharmaceutical companies or other commercial organisations. Any events or meetings I attend in relation to my work for the charity are funded by the charity, this includes: registration fees, travel, subsistence and accommodation. Family member also works for the same charity, and the above, also applies.

Another 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.

David Dockrell	CHM, COVID- 19 Therapeutic EWG, IEAG	Personal	NIL	N/A	N/A
David Dockrell	CHM, COVID- 19 Therapeutic EWG, IEAG	Conference s/Scientific Meetings	Meeting received sponsorship from Gilead, Merck, ViiV, Janssen, Hologic, Theratechnologies Inc (per abstract book)	CROI - I received no person support and paid for registration out of my own research grant funding. Companies listed will have contributed to venue hire, costs of staging conference along with the International AIDS Society the primary sponsor.	No
David Dockrell	CHM, COVID- 19 Therapeutic EWG, IEAG	Conference s/Scientific Meetings	University of Liverpool (likely some industry sponsorship but not apparent from website. Would expect some support from leading pneumococcal vaccine manufacturers e.g.	Europneumo (Liverpool) - I received no personal support and paid for travel, accommodation and registration from personal research grant support. Industry will likely have contributed to	No

		Sanofi, Astellas)	social programme in evenings during conference.	
CHM, COVID- 19 Therapeutic EWG, IEAG	Non- Personal	GSK	Access to Nrf2 agonist compounds for research by own personal group and collaborators. Commitment to continue to provide further Nrf2 agonist compounds on ongoing MRC Programme grant awarded	Yes
CHM, COVID- 19 Therapeutic EWG, IEAG	Non- Personal	Adiso Therapeutics, Inc GlaxoSmithKline Pfizer Inc Chan Zuckerberg Initiative Santersus AG IPInc Intercept Pharmaceuticals inc Gene One Genentech Inc Stryker International Sanofi Pasteur MSD Limited GlaxoSmithKline UCBC UCB BioPharma Srl Novartis Pharma AG Galecto Biotech AB Corin Ltd Scottish Power	Industry companies for whom the academic centre I am director of (Centre for Inflammation Research, University of Edinburgh) has current industry sponsorship through grants or other support to investigators. Other than GSK above not direct to my group.	No
	19 Therapeutic EWG, IEAG CHM, COVID- 19 Therapeutic	19 Therapeutic Personal EWG, IEAG  CHM, COVID- Non-19 Therapeutic Personal	CHM, COVID- 19 Therapeutic EWG, IEAG  Non- 19 Therapeutic EWG, IEAG  Personal  Adiso Therapeutics, Inc GlaxoSmithKline Pfizer Inc Chan Zuckerberg Initiative Santersus AG IPInc Intercept Pharmaceuticals inc Gene One Genentech Inc Stryker International Sanofi Pasteur MSD Limited GlaxoSmithKline UCBC UCB BioPharma Srl Novartis Pharma AG Galecto Biotech AB Corin Ltd	CHM, COVID- 19 Therapeutic EWG, IEAG  Non- Personal  Non- Personal  Resort Access to Nrf2 agonist compounds for research by own personal group and collaborators. Commitment to continue to provide further Nrf2 agonist compounds on ongoing MRC Programme grant awarded  CHM, COVID- 19 Therapeutic EWG, IEAG  Non- Personal  Personal  Adiso Therapeutics, Inc GlaxoSmithKline Pfizer Inc Chan Zuckerberg Initiative Santersus AG IPInc Intercept Pharmaceuticals inc Gene One Genentech Inc Stryker International Sanofi Pasteur MSD Limited GlaxoSmithKline UCBC UCB BioPharma Srl Novartis Pharma AG Galecto Biotech AB Corin Ltd  Access to Nrf2 agonist compounds for research by own personal group and collaborators. Commitment to continue to provide further Nrf2 agonist compounds for research by own personal group and collaborators. Commitment to continue to provide further Nrf2 agonist compounds for research by own personal group and collaborators. Commitment to continue to provide further Nrf2 agonist compounds for research by own personal group and collaborators. Commitment to continue to provide further Nrf2 agonist compounds for research by own personal group and collaborators. Commitment to continue to provide further Nrf2 agonist compounds for research by own personal group and collaborators. Commitment to continue to provide further Nrf2 agonist compounds for research by own personal group and collaborators. Commitment to continue to provide further Nrf2 agonist compounds for whom the academic centre I am director of (Centre for Inflammation Research, University of Edinburgh) has current industry sponsorship through grants or other support to investigators. Other than GSK above not direct to my group.

## Astra Zeneca Canon

			Canon		
David Dockrell	CHM, COVID- 19 Therapeutic EWG, IEAG	Non- Personal	Astra Zeneca		
David Goldblatt	COVID-19 VBREWG	Personal	NIL	N/A	N/A
David Goldblatt	COVID-19 VBREWG	Non- Personal	NIL	N/A	N/A
David Hunt	CHM, NPP EAG, Valproate Implementation EWG	Personal	NIL	N/A	N/A
David Hunt	CHM, NPP EAG, Valproate Implementation EWG	Non- Personal	NIL	N/A	N/A
David Moore	СНМ	Personal	NIL	N/A	N/A
David Moore	СНМ	Non- Personal	NIL	N/A	N/A

I have been an advisor on a research project and have reviewed and been included on a research publication-not yet published. Compounds involved in assays listed. No financial benefit

David Owens	NPPEAG, Valproate Implementation EWG	Personal	NIL	N/A	N/A
David Owens	NPPEAG, Valproate Implementation EWG	Non- Personal	NIL	N/A	N/A
David Taylor	Valproate Implementation EWG	Personal	NIL	N/A	N/A
David Taylor	Valproate Implementation EWG	Non- Personal	NIL	N/A	N/A
Deenan Pillay	COVID-19 Therapeutic EWG	Personal	NIL	N/A	N/A
Deenan Pillay	COVID-19 Therapeutic EWG	Non- Personal	NIL	N/A	N/A
Diana Wellesley	MWHEAG	Personal	NIL	N/A	N/A
Diana Wellesley	MWHEAG	Non- Personal	NIL	N/A	N/A
Ertan Saridogan	MWHEAG	Personal	Hologic	Consultancy, honoraria for lectures	Yes
Ertan Saridogan	MWHEAG	Personal	Karl Storz	Honorarium for a lecture	No

Ertan Saridogan	MWHEAG	Personal	DE GRUYTER	Royalty on edited a book	Yes
Ertan Saridogan	MWHEAG	Conference /Scientific Meetings	Arthrex	Laparoscopic hysterectomy cadaveric course - fees	No
Ertan Saridogan	MWHEAG	Conference /Scientific Meetings	Hologic	Innovation forum - fees	No
Ertan Saridogan	MWHEAG	Non- Personal	NIL	N/A	N/A
Farzin Farzeneh	CTBVEAG	Personal	Apterna	Consultancy	Yes
Farzin Farzeneh	CTBVEAG	Personal	Autolus Therapeutics	Shares, Consultancy Payments, Contract Manufacture and R & D Collaborations	Yes
Farzin Farzeneh	CTBVEAG	Personal	Cellectis, France	Consultancy, Contract Manufacture and R & D Collaborations	No
Farzin Farzeneh	CTBVEAG	Personal	VacV Therapeutics	Consultancy	Yes
Farzin Farzeneh	CTBVEAG	Personal	Dawn Theraputics	Shares and Consultancy	Yes
Farzin Farzeneh	CTBVEAG	Personal	GSK	Consultancy – Member of "Cell and Therapy Scientific Advisory Board	Yes

Farzin Farzeneh	CTBVEAG	Personal	ViroCell Biologics Ltd	Chief Scientific Officer, Co-Founder and Share Holder	Yes
Farzin Farzeneh	CTBVEAG	Personal	King's College London	Lecturer	Yes
Farzin Farzeneh	CTBVEAG	Personal	Guys Hospital NHS Trust	Qualified Person	Yes
Farzin Farzeneh	CTBVEAG	Personal	University of Dresden, Germany	Trans-Campus Professor of Molecular Medicine, in partnership with King's College London	Yes
Farzin Farzeneh	CTBVEAG	Personal	University College London	Honorary Professor of Molecular Medicine	Yes
Farzin Farzeneh	CTBVEAG	Non- Personal	NIL	N/A	N/A
Fergus Rugg- Gunn	NPPEAG	Personal	NIL	N/A	N/A
Fergus Rugg- Gunn	NPPEAG	Non- Personal	NIL	N/A	N/A
Finbar O'Callaghan	Valproate Implementation EWG	Personal	NIL	N/A	N/A
Finbar O'Callaghan	Valproate Implementation EWG	Non- Personal	NIL	N/A	N/A

Geraint Davies	IEAG	Personal	Viiv Healthcare	Research grant (co- investigator, no personal, salary or other benefits)	Yes
Geraint Davies	IEAG	Non- Personal	NIL	N/A	N/A

Additional

**Geraint Davies** 

**IEAG** 

From 2011-2017 I was the academic co-ordinator of the PreDiCT-TB consortium, a public-private partnership funded by the **EU Innovative Medicines** Initiative and the European Federation of Pharmaceutical Industries and Associations. However, though this role involved engagement with industrial partners (GSK, Sanofi, Janssen) in precompetitive areas of research into TB drug development, these activities were fully supported by public funding from the EU and neither myself nor my research institution received any funding from EFPIA or from the individual industrial partners.

Geraint Davies IEAG Additional

Geraint Davies IEAG Additional

Since 2017 I have been an academic partner to the PanACEA clinical trials consortium, funded by the European and Developing **Countries Clinical Trials** Partnership. Though the consortium has involved contact and collaboration with pharmaceutical partners, my role is as a partner without budget supporting the clinical trials site at the College of Medicine in Blantyre, Malawi, Neither myself, the University of Liverpool nor the University of Malawi College of Medicine receive any funding from pharmaceutical collaborators as part of these activities.

Since 2020 I have been an academic partner to the UNITE4TB consortium, a new public-private partnership funded by the EU Innovative Medicines Initiative and the European Federation of Pharmaceutical Industries until 2028. However, though this role involved

NIL

NIL

Gerri

Gerri

Gerri

Mortimore

Mortimore

Mortimore

CHM, Non-

CHM, Non-

Prescribing EWG

CHM, Non-

Prescribing

Medical

**EWG** 

Medical

Medical Prescribing

**EWG** 

Personal

Non-

Personal

Additional

engagement with industrial partners (GSK, Janssen, Evotech) in pre-competitive areas of research into TB drug development, these activities were fully supported by public funding from the EU and neither myself nor my research institution received any funding from EFPIA or from the individual industrial partners.

I have attended expert advisory meetings relating to TB drug development convened by GSK and Janssen for which I received no payment or benefit (honorarium, expenses, hospitality)

N/A

N/A

A member of the BASL non-alcoholic fatty liver SIG and BASL Haemochromatosis SIG,

N/A

N/A

Director of Mortimore
Healthcare Services Itd, a
private practice owned by
immediate family member.
I am not paid a salary from
this account.

Gordon Dougan	COVID-19 VBREWG	Personal	NIL	N/A	N/A
Gordon Dougan	COVID-19 VBREWG	Non- Personal	NIL	N/A	N/A
Graham Buckton	CPSEAG	Personal	SYNTHON	Consultancy	Yes
Graham Buckton	CPSEAG	Personal	ALVOGEN	Consultancy	Yes
Graham Buckton	CPSEAG	Personal	MYLAN	Consultancy	Yes
Graham Buckton	CPSEAG	Personal	AZURITY	Consultancy	Yes
Graham Buckton	CPSEAG	Personal	LUPIN	Consultancy	Yes
Graham Buckton	CPSEAG	Personal	SUN	Consultancy	Yes
Graham Buckton	CPSEAG	Personal	APOTEX	Consultancy	Yes
Graham Buckton	CPSEAG	Personal	TEVA	Consultancy	No

Graham Buckton	CPSEAG	Personal	PADAGIS	Consultancy	Yes
Graham Buckton	CPSEAG	Personal	GLENMARK	Consultancy	Yes
Graham Buckton	CPSEAG	Personal	SANDOZ	Consultancy	No
Graham Buckton	CPSEAG	Personal	ZYDUS	Consultancy	Yes
Graham Buckton	CPSEAG	Personal	AJANTA	Consultancy	Yes
Graham Buckton	CPSEAG	Personal	NOVARTIS	Consultancy	Yes
Graham Buckton	CPSEAG	Non- Personal	NIL	N/A	N/A
Guido Pieles	PMEAG, OHEAG	Personal	Canon Medical Systems	Consultancy	No
Guido Pieles	PMEAG, OHEAG	Non- Personal	Canon Medical Systems	Contractual research partnership (lead researcher for University of Bristol)	No
Hadar Zaman	CPSEAG	Personal	NIL	N/A	N/A
Hadar Zaman	CPSEAG	Non- Personal	NIL	N/A	N/A
Hannah Batchelor	CPSEAG	Personal	NIL	N/A	N/A

Hannah Batchelor	CPSEAG	Non- Personal	UCB	Grant awarded to support a PhD student under my supervision	Yes
Hannah Batchelor	CPSEAG	Non- Personal	GSK	Grant awarded to support a PhD student under my supervision	Yes
Heather Wallace	CHM, PMEAG	Personal	CellProTx	Director	No
Heather Wallace	CHM, PMEAG	Personal	NovaBiotics	Shares less than 0.01% of company	No
Heather Wallace	CHM, PMEAG	Non- Personal	NIL	N/A	N/A
Heather	CHM, PMEAG	Additional			

Wallace

Immediate Past President of EUROTOX. The annual **EUROTOX** conference does attract sponsorship from a number of industries. This pays for the speakers at the conference. I am Chair of Medical Research Scotland. We fund PhD studentships, and each studentship has an external partner organisation (EPO). This can be industry or charity. The relationship is between the student, supervisor and university. Medical Research Scotland

provides funds to the University who funds the student but has no relationship with the student or the EPO. I am the Vice chair of the CONTAM Panel at EFSA where we provide scientific opinions in contaminants in food and feed.

Helen Cross	PEAG, Valproate Implementation EWG	Personal	NIL	N/A	N/A
Helen Cross	PEAG, Valproate Implementation EWG	Non- Personal	NIL	N/A	N/A
Helen Lachmann	CTBVEAG, COVID-19 VBREWG	Personal	Novartis	PI on trial	No
Helen Lachmann	CTBVEAG, COVID-19 VBREWG	Personal	SOBI	Consultancy	No
Helen Lachmann	CTBVEAG, COVID-19 VBREWG	Personal	Medscape	Payment for convening session on AOSD	No
Helen Lachmann	CTBVEAG, COVID-19 VBREWG	Personal	Gyroscope	Novartis bought company of which family member was a cofounder (we hold no shares)	No

Helen Lachmann	CTBVEAG, COVID-19 VBREWG	Personal	Uptodate	Section editor for AA amyloidosis – paid share of royalties each year	No
Helen Lachmann	CTBVEAG, COVID-19 VBREWG	Non- Personal	SOBI	I lead the NHS unit which is the largest user in the UK (for treatment of auto inflammatory diseases)	No
Helen Lachmann	CTBVEAG, COVID-19 VBREWG	Non- Personal	NOVARTIS	I lead the NHS unit which is the largest user in the UK (for treatment of auto inflammatory diseases)	No
Helen Lachmann	CTBVEAG, COVID-19 VBREWG	Non- Personal	Alnylam	I lead the NHS unit which is the largest user in the UK (for treatment of hTTR amyloid)	No
Helen Lachmann	CTBVEAG, COVID-19 VBREWG	Non- Personal	Ackea therapeutics	I lead the NHS unit which is the largest user in the UK (for treatment of hTTR amyloid)	No
Hilary Shenton	IEAG	Personal	NIL	N/A	N/A
Hilary Shenton	IEAG	Non- Personal	NIL	N/A	N/A
Hoo Kee Tsang	NPP EAG	Personal	Bristol NHS trust sponsored research	Principle investigator for Liverpool University NHS Trust study site	N/A
Hoo Kee Tsang	NPP EAG	Non- Personal	NIL	N/A	N/A

Hugo Ford	OHEAG	Personal	NIL	N/A	N/A	
Hugo Ford	OHEAG	Non- Personal	NIL	N/A	N/A	
Hugo Ford	OHEAG	Additional				Immediate family member is the Member of Parliament and former Government Minister, but they have not had any direct or indirect interests in the pharmaceutical industry.
lan Douglas	PEAG	Personal	GlaxoSmithKline	Shares	Yes	
lan Douglas	PEAG	Non- Personal	GlaxoSmithKline	Research Grants	Yes	
lan Douglas	PEAG	Non- Personal	AstraZeneca	Research Grants	Yes	
Jacqueline McMurtrie	PMEAG	Personal	NIL	N/A	N/A	
Jacqueline McMurtrie	PMEAG	Non- Personal	NIL	N/A	N/A	
Jacqueline McMurtrie	PMEAG	Additional	WRK Orthopedics		Yes	Director at immediate family member's private practice. Neither of us have any affiliation with any pharmaceutical or medical appliance companies.
James Spicer	OHEAG	Personal	Epsilogen Ltd	Founding minority shareholder	Yes	

James Spicer	OHEAG	Conference /Scientific Meetings	MSD	ASCO - Expenses	Yes
James Spicer	OHEAG	Conference /Scientific Meetings	BMS	ASCO - Expenses	No
James Spicer	OHEAG	Non- Personal	Achilles	Reimbursement to my institution for recruitment to clinical trial	Yes
James Spicer	OHEAG	Non- Personal	BergenBio	Reimbursement to my institution for recruitment to clinical trial	Yes
James Spicer	OHEAG	Non- Personal	Gilead	Reimbursement to my institution for recruitment to clinical trial	Yes
James Spicer	OHEAG	Non- Personal	GSK	Reimbursement to my institution for recruitment to clinical trial	Yes
James Spicer	OHEAG	Non- Personal	IO Biotech	Reimbursement to my institution for recruitment to clinical trial	Yes
James Spicer	OHEAG	Non- Personal	MSD	Reimbursement to my institution for recruitment to clinical trial	Yes
James Spicer	OHEAG	Non- Personal	Roche	Reimbursement to my institution for recruitment to clinical trial	Yes
James Spicer	OHEAG	Non- Personal	RS Oncology	Reimbursement to my institution for recruitment to clinical trial	Yes

James Spicer	OHEAG	Non- Personal	SeaGen	Reimbursement to my institution for recruitment to clinical trial	Yes
James Spicer	OHEAG	Non- Personal	Starpharma	Reimbursement to my institution for recruitment to clinical trial	Yes
James Spicer	OHEAG	Non- Personal	Apobec	Reimbursement to my institution for recruitment to clinical trial	Yes
James Spicer	OHEAG	Non- Personal	AstraZeneca	Reimbursement to my institution for recruitment to clinical trial	Yes
James Spicer	OHEAG	Non- Personal	BMS	Reimbursement to my institution for recruitment to clinical trial	Yes
James Spicer	OHEAG	Non- Personal	Avacta	Reimbursement to my institution for recruitment to clinical trial	Yes
James Spicer	OHEAG	Non- Personal	Roche	Reimbursement to my institution for recruitment to clinical trial	Yes
Jamie Coleman	CHM, PEAG	Personal	NIL	N/A	N/A
Jamie Coleman	CHM, PEAG	Non- Personal	NIL	N/A	N/A
Jamie Fraser	CHM, Non- Medical Prescribing EWG	Personal	NIL	N/A	N/A

Jamie Fraser	CHM, Non- Medical Prescribing EWG	Non- Personal	NIL	N/A	N/A
Janet Brown	OHEAG	Personal	NIL	N/A	N/A
Janet Brown	OHEAG	Non- Personal	NIL	N/A	N/A
Jayesh Bhatt	PMEAG	Personal	Sanofi	RSV Advisory Board	No
Jayesh Bhatt	PMEAG	Non- Personal	Astra Zeneca	Principle Investigator	No
Jayesh Bhatt	PMEAG	Non- Personal	Astra Zeneca	Chief Investigator	Yes
Jayesh Bhatt	PMEAG	Non- Personal	Enanta Pharmaceuticals, Inc.	Principle Investigator	Yes
Jonathan Friedland	CHM, COVID- 19 Therapeutic EWG, IEAG	Personal	NIL	N/A	N/A
Jonathan Friedland	CHM, COVID- 19 Therapeutic EWG, IEAG	Non- Personal	Astra Zeneca	The commercial company is a sponsor / funder of research at St. George's, University of London which does not involve me (and of which I am generally unaware of the topic)	Yes
Jonathan Friedland	CHM, COVID- 19 Therapeutic EWG, IEAG	Non- Personal	Attune Medical Inc	As above	No

Jonathan Friedland	CHM, COVID- 19 Therapeutic EWG, IEAG	Non- Personal	Beckman Coulter	As above	No
Jonathan Friedland	CHM, COVID- 19 Therapeutic EWG, IEAG	Non- Personal	Boston Scientific	As above	No
Jonathan Friedland	CHM, COVID- 19 Therapeutic EWG, IEAG	Non- Personal	Chiesi Limited	As above	Yes
Jonathan Friedland	CHM, COVID- 19 Therapeutic EWG, IEAG	Non- Personal	Fondazione PENTA ONLUS	As Above	Yes
Jonathan Friedland	CHM, COVID- 19 Therapeutic EWG, IEAG	Non- Personal	Gilead Sciences Ltd.	As above	Yes
Jonathan Friedland	CHM, COVID- 19 Therapeutic EWG, IEAG	Non- Personal	GlaxoSmithKline	As above	Yes
Jonathan Friedland	CHM, COVID- 19 Therapeutic EWG, IEAG	Non- Personal	Knopp Biosciences	As above	No
Jonathan Friedland	CHM, COVID- 19 Therapeutic EWG, IEAG	Non- Personal	Merck Sharpe & Dohme Ltd	As above	No
Jonathan Friedland	CHM, COVID- 19 Therapeutic EWG, IEAG	Non- Personal	Minerva X	As above	No

Jonathan Friedland	CHM, COVID- 19 Therapeutic EWG, IEAG	Non- Personal	Novovax Inc	As above	No
Jonathan Friedland	CHM, COVID- 19 Therapeutic EWG, IEAG	Non- Personal	Pfizer UK / Global / USA	As above	Yes
Jonathan Friedland	CHM, COVID- 19 Therapeutic EWG, IEAG	Non- Personal	Shockwave Medical Incorporated	As above	No
Jonathan Friedland	CHM, COVID- 19 Therapeutic EWG, IEAG	Non- Personal	SPD Development Co Ltd	As above	No
Jonathan Friedland	CHM, COVID- 19 Therapeutic EWG, IEAG	Non- Personal	St Jude Medical, AFD Inc.	As above	No
Jonathan Friedland	CHM, COVID- 19 Therapeutic EWG, IEAG	Non- Personal	Takeda UK Ltd	As above	No
Judith Breuer	COVID-19 VBREWG	Personal	GSK	CI on a GSK sponsored study commissioned by MHRA to understand emergence of sotrovimab resistance mutations in sars cov 2	Yes
Judith Breuer	COVID-19 VBREWG	Non- Personal	NIL	N/A	N/A
Julia Cons	CHM	Personal	NIL	N/A	N/A
Julia Cons	CHM	Non- Personal	NIL	N/A	N/A

Julia Cons CHM Additional

I am vice chair of the Ministry of Defence Research Ethics Committee. I think a conflict of interests is extremely unlikely to arise. However, if any opportunity were to arise for any perceived conflict, I would absent myself from any discussions. I am Independent Chair of NHS England's Individual Funding Request Panel. I see no obvious opportunity for a conflict of interests to arise.

Management of Acne Guideline Committee until. The Guideline published in June 2021 so I see no opportunity for a conflict of interests to arise. I was a member and deputy chair of the NICE Self-harm: Assessment, Management and Preventing Recurrence Guideline Committee. The Guideline published in July 2022 so I see no opportunity for a conflict of interests to arise.

I chaired the NICE

Julia Prague	MWH EAG	Personal	AstraZeneca Synairgen Sareum Holdings GSK Haleon	Immediate family member has very minor shareholding	Yes	
Julia Prague	MWH EAG	Non- Personal	NIL	N/A	N/A	
Julia Prague	MWH EAG	Additional				I am an Associate Editor of Endocrine Related Cancer Journal (not associated with any financial remuneration)
Karen Miller	PEAG, Non- Medical Prescribing EWG	Personal	NIL	N/A	N/A	
Karen Miller	PEAG, Non- Medical Prescribing EWG	Non- Personal	NIL	N/A	N/A	
Karen Provan	Emergency Contraception Ad Hoc Stakeholder Group	Personal	NIL	N/A	N/A	
Karen Provan	Emergency Contraception Ad Hoc Stakeholder Group	Non- Personal	NIL	N/A	N/A	

Kate Campbell	Emergency Contraception Ad Hoc Stakeholder Group	Personal	NIL	N/A	N/A
Kate Campbell	Emergency Contraception Ad Hoc Stakeholder Group	Non- Personal	NIL	N/A	N/A
Kathryn Johnson	PMEAG	Personal	NIL	N/A	N/A
Kathryn Johnson	PMEAG	Non- Personal	NIL	N/A	N/A
Kenneth Baillie	COVID-19 Therapeutic EWG	Personal	NIL	N/A	N/A
Kenneth Baillie	COVID-19 Therapeutic EWG	Conference /Scientific Meetings	International Sepsis Forum (an industry- funded advocacy group)	Sepsis 2022 - Travel and accommodation	No
Kenneth Baillie	COVID-19 Therapeutic EWG	Non- Personal	NIL	N/A	N/A
Kenneth Hodson	MWHEAG	Personal	NIL	N/A	N/A
Kenneth Hodson	MWHEAG	Non- Personal	Pfizer	Local primary investigator for a study investigating the efficacy and safety of Pfizer-BioNTech vaccine in pregnancy.	Yes

Kevin Taylor	COVID-19 VBREWG, CPSEAG, Emergency Contraception Ad Hoc Stakeholder Group	Personal	NIL	N/A	N/A
Kevin Taylor	COVID-19 VBREWG, CPSEAG, Emergency Contraception Ad Hoc Stakeholder Group	Non- Personal	NIL	N/A	N/A
Kim Morley	Valproate Implementation EWG	Personal	NIL	N/A	N/A
Kim Morley	Valproate Implementation EWG	Non- Personal	NIL	N/A	N/A
Kimme Hyrich	COVID-19 VBREWG	Personal	NIL	N/A	N/A
Kimme Hyrich	COVID-19 VBREWG	Non- Personal	Abbvie	Speaker's fees for speaking at educational meeting about treatment decision making and managing risk in inflammatory arthritis. Fees paid to my institution.	No

Kimme Hyrich	COVID-19 VBREWG	Non- Personal	Bristol Myers Squibb	Co-investigator on investigator-initiated grant looking at role of autoantibodies in response to treatment in rheumatoid arthritis.  Grant paid to institution	No
Kimme Hyrich	COVID-19 VBREWG	Non- Personal	Pfizer	Co-investigator on Aspire UK grant studying adherence to tofacitinib in patients with rheumatoid arthritis. Grant paid to my institution.	No
Kirstie Shearman	CTBV EAG	Personal	NIL	N/A	N/A
Kirstie Shearman	CTBV EAG	Non- Personal	NIL	N/A	N/A
Laurie Tomlinson	MWHEAG	Personal	NIL	N/A	N/A
Laurie Tomlinson	MWHEAG	Non- Personal	Bayer	I was an external consultant for a real world evidence study about chronic kidney disease. Payment was to department.	No
Laurie Tomlinson	MWHEAG	Non- Personal	GSK	I participate in a collaboration between GSK and my department where they fund research PhD students and a post-doc to	Yes

				methodology for developing real-world evidence. I receive no personal payment.	
Laurie Tomlinson	MWHEAG	Non- Personal	GSK	I was a collaborator on a grant funded by GSK NCD OpenLAB aimed at investigating the prevalence of kidney disease in sub-Saharan Africa.	No
Lim Jones	IEAG	Personal	Shionogi	Expenses for chairing an industry sponsored educational workshop	No
Lim Jones	IEAG	Personal	Menarini	Consultancy	No
Lim Jones	IEAG	Non- Personal	NIL	N/A	N/A
Linda Pepper	MWHEAG	Personal	NIL	N/A	N/A
Linda Pepper	MWHEAG	Non- Personal	NIL	N/A	N/A
Linda Pepper	MWHEAG	Additional			

I am a lay examiner with RCOG MRCOG exams I am a member of RCOG Invited Reviews team I am a member of RCOG Women's Voices Involvement Panel (WVIP) I am a public governor with

conduct research aimed

at improving

Lisa Brownell	NPPEAG	Personal	NIL	N/A	N/A
Lisa Brownell	NPPEAG	Non- Personal	NIL	N/A	N/A
Louis Grandjean	IEAG	Personal	Pfizer	Consultancy	Yes
Louis Grandjean	IEAG	Conference s/Scientific Meetings	Gilead	START Meeting - Conference support (organizing conference)	No
Louis Grandjean	IEAG	Conference /Scientific Meetings	Pfizer	START Meeting - Conference support (organizing conference)	No
Louis Grandjean	IEAG	Non- Personal	NIL	N/A	N/A
Lucy Kinton	Valproate Implementation EWG	Personal	NIL	N/A	N/A
Lucy Kinton	Valproate Implementation EWG	Non- Personal	NIL	N/A	N/A
Lucy Mackillop	MWH EAG	Personal	Sensyne Health plc	Paid employee and shareholder	No
Lucy Mackillop	MWH EAG	Personal	NIHR Oxford Biomedical Research Centre	Paid 1 session a week	No

Lucy Mackillop	MWH EAG	Personal	Oxford University Innovation	Payment for royalties	No	
Lucy Mackillop	MWH EAG	Personal	EMIS group plc	Paid employee	Yes	
Lucy Mackillop	MWH EAG	Conference /Scientific Meetings	Hatter Institute	Hatter Cardiovascular Institute Horizon GP meeting - Honorarium	No	
Lucy Mackillop	MWH EAG	Non- Personal	NIL	N/A	N/A	
Madeleine Wang	COVID-19 VBREWG, PEAG	Personal	NIL	N/A	N/A	
Madeleine Wang	COVID-19 VBREWG, PEAG	Non- Personal	NIL	N/A	N/A	
Majella Lane	CPSEAG	Personal	NIL	N/A	N/A	
Majella Lane	CPSEAG	Non- Personal	NIL	N/A	N/A	
Majella Lane	CPSEAG	Additional				I have established a consultancy company called Melderm Ltd. The company provides expert witness services for patent litigation cases in the United States and Europe.
Malcolm Macleod	CHM, NPPEAG	Personal	NIL	N/A	N/A	

Malcolm Macleod	CHM, NPPEAG	Non- Personal	NIL	N/A	N/A
Marc Turner	CHM, COVID- 19 VBREWG, CTBVEAG	Personal	NIL	N/A	N/A
Marc Turner	CHM, COVID- 19 VBREWG, CTBVEAG	Non- Personal	NIL	N/A	N/A
Mark Evans	CDRRA EAG	Personal	Abbott Diabetes Care	Speakers fees	No
Mark Evans	CDRRA EAG	Personal	NovoNordisk	Speakers fees	No
Mark Evans	CDRRA EAG	Personal	Eli Lilly	Speakers fees	No
Mark Evans	CDRRA EAG	Personal	Pila Pharma	Advisory board	No
Mark Evans	CDRRA EAG	Personal	Zucara	Advisory board	No
Mark Evans	CDRRA EAG	Personal	Dexcom	Advisory board	No
Mark Evans	CDRRA EAG	Conference /Scientific Meetings	Eli Lilly	UKCDF conference - Speaker and attendee (travel, registration and hotel costs)	No
Mark Evans	CDRRA EAG	Non- Personal	Abbott Diabetes Care	Research collaboration through EU Horizon 2020 project	No

Mark Evans	CDRRA EAG	Non- Personal	NovoNordisk	Research collaboration through EU Horizon 2020 project and a Case PhD studentship Phase 3 triallist	No
Mark Evans	CDRRA EAG	Non- Personal	Imcyse	Triallist	No
Mark Evans	CDRRA EAG	Non- Personal	Novartis	Planned triallist	No
Mark Evans	CDRRA EAG	Non- Personal	ITB-Medical	Planned triallist	No
Mark Evans	CDRRA EAG	Non- Personal	Sanofi	Planned triallist	No
Mark Glover	PEAG	Personal	NIL	N/A	N/A
Mark Glover	PEAG	Non- Personal	NIL	N/A	N/A
Martin Wilson	CHM, Non- Medical Prescribing EWG, Valproate Implementation EWG	Personal	NIL	N/A	N/A
Martin Wilson	CHM, Non- Medical Prescribing EWG, Valproate	Non- Personal	NIL	N/A	N/A

Implementation	
EWG	

Matthias	IEAG	Personal	NIL	N/A	N/A
Schmid					
Matthias Schmid	IEAG	Non- Personal	NIL	N/A	N/A
Meriel Jenney	PMEAG	Personal	Bayer	I am chief investigator for an international clinical trial – the Frontline and Relapse study in Rhabdomyosarcoma (the FaR-RMS trial). We have recently opened the relapse arm of the study where we have a contract with BAYER as the trial is part of their regorafenib PIP. I have no personal interests, however the funding provided by Bayer fully supports the trial though trial running and drug costs.	No
Meriel Jenney	PMEAG	Non- Personal	NIL	N/A	N/A
Michael Ardern-Jones	GRIDEAG	Personal	AbbVie	Consultancy, Speaker, Expenses, Advisory board fees	Yes

Michael Ardern-Jones	GRIDEAG	Personal	Almirall	Consultancy, Speaker, Expenses, Advisory board fees	No
Michael Ardern-Jones	GRIDEAG	Personal	Galderma	Consultancy, Speaker, Expenses, Advisory board fees	No
Michael Ardern-Jones	GRIDEAG	Personal	Janssen	Consultancy, Speaker, Expenses, Advisory board fees	No
Michael Ardern-Jones	GRIDEAG	Personal	Leo Pharma	Consultancy, Speaker, Expenses, Advisory board fees	Yes
Michael Ardern-Jones	GRIDEAG	Personal	Lilly	Consultancy, Speaker, Expenses, Advisory board fees	No
Michael Ardern-Jones	GRIDEAG	Personal	Novartis	Consultancy, Speaker, Expenses, Advisory board fees	No
Michael Ardern-Jones	GRIDEAG	Personal	Pfizer	Consultancy, Speaker, Expenses, Advisory board fees	Yes
Michael Ardern-Jones	GRIDEAG	Personal	Sanofi-Genzyme	Consultancy, Speaker, Expenses, Advisory board fees	No
Michael Ardern-Jones	GRIDEAG	Personal	Regeneron	Consultancy, Speaker, Expenses, Advisory board fees	Yes
Michael Ardern-Jones	GRIDEAG	Personal	UCB	Consultancy, Speaker, Expenses, Advisory board fees	Yes

Michael Ardern-Jones	GRIDEAG	Conference /Scientific Meetings	Sponsored by Janssen	American Academy of Dermatology Annual congress - Expenses	No	
Michael Ardern-Jones	GRIDEAG	Conference /Scientific Meetings	Sponsored by Almirall	British Assoc Dermatology Annual congress - Expenses	No	
Michael Ardern-Jones	GRIDEAG	Conference /Scientific Meetings	Sponsored by Galderma	European Academy of Dermato Venerology Annual Congress - Expenses	No	
Michael Ardern-Jones	GRIDEAG	Non- Personal	Almirall	UHS Commercial clinical trial	No	
Michael Ardern-Jones	GRIDEAG	Non- Personal	Abbvie	UHS Commercial clinical trial	No	
Michael Ardern-Jones	GRIDEAG	Non- Personal	Leo Pharma	UHS Commercial clinical trial	No	
Michael Ardern-Jones	GRIDEAG	Non- Personal	Amgen	UHS Commercial clinical trial	No	
Michael Ardern-Jones	GRIDEAG	Additional	Unilever			Biotechnology and Biological Sciences Research Council iCASE industrial studentships have been funded at my institution with Unilever. I supervised PhDs.
Michael Jacobs	COVID-19 Therapeutic EWG, COVID- 19 VBREWG	Personal	NIL	N/A	N/A	

Michael Jacobs	COVID-19 Therapeutic EWG, COVID- 19 VBREWG	Non- Personal	NIL	N/A	N/A
Michael Steiner	CDRRA EAG	Personal	NIL	N/A	N/A
Michael Steiner	CDRRA EAG	Non- Personal	NIL	N/A	N/A
Michael Threadgill	CPSEAG	Personal	NIL	N/A	N/A
Michael Threadgill	CPSEAG	Non- Personal	NIL	N/A	N/A
Morris Zwi	PMEAG	Personal	NIL	N/A	N/A
Morris Zwi	PMEAG	Non- Personal	NIL	N/A	N/A
Munir Pirmohamed	CHM, COVID- 19 Therapeutic EWG, COVID- 19 VBREWG, COVID-19 VSSMEAG	Personal	NIL	N/A	N/A
Munir Pirmohamed	CHM, COVID- 19 Therapeutic EWG, COVID- 19 VBREWG, COVID-19 VSSMEAG	Non- Personal	Astra Zeneca/EPSRC	Research grant to UOL to support PhD studentship in drug interactions	Yes

Munir Pirmohamed	CHM, COVID- 19 Therapeutic EWG, COVID- 19 VBREWG, COVID-19 VSSMEAG	Non- Personal	BMS (Bristol Myers Squibb)	Unrestricted educational grant to UOL to support UK Pharmacogenetics and Stratified Medicine network open meeting	Yes
Munir Pirmohamed	CHM, COVID- 19 Therapeutic EWG, COVID- 19 VBREWG, COVID-19 VSSMEAG	Non- Personal	Eli Lilly	Research grant to University of Liverpool (UoL) to support clinical training fellowships jointly with the Medical Research Council (MRC)	Yes
Munir Pirmohamed	CHM, COVID- 19 Therapeutic EWG, COVID- 19 VBREWG, COVID-19 VSSMEAG	Non- Personal	Novartis	Research grant to UoL to support clinical training fellowships jointly with MRC	Yes
Munir Pirmohamed	CHM, COVID- 19 Therapeutic EWG, COVID- 19 VBREWG, COVID-19 VSSMEAG	Non- Personal	Roche	Research grant to UoL to support clinical training fellowships jointly with MRC	Yes
Munir Pirmohamed	CHM, COVID- 19 Therapeutic EWG, COVID- 19 VBREWG, COVID-19 VSSMEAG	Non- Personal	UCB Pharma	Research grant to UoL to support clinical training fellowships jointly with MRC	Yes

Munir Pirmohamed	CHM, COVID- 19 Therapeutic EWG, COVID- 19 VBREWG, COVID-19 VSSMEAG	Non- Personal	Simed Global
Munir Pirmohamed	CHM, COVID- 19 Therapeutic EWG, COVID- 19 VBREWG, COVID-19 VSSMEAG	Additional	

No personal financial remuneration Advisor

Yes

I am part of the IMI Consortium called ARDAT (https://ardat.org/). As is well known, this is partnership funding for research through the EU Commission, with academic partners like myself receiving funding via the EU (to the University of Liverpool), while Industry partners provide their expertise as an in-kind contribution. The companies involved in the IMI programme are: Pfizer, Bayer, Janssen Pharmaceutica NV, Lonza AG, Novartis, Novo Nordisk, Sanofi-Aventis, Spark Therapeutics, Inc., Takeda Pharmaceuticals International AG, Viscofan SA, Astellas Pharma Europe BV. These are declared as NP/NS when any of their products come

up on the agenda.

Naomi Fineberg	NPPEAG, Valproate Implementation EWG	Personal	NIL	N/A	N/A
Naomi Fineberg	NPPEAG, Valproate Implementation EWG	Conference s/Scientific Meetings	British Association for Psychopharmacology	British Association for Psychopharmacology public lecture – Expenses Paid	Yes
Naomi Fineberg	NPPEAG, Valproate Implementation EWG	Conference s/Scientific Meetings	European College of Neuropsychopharmacolo gy	European College of Neuropsychopharmacol ogy Annual Congress - Expenses Paid	Yes
Naomi Fineberg	NPPEAG, Valproate Implementation EWG	Conference s/Scientific Meetings	Lisbon Addictions	Expenses	Yes
Naomi Fineberg	NPPEAG, Valproate Implementation EWG	Conference s/Scientific Meetings	British Association for Psychopharmacology	British Association for Psychopharmacology Masterclass - expenses paid	Yes
Naomi Fineberg	NPPEAG, Valproate Implementation EWG	Non- Personal	Biohaven	Corporate Membership fees were paid to the International College of Obsessive-Compulsive Spectrum Disorders (ICOCS), a medical charity, of which I am the Secretary	No
Naomi Fineberg	NPPEAG, Valproate	Additional			

Implementation EWG

I work as a clinical lead of an NHS England Service PROVIDING pharmacological treatment

for obsessive compulsive disorders.

I act as an unpaid medical adviser and trustee to National Consumer Charities for OCD and related disorders.

I chair the World Psychiatric Association Scientific section on anxiety, OCD and related disorders.

I have contributed to the current British Association for Psychopharmacology (BAP) treatment guidelines for anxiety disorders (2014) and the NICE treatment guidelines including the most recent update (2013).

I chair the External Review Board of the European College of Neuropsychopharmacology (ECNP).

I am secretary of the International College of Obsessive-Compulsive spectrum Disorders (ICOCS), which has received corporate

Naomi NPPEAG, Additional Fineberg Valproate

Implementation

**EWG** 

Naomi NPPEAG, Additional

Fineberg Valproate

Implementation

**EWG** 

Naomi NPPEAG, Additional

Fineberg Valproate Implementation

FWG

Naomi NPPEAG, Additional

Fineberg Valproate

**Implementation** 

EWG

Naomi NPPEAG, Additional

Fineberg Valproate

Implementation

**EWG** 

membership fees from Biohaven.

I have received reseach grants from the NIHR and HORIZON 2020 (cost).

I receive an honorarium from Elsevier for editorial duties for the Journal Comprehensive Psychiatry. I have received honoraria for educational lectures on diagnosis from the Global Mental Health Academy.

I am a board member of the Consumer Charity Orchard (registered charity No: 1174480). i have received reimbursement for personal expenses for giving lectures at national and international meetings of various academic bodies in non-industry sponsored symposia.

Naomi NPPEAG, Additional Fineberg Valproate

Implementation EWG

Naomi NPPEAG, Additional Fineberg Valproate

Implementation

EWG

Naomi NPPEAG, Additional Fineberg Valproate Implementation EWG

Neil French COVID-19 Personal Glaxo Smith VBREWG Kline

As a named Investigator, Yes I hold an award from Glaxo Smith Kline in relation to the 6 of 11 evaluation of the effectiveness of RTS'S

				malaria vaccine in Malawi.	
Neil French	COVID-19 VBREWG	Personal	Seqirus	As a named Investigator, I hold an award from Seqirus to evaluate influenza and influenza vaccination in the UK population using data science.	Yes
Neil French	COVID-19 VBREWG	Non- Personal	NIL	N/A	N/A
Nidhi Sofat	GRIDEAG	Personal	Paradigm Pharmaceuticals	Investigator in Clinical Trial	No
Nidhi Sofat	GRIDEAG	Personal	Bristol Myers Squibb	Grant	No
Nidhi Sofat	GRIDEAG	Non- Personal	NIL	N/A	N/A
Nigel Klein	COVID-19 Therapeutic EWG, PMEAG	Personal	NIL	N/A	N/A
Nigel Klein	COVID-19 Therapeutic EWG, PMEAG	Non- Personal	NIL	N/A	N/A
Pallav Shah	CDRRA EAG	Personal	Olympus	Consultancy	No
Pallav Shah	CDRRA EAG	Personal	Pulmonx	Consultancy/ Lecture	No
Pallav Shah	CDRRA EAG	Non- Personal	ERBE	Sponsor Imperial college for bronchoscopy course	No

Pallav Shah	CDRRA EAG	Non- Personal	Medtronic	Sponsor Imperial college for bronchoscopy course	No
Pallav Shah	CDRRA EAG	Non- Personal	Olympus	Sponsor Imperial college for bronchoscopy course	No
Pallav Shah	CDRRA EAG	Non- Personal	PneumRX/BT	Sponsor Imperial college for bronchoscopy course	No
Pallav Shah	CDRRA EAG	Non- Personal	Pulmonx	Sponsor Imperial college for bronchoscopy course	No
Pallav Shah	CDRRA EAG	Non- Personal	Boston Scientific	Sponsor Imperial college for bronchoscopy course	No
Pallav Shah	CDRRA EAG	Non- Personal	Nuvaria	Sponsor Imperial college for bronchoscopy course	No
Pallav Shah	CDRRA EAG	Non- Personal	Broncus	Sponsor Imperial college for bronchoscopy course	No
Pallav Shah	CDRRA EAG	Non- Personal	Pulmonx	RCT with endobronchial valves - Royal Brompton Hospital reimbursed for clinical trial expenses	No
Pallav Shah	CDRRA EAG	Non- Personal	Nuvaira	RCT with vagal nerve ablation - Royal Brompton Hospital and Chelsea & Westminster Hospital reimbursed for clinical trial expenses	No
Pallav Shah	CDRRA EAG	Non- Personal	CSA	RCT with RejuvenAir Chelsea & Westminster Hospital reimbursed for clinical trial expenses	No

Patrick Holmes	CDRRA EAG	Personal	AstraZeneca	Speaker Fees	No
Patrick Holmes	CDRRA EAG	Personal	Boehringer Ingelheim	Consultancy Fee	No
Patrick Holmes	CDRRA EAG	Personal	Lilly	Speaker Fees	No
Patrick Holmes	CDRRA EAG	Personal	NovoNordisk	Speaker Fees	No
Patrick Holmes	CDRRA EAG	Non- Personal	NIL	N/A	N/A
Patrick Mark	CDRRA EAG	Personal	AstraZeneca	Consultancy	No
Patrick Mark	CDRRA EAG	Personal	Boehringer Ingelheim	Consultancy	No
Patrick Mark	CDRRA EAG	Personal	GSK	Consultancy	No
Patrick Mark	CDRRA EAG	Personal	Otuska	Lecture Fee	No
Patrick Mark	CDRRA EAG	Conference /Scientific Meetings	Pharmacosmos	Iron meeting RCP Glasgow - Lecture Fee	No
Patrick Mark	CDRRA EAG	Conference /Scientific Meetings	Otsuka	Symposium at European Renal Association - Lecture Fee	No
Patrick Mark	CDRRA EAG	Conference /Scientific Meetings	AstraZeneca	Hong Kong Cardiovascular meeting virtual - Lecture Fee	No
Patrick Mark	CDRRA EAG	Non- Personal	NIL	N/A	N/A

Paul Dargan	CHM	Personal	Glaxo Smith Klein	I was a member of the GSK Global Pain Faculty until May 2022. I provided general advice on the toxicity of analgesic products. the last meeting that I attended, and the last time that i provided any advice to this group, was a virtual meeting in December 2020. I resigned from this group on 21 May 2022 after my interview for, and prior to my appointment to CHM.	No
Paul Dargan	СНМ	Non- Personal	Janssen	I am the PI within my hospital for the Janssen EMSEMBLE2 COVID-19 vaccine study [VAC31518COV3009]. All funding for this study comes to my hospital.	Yes
Paul Dargan	СНМ	Non- Personal	AstraZeneca	I was the PI within my hospital for the AstraZeneca D7220C00001 (AZD2816) COVID-19 Vaccine Trial. All funding for this study came to my hospital.	No

Paul Dargan	CHM	Non- Personal	Moderna
Paul Dargan	CHM	Additional	
Paul Dargan	СНМ	Additional	

I am the PI within my hospital for the Moderna mRNA-1273-P305
COVID-19 vaccine study. All funding for this study comes to my hospital.

I am the Chair of the Royal College of Emergency Medicine and National Poisons Information Service Antidote Guidelines Group which oversees advice to hospitals in England for the stocking of antidotes; I have Chaired this group since 2008. This group provides advice on the amount of antidote to be stocked by hospitals and the time-frame that the antidotes should be available. The advice is based on the published literature and there is no liaison with the pharmaceutical industry in relation to the guidance published by this group.

**EAPCCT President Elect: I** 

Paul Dargan CHM Additional

## (EAPCCT:

http://www.eapcct.org/) – my term as President will be 2024-2026. The EAPCCT is the European Clinical Toxicology Society and its main role is to organise the annual European Toxicology Conference "with the specific goal of advancing knowledge and understanding of the diagnosis and treatment of all forms of poisoning".

I am an expert adviser on clinical toxicology to the World Health Organisation - this has predominantly involved advising on issues in relation to lead and mercury poisoning. I have contributed to WHO monographs and guidelines for lead and mercury poisoning. I gave the introductory lecture at the launch of the WHO Lead Poisoning Management Guidelines in October 2021.

Paul Dargan	СНМ	Additional			
Paul Dargan	СНМ	Additional			
Paul Lehner	COVID-19 VBREWG	Personal	NIL	N/A	N/A
Paul Lehner	COVID-19 VBREWG	Non- Personal	NIL	N/A	N/A
Philip Boyle	Emergency Contraception Ad Hoc Stakeholder Group	Personal	NIL	N/A	N/A
Philip Boyle	Emergency Contraception Ad Hoc Stakeholder Group	Non- Personal	NIL	N/A	N/A
Philip Hannaford	MWHEAG	Personal	NIL	N/A	N/A
Philip Hannaford	MWHEAG	Non- Personal	NIL	N/A	N/A
Portia Jackson	Emergency Contraception Ad Hoc Stakeholder Group	Personal	Gilead	Payment for delivery of session on the Role of the Pharmacist in identifying drug-drug interactions.	No

I am on the Senior Editorial

Immediate family member is a practising NHS GP

Board of Clinical Toxicology and the International Editorial Board of British Journal of Clinical Pharmacology.

Portia Jackson	Emergency Contraception Ad Hoc Stakeholder Group	Personal	Gilead	Payment for participation on Digital Advisory Board regarding the national procurement of HIV treatment.	No
Portia Jackson	Emergency Contraception Ad Hoc Stakeholder Group	Non- Personal	NIL	N/A	N/A
Poulam Patel	CHM, OHEAG	Personal	NIL	N/A	N/A
Poulam Patel	CHM, OHEAG	Non- Personal	Astra Zeneca	Collaboration on research project and prospective phase 1 trial where AZ are providing drug to be added during preparation of dendritic cell vaccine	Yes
Poulam Patel	CHM, OHEAG	Non- Personal	BMS	Local PI for multicentre company sponsored trial	Yes
Poulam Patel	CHM, OHEAG	Non- Personal	Merck	Local PI for multicentre company sponsored trial	Yes
Poulam Patel	CHM, OHEAG	Non- Personal	Pfizer	Co Investigator/Co- supervisor for translational research project into hepatotoxicity. Project part funded by educational grant from Pfizer	Yes

Poulam Patel	CHM, OHEAG	Non- Personal	Pfizer	Local PI for multicentre company sponsored trial	Yes
Poulam Patel	CHM, OHEAG	Non- Personal	Scancell	Co- supervisor for translational research project into hepatotoxicity. Project part funded by grant from Scancell	Yes
Poulam Patel	CHM, OHEAG	Non- Personal	Scancell	Chief Investigator for company sponsored clinical trial	Yes
Poulam Patel	CHM, OHEAG	Non- Personal	Scancell	Local PI for multicentre company sponsored trial	No
Rachel Tribe	MWH EAG	Personal	NIL	N/A	N/A
Rachel Tribe	MWH EAG	Non- Personal	Mirvie Inc.	Funding for a collaboration on cell free RNA for prediction of pregnancy problems	Yes
Rachel Tribe	MWH EAG	Non- Personal	Evolve Biosystems	Grant funding	No
Ravishankar Sargur	GRIDEAG	Personal	NIL	N/A	N/A
Ravishankar Sargur	GRIDEAG	Non- Personal	NIL	N/A	N/A
Rebecca Kristeleit	OHEAG	Personal	Basilea	Consultancy	Yes
Rebecca Kristeleit	OHEAG	Personal	Amphista	Consultancy	Yes

Rebecca Kristeleit	OHEAG	Personal	Astra Zeneca	Consultancy	Yes
Rebecca Kristeleit	OHEAG	Personal	Clovis	Consultancy	Yes
Rebecca Kristeleit	OHEAG	Personal	Roche	Consultancy	Yes
Rebecca Kristeleit	OHEAG	Personal	GSK	Consultancy	Yes
Rebecca Kristeleit	OHEAG	Non- Personal	Various	Academic and Commercial Clinical Trial Programme with payments for trial work given to my Institution	Yes
Rebecca Mann	CHM	Personal	NIL	N/A	N/A
Rebecca Mann	СНМ	Non- Personal	Sanofi	No remunerated PI	No
Rebecca Shephard	Emergency Contraception Ad Hoc Stakeholder Group	Personal	NIL	N/A	N/A
Rebecca Shephard	Emergency Contraception Ad Hoc Stakeholder Group	Non- Personal	NIL	N/A	N/A
Reecha Sofat	PEAG	Personal	NIL	N/A	N/A

Reecha Sofat	PEAG	Non- Personal	NIL	N/A	N/A
Rhian Thomas- Turner	PMEAG	Personal	NIL	N/A	N/A
Rhian Thomas- Turner	PMEAG	Non- Personal	Aparito	Secondment 2 days a week	No
Rhian Thomas- Turner	PMEAG	Non- Personal	Aeglea	Clinical Trial running on the research unit. Set up via HRA/HCRW process.	No
Rhian Thomas- Turner	PMEAG	Non- Personal	Amgen	Clinical Trial running on the research unit. Set up via HRA/HCRW process.	No
Rhian Thomas- Turner	PMEAG	Non- Personal	Sanofi	Clinical Trial running on the research unit. Set up via HRA/HCRW process.	Yes
Rhian Thomas- Turner	PMEAG	Non- Personal	Zynerba Pharma	Clinical Trial running on the research unit. Set up via HRA/HCRW process.	Yes
Rhian Thomas- Turner	PMEAG	Non- Personal	Sobi	Clinical Trial running on the research unit. Set up via HRA/HCRW process.	Yes
Rhian Thomas- Turner	PMEAG	Non- Personal	Takada	Clinical Trial running on the research unit. Set up via HRA/HCRW process.	Yes

Rhian Thomas- Turner	PMEAG	Non- Personal	Vertex	Clinical Trial running on the research unit. Set up via HRA/HCRW process.	Yes
Rhys Williams	Emergency Contraception Ad Hoc Stakeholder Group	Personal	NIL	N/A	N/A
Rhys Williams	Emergency Contraception Ad Hoc Stakeholder Group	Non- Personal	NIL	N/A	N/A
Richard Fitzgerald	PEAG	Personal	NIL	N/A	N/A
Richard Fitzgerald	PEAG	Non- Personal	NIL	N/A	N/A
Richard	PEAG	Additional			

Fitzgerald

I am Director of NIHR
Liverpool CRF which
receives direct funding from
NIHR for the conduct of
early phase and
experimental medicine
studies. All staff costs, and
other indirect costs, are
covered by the NIHR award
or from Liverpool University
Hospitals NHS Foundation
Trust as the host
organisation for the CRF,
on a permanent contract

basis. The CRF conducts both academic and commercial trials but there is no specific personal or non-personal interest.

Richard Gilson	CHM, COVID- 19 Therapeutic EWG, IEAG	Personal	NIL	N/A	N/A
Richard Gilson	CHM, COVID- 19 Therapeutic EWG, IEAG	Non- Personal	Gilead Sciences	My department is a collaborating site in clinical trials sponsored by Gilead Sciences, who have provided research funds to the department (Central and North West London NHS Foundation Trust). I have been a local principal investigator and sub-investigator for trials sponsored Gilead Sciences.	No
Richard Gilson	CHM, COVID- 19 Therapeutic EWG, IEAG	Non- Personal	GSK	My department is a collaborating site in clinical trials sponsored by GSK, who have provided research funds to the department (received by Central and North West London NHS Foundation Trust). I have been local principal	No

				investigator for trials sponsored GSK.	
Richard Gilson	CHM, COVID- 19 Therapeutic EWG, IEAG	Non- Personal	Janssen	My department is a collaborating site in clinical trials sponsored by Janssen, who have provided research funds to the department (Central and North West London NHS Foundation Trust)	No
Richard Gilson	CHM, COVID- 19 Therapeutic EWG, IEAG	Non- Personal	Merck	My department is a collaborating site in clinical trials sponsored by Merck, who have provided research funds to the department (Central and North West London NHS Foundation Trust)	No
Richard Gilson	CHM, COVID- 19 Therapeutic EWG, IEAG	Non- Personal	Pfizer	My department is a collaborating site in clinical trials sponsored by Pfizer, who have provided research funds to the department (received by UCL and by Central and North West London NHS Foundation Trust)	No
Richard Gilson	CHM, COVID- 19 Therapeutic EWG, IEAG	Non- Personal	ViiV	My department is a collaborating site in clinical trials sponsored	No

by ViiV, who have provided research funds to the department (received by UCL and by Central and North London NHS Foundation Trust)

Richard Gilson	CHM, COVID-	Additiona
	19 Therapeutic	
	EWG, IEAG	

Members of the UCL Institute for Global Health are investigators or subinvestigators on trials of COVID vaccines and antiviral therapies. I have not been directly involved in these studies, except for one study of an antiviral product from Gilead Sciences on which I was a sub-investigator. I was the interim director of the Institute for Global Health and therefore had overall responsibility for the research undertaken in the Institute.

Robert Lowe	COVID-19 VBREWG, CPSEAG	Personal	NIL	N/A	N/A
Robert Lowe	COVID-19 VBREWG, CPSEAG	Non- Personal	NIL	N/A	N/A

Robin Thorpe	COVID-19 VBREWG, CTBVEAG	Personal	NIL	N/A	N/A
Robin Thorpe	COVID-19 VBREWG, CTBVEAG	Non- Personal	NIL	N/A	N/A
Ruben Thanacoody	PEAG	Personal	NIL	N/A	N/A
Ruben Thanacoody	PEAG	Conference s/Scientific Meetings	SERB SA	Fees for Advisory Board meeting on glucarpidase for toxicity from highdose methotrexate	No
Ruben Thanacoody	PEAG	Non- Personal	NIL	N/A	N/A
Rubin Minhas	PMEAG	Personal	NIL	N/A	N/A
Rubin Minhas	PMEAG	Non- Personal	NIL	N/A	N/A
Rui Providencia	CHM	Personal	NIL	N/A	N/A
Rui Providencia	CHM	Non- Personal	Biosense Webster	Research grant for PhD student	Yes
Rupert Payne	PEAG	Personal	NIL	N/A	N/A
Rupert Payne	PEAG	Non- Personal	NIL	N/A	N/A

Rupert Payne  Ruth Paulin	PEAG	Additional	NIL	N/A	N/A	I receive freelance payment as consultant editor for Prescriber magazine (Wiley publishers) which carries advertising for the pharmaceutical industry. I have no involvement in the advertising side of the publication. I have received funding for primary care research from NIHR, MRC and Wellcome Trust. This is not specific to any particular pharmaceutical product.
Nulli Faulli	OFSLAG	Fersonal	INIL	IV/A	IN/A	
Ruth Paulin	CPSEAG	Non- Personal	NIL	N/A	N/A	
Lay member (Anonymous)	Emergency Contraception Ad Hoc Stakeholder Group	Personal	NIL	N/A	N/A	
Lay member (Anonymous)	Emergency Contraception Ad Hoc Stakeholder Group	Non- Personal	NIL	N/A	N/A	
Sandosh Padmanabhan	CHM, CDRRA EAG, Non- Medical	Personal	Kvatchii Limited	Founder shares	No	

	Prescribing EWG					
Sandosh Padmanabhan	CHM, CDRRA EAG, Non- Medical Prescribing EWG	Personal	MedKal Health Limited	CSO shares	No	
Sandosh Padmanabhan	CHM, CDRRA EAG, Non- Medical Prescribing EWG	Non- Personal	NIL	N/A	N/A	
Sara Payne	PMEAG	Personal	PHG Foundation (Cambridge)	Associate (P/T)	Yes	
Sara Payne	PMEAG	Non- Personal	NIL	N/A	N/A	
Sara Payne	PMEAG	Additional	N/A	N/A	N/A	Immediate family member is a high court judge in Intellectual Property, cases include medicine and medical devices disputes.
Sarah Wild	CDRRA EAG	Personal	NIL	N/A	N/A	
Sarah Wild	CDRRA EAG	Conference /Scientific Meetings	Novo Nordisk	Scottish Study Group for Care of Diabetes in the Young - Subsidised conference fee/accommodation /subsistence	No	
Sarah Wild	CDRRA EAG	Non- Personal	NIL	N/A	N/A	

Seán MacBride- Stewart	Non-Medical Prescribing EWG	Personal	NIL	N/A	N/A
Seán MacBride- Stewart	Non-Medical Prescribing EWG	Non- Personal	NIL	N/A	N/A
Shahida Din	GRID	Personal	Janssen	Fee for Presentation at Educational. Event: NHS Lanarkshire IBD Academy	No
Shahida Din	GRID	Personal	Takeda	Fee for Presentation at Educational Event: Leeds IBD Summit	No
Shahida Din	GRID	Personal	AbbVie	Fee for Presentation at Educational Event: RINVOQ® (Upadacitinib) Roadshow: THE Clinical Data IN UC	No
Shahida Din	GRID	Conference /Scientific Meetings	Janssen	Digestive Diseases Annual Week 2022 (online) - Online Access	No
Shahida Din	GRID	Conference /Scientific Meetings	Dr Falk	Dr Falk Symposium Frankfurt Symposium 230 - Flights, Accommodation, Symposium, Registration Fees	No

Shahida Din	GRID	Non- Personal	Edinburgh & Lothian Health Foundations Award	Research Funding	Yes	
Shahida Din	GRID	Non- Personal	Pathological Society of Great Britain & Northern Ireland	Research Funding	Yes	
Shahida Din	GRID	Non- Personal	Helmsley Charitable Trust Disease	Research Funding	Yes	
Shahida Din	GRID	Non- Personal	Helmsley Charitable Trust	Research Fundings	Yes	
Shahida Din	GRID	Additional				Collaborator for Clinical Trial - MARVEL Mitochondrial Anti-oxidant therapy to Resolve Inflammation in Ulcerative Colitis (MARVEL): A randomised placebo- controlled trial on oral MitoQ in moderate to severe active UC Funder John Moulton Foundation Sponsor NHS Lothian/University of Edinburgh
Shahida Din	GRID	Additional			Yes	Collaborator for Clinical Trial Funder Wellcome Trust (200448/Z/16/Z)

Shahida Din	GRID	Additional			Yes	Collaborator for Commercial Trial funded by Abbvie
Shahida Din	GRID	Additional			Yes	Collaborator for Commercial Trials funded by Gilead
Sharon Dickson	Emergency Contraception Ad Hoc Stakeholder Group	Personal	NIL	N/A	N/A	
Sharon Dickson	Emergency Contraception Ad Hoc Stakeholder Group	Non- Personal	NIL	N/A	N/A	
Shirley Price	CHM, COVID- 19 Therapeutics EWG, COVID- 19 VBREWG	Personal	NIL	N/A	N/A	
Shirley Price	CHM, COVID- 19 Therapeutics EWG, COVID- 19 VBREWG	Non- Personal	AstraZeneca	Donations provided by AstraZeneca to the British Toxicology Society (BTS) to support their Annual Congress and educational activities. I am currently the Immediate Past President and General Secretary of the BTS	No	

Shirley Price	CHM, COVID- 19 Therapeutics EWG, COVID- 19 VBREWG	Non- Personal	GSK	Donations provided by GlaxoSmithKline to the British Toxicology Society (BTS) to support their Annual Congress and educational activities. I am currently the Immediate Past President and General Secretary of the BTS.	No
Shuaib Nasser	CDRRA EAG	Personal	AZ	Consultancy	Yes
Shuaib Nasser	CDRRA EAG	Personal	ALK	Consultancy	Yes
Shuaib Nasser	CDRRA EAG	Non- Personal	AZ	Clinical trial	Yes
Simon Drysdale	PMEAG	Personal	Sanofi	Received consultancy fees for sitting on 2 RSV advisory boards and 1 conference session.	No
Simon Drysdale	PMEAG	Personal	Merck	Received consultancy fee for sitting on an RSV advisory board	No
Simon Drysdale	PMEAG	Non- Personal	Merck	I have been a local PI or national CI for multiple research studies for multiple pharmaceutical companies. All funds have been paid to my institution and I have	Yes

				received no personal fees.	
Simon Drysdale	PMEAG	Non- Personal	Astra Zeneca	As Above	Yes
Simon Drysdale	PMEAG	Non- Personal	ILiAD	As Above	Yes
Simon Drysdale	PMEAG	Non- Personal	Moderna	As Above	Yes
Simon Drysdale	PMEAG	Non- Personal	Valneva	As Above	Yes
Simon Drysdale	PMEAG	Non- Personal	Sanofi Pasteur	As Above	Yes
Simon Drysdale	PMEAG	Non- Personal	Janssen	As Above	Yes
Simon Drysdale	PMEAG	Non- Personal	Pfizer	As Above	Yes
Simon Drysdale	PMEAG	Non- Personal	Merck	Consultancy fees will be paid to my institution for working with them on a research project	No
Simon Drysdale	PMEAG	Non- Personal	Sanofi	Consultancy fee will be paid to my institution for chairing a conference session on RSV.	No
Simon	PMEAG	Additional			

Drysdale

Family member works in the same academic department and has worked on many of the same and other studies.

They received no persona
fees for any of these
studies, all funds are paid
to the institution.

						to the institution.
Siow Ming Lee	PMEAG	Personal	NIL	N/A	N/A	
Siow Ming Lee	PMEAG	Conference / Scientific Meetings	Roche	ESMO Congress 2022 - To present trial results as Chair of the IPSOS Study Group	No	
Siow Ming Lee	PMEAG	Non- Personal	NIL	N/A	N/A	
Siow Ming Lee	PMEAG	Additional				Global Chief Investigator: Randomised phase 3 trial of atezolizumab to treat advanced lung cancer with poor performance status Chief Investigator: Randomised trial of high dose hydroxychloroquine in combination with chemotherapy to treat patients with metastatic small cell lung cancer
Siraj Misbah	PMEAG	Personal	NIL	N/A	N/A	
Siraj Misbah	PMEAG	Non- Personal	NIL	N/A	N/A	
Siraj Misbah	PMEAG	Additional				Non-remunerated discussions with Astra Zeneca on therapeutic approaches to Covid

vaccine-induced thrombosis and thrombocytopenia.

						unombodytopema.
Sofia Eriksson	Valproate Implementation EWG	Personal	NIL	N/A	N/A	
Sofia Eriksson	Valproate Implementation EWG	Conference s/Scientific Meetings	UCB pharma	Forum of excellence - Conference attendance including, food and accommodation	No	
Sofia Eriksson	Valproate Implementation EWG	Non- Personal	NIL	N/A	N/A	
Sofia Eriksson	Valproate Implementation EWG	Additional				Have an interest in the safe prescribing of valproate and developed and led an audit on the topic which has been published: "Audit on neurologists' ompliance with the MHRA guidance."
Sophie Kemball	Emergency Contraception Ad Hoc Stakeholder Group	Personal	NIL	N/A	N/A	
Sophie Kemball	Emergency Contraception Ad Hoc Stakeholder Group	Non- Personal	NIL	N/A	N/A	

Stephen Devereux	OHEAG	Personal	NIL	N/A	N/A
Stephen Devereux	OHEAG	Non- Personal	NIL	N/A	N/A
Steven Cunningham	CHM, PMEAG	Personal	NIL	N/A	N/A
Steven Cunningham	CHM, PMEAG	Non- Personal	Boehringer Ingelheim	Consultancy with fees paid to the University of Edinburgh for trial steering committee. Local PI for clinical study.	No
Steven Cunningham	CHM, PMEAG	Non- Personal	GSK	Local PI for maternal RSV vaccine study	No
Steven Cunningham	CHM, PMEAG	Non- Personal	Pfizer	Bronchiolitis RSV antiviral trial development. Fees paid to University of Edinburgh.	No
Steven Cunningham	CHM, PMEAG	Non- Personal	US Cystic Fibrosis Foundation (AbbVie)	Member of the US CFF Data Safety Monitoring Committee allocated AbbVie study with fees paid by US CFF to Edinburgh University.	No
Steven Cunningham	CHM, PMEAG	Non- Personal	Vertex	Local PI for ARRIVAL study (VX15-770- 124/126)	No

Steven Cunningham	CHM, PMEAG	Non- Personal	ArkBiosciences	Bronchiolitis RSV antiviral trial development. Fees paid to University of Edinburgh.	No	
Steven Cunningham	CHM, PMEAG	Non- Personal	Gilead	Bronchiolitis RSV antiviral trial development. Fees paid to University of Edinburgh.	No	
Steven Cunningham	CHM, PMEAG	Additional				Jan-Dec 2022: I am a member of an EU IMI research consortium (RESCEU) which has Oxford University and Imperial College as academic partners.
Steven Cunningham	CHM, PMEAG	Additional				Jan-Dec 2021: I am Chair of the UK Cystic Fibrosis Trust Registry Research Committee. Within this role I have oversight role for the Post Authorisation Safety Study of Ivacaftor in children aged 2-5 years. Edinburgh University receives payment for my time in this role.
Stuart Ralston	GRIDEAG, MWHEAG	Personal	NIL	N/A	N/A	

Stuart Ralston	GRIDEAG, MWHEAG	Conference s/Scientific Meetings	UCB	British Society of Rheumatology - Travel expenses, registration and accommodation	No
Stuart Ralston	GRIDEAG, MWHEAG	Conference s/Scientific Meetings	Abbvie	AxSPA Educational meeting - Travel expenses, registration and accommodation	No
Stuart Ralston	GRIDEAG, MWHEAG	Non- Personal	Abbvie	Unrestricted educational grant to institution	No
Stuart Ralston	GRIDEAG, MWHEAG	Non- Personal	Alexion	Unrestricted educational grant to institution	No
Stuart Ralston	GRIDEAG, MWHEAG	Non- Personal	Amgen	Unrestricted educational grant to institution	No
Stuart Ralston	GRIDEAG, MWHEAG	Non- Personal	Accord	Unrestricted educational grant to institution	No
Stuart Ralston	GRIDEAG, MWHEAG	Non- Personal	Novartis	Unrestricted educational grant to institution	No
Stuart Ralston	GRIDEAG, MWHEAG	Non- Personal	Pfizer	Unrestricted educational grant to institution	No
Stuart Ralston	GRIDEAG, MWHEAG	Non- Personal	Sandoz	Unrestricted educational grant to institution	No
Stuart Ralston	GRIDEAG, MWHEAG	Non- Personal	Thornton and Ross	Unrestricted educational grant to institution	No
Stuart Ralston	GRIDEAG, MWHEAG	Non- Personal	Jannsen	Unrestricted educational grant to institution	No
Stuart Ralston	GRIDEAG, MWHEAG	Non- Personal	Lilly	Unrestricted educational grant to institution	No

Stuart Ralston	GRIDEAG, MWHEAG	Non- Personal	UCB	Unrestricted educational grant to institution	No
Stuart Ralston	GRIDEAG, MWHEAG	Non- Personal	Kyowa Kirin	Consultancy fees to institution	No
Stuart Ralston	GRIDEAG, MWHEAG	Non- Personal	UCB	Consultancy fees to institution	No
Susan Bradford	CHM, COVID- 19 Therapeutics EWG	Personal	NIL	N/A	N/A
Susan Bradford	CHM, COVID- 19 Therapeutics EWG	Non- Personal	NIL	N/A	N/A
Susan Hopkins	IEAG	Personal	NIL	NIL	N/A
Susan Hopkins	IEAG	Non- Personal	NIL	NIL	N/A
Susan Hunneyball	PEAG, COVID- 19 VBREWG	Personal	NIL	N/A	N/A
Susan Hunneyball	PEAG, COVID- 19 VBREWG	Non- Personal	NIL	N/A	N/A
Susan Hunneyball	PEAG, COVID- 19 VBREWG	Additional			

Writes articles published in the Chemist and Druggist magazine, a trade magazine for pharmacists but receives no payment for those articles. The information referred to is in the public domain. Ms

Hunneyball makes it clear that these are her personal views and reflections and references all sources of information used.

Susannah Walsh	COVID-19 VBREWG, CPSEAG	Personal	Better Vision Solutions	Consultancy and licence agreement for technology. Named on patents.	Yes
Susannah Walsh	COVID-19 VBREWG, CPSEAG	Personal	Chemical Biological Center of Combat Capabilities Development Command and Defence Threat Reduction Agency	Research collaboration and MTA. Named on DMU Patents associated with work.	Yes
Susannah Walsh	COVID-19 VBREWG, CPSEAG	Personal	DSTL	Research grant. Named on DMU patents associated with grant.	No
Susannah Walsh	COVID-19 VBREWG, CPSEAG	Personal	PAL	Research collaboration and MTA. Named on DMU patents associated with work.	Yes
Susannah Walsh	COVID-19 VBREWG, CPSEAG	Personal	Techfest	Director (education/ outreach STEM charity)	Yes
Susannah Walsh	COVID-19 VBREWG, CPSEAG	Personal	University of Reading	External examiner (educational consultancy)	No
Susannah Walsh	COVID-19 VBREWG, CPSEAG	Personal	University of Wolverhampton	External examiner (educational consultancy)	Yes

Susannah Walsh	COVID-19 VBREWG, CPSEAG	Personal	Kingston University	External examiner (educational consultancy)	Yes
Susannah Walsh	COVID-19 VBREWG, CPSEAG	Personal	DEB	Research grant. Named on DMU patents associated with grant.	No
Susannah Walsh	COVID-19 VBREWG, CPSEAG	Personal	Reckitt Benckiser	Commercial contract. Named on DMU patents associated with contract.	No
Susannah Walsh	COVID-19 VBREWG, CPSEAG	Personal	Safer Disinfectant Network	I have attended some online meetings involving academics and disinfection companies run by the Safer Disinfectant Network. I have not attended a meeting for more than a year and am not sure if this organisation is still active. I have no personal links to the companies who are signed up to their charter (to promote best practice and support public health in the workplace) beyond those detailed above.	No
Susannah Walsh	COVID-19 VBREWG, CPSEAG	Non- Personal	NIL	N/A	N/A

Tamann Miah	Emergency Contraception Ad Hoc Stakeholder Group	Personal	NIL	N/A	N/A
Tamann Miah	Emergency Contraception Ad Hoc Stakeholder Group	Non- Personal	NIL	N/A	N/A
Theresa McDonagh	CDRRA EAG	Personal	Astra Zeneca	Consultancy	No
Theresa McDonagh	CDRRA EAG	Personal	Edwards	Consultancy and Speaker fee	No
Theresa McDonagh	CDRRA EAG	Personal	Abbott	Speaker Fee	No
Theresa McDonagh	CDRRA EAG	Personal	Boerhinger Ingelheim	Consultancy	No
Theresa McDonagh	CDRRA EAG	Non- Personal	NIL	N/A	N/A
Tom Solomon	COVID-19 VBREWG	Personal	NIL	N/A	N/A
Tom Solomon	COVID-19 VBREWG	Non- Personal	NIL	N/A	N/A
Vanessa Raymont	CHM, Valproate	Personal	Roche	Short term consultancy	No

	Implementation EWG				
Vanessa Raymont	CHM, Valproate Implementation EWG	Personal	Biogen	Short term consultancy	No
Vanessa Raymont	CHM, Valproate Implementation EWG	Non- Personal	Janssen	Joint funder for research study with Wellcome Trust for which I was Chief Investigator	No
Vanessa Raymont	CHM, Valproate Implementation EWG	Non- Personal	Biogen	Funder for research registry for which I was Principal Investigator	No
V'lain Fenton- May	COVID-19 VBREWG, CPSEAG	Personal	NIL	N/A	N/A
V'lain Fenton- May	COVID-19 VBREWG, CPSEAG	Non- Personal	NIL	N/A	N/A
Wajid Hussain	CDRRA EAG	Personal	NIL	N/A	N/A
Wajid Hussain	CDRRA EAG	Conference /Scientific Meetings	Bayer Pharmaceuticals	Bayer Cardiovascular Summit – Speaker fee	No
Wajid Hussain	CDRRA EAG	Non- Personal	NIL	N/A	N/A
Waqar Rashid	NPPEAG	Personal	MS Society	Medical advisor to MS charity	Yes
Waqar Rashid	NPPEAG	Non- Personal	NIL	N/A	N/A

William Herrington	CDRRA EAG	Personal	NIL	N/A	N/A	
William Herrington	CDRRA EAG	Non- Personal	Boehringer Ingelheim & Eli Lilly	Grant holder of grant to university to design and conduct the EMPA-KIDNEY trial	No	
William Herrington	CDRRA EAG	Additional				Unpaid role on Data Monitoring Committee for Bayer
William John Watkins	PMEAG	Personal	NIL	N/A	N/A	
William John Watkins	PMEAG	Non- Personal	NIL	N/A	N/A	
Wing Tang	Emergency Contraception Ad Hoc Stakeholder Group	Personal	NIL	N/A	N/A	
Wing Tang	Emergency Contraception Ad Hoc Stakeholder Group	Non- Personal	NIL	N/A	N/A	
Yvonne Perrie	CHM, COVID- 19 VBREWG, CPSEAG	Personal	NIL	N/A	N/A	
Yvonne Perrie	CHM, COVID- 19 VBREWG, CPSEAG	Non- Personal	CURIA	Knowledge exchange research contracts from company to University of Strathclyde and joint PhD funding.	No	

Yvonne Perrie	CHM, COVID- 19 VBREWG, CPSEAG	Non- Personal	Pfizer Inc, AstraZeneca, Precision Nanosystems, Centre for process Innovation Ltd, Malvern Instruments, Croda.	Research Grant to University of Strathclyde which includes contributions from listed companies to University of Strathclyde.	No
Yvonne Perrie	CHM, COVID- 19 VBREWG, CPSEAG	Non- Personal	Imperial College London	Research Contract with CRUK Formulation Unit based within UoS.	No
Yvonne Perrie	CHM, COVID- 19 VBREWG, CPSEAG	Non- Personal	Imperial College London	Research Collaborator: Development and award of IUK Grant awarded Dec 2022. Development, award and collaboration on Wellcome Leap Grant to University of Strathclyde.	No
Yvonne Perrie	CHM, COVID- 19 VBREWG, CPSEAG	Non- Personal	Microfluidics Inc	Equipment loan to University of Strathclyde and in-kind research support (consumables).	No
Yvonne Perrie	CHM, COVID- 19 VBREWG, CPSEAG	Non- Personal	Avanti polar lipids/CRODA	BBSRC Icase PhD studentship Grant to University of Strathclyde	No
Yvonne Perrie	CHM, COVID- 19 VBREWG, CPSEAG	Non- Personal	Precisions Nanosystems Inc	Equipment loan to University of Strathclyde. SmartScotland Grant with PNI. PhD studentship funding.	No

Yvonne Perrie	CHM, COVID- 19 VBREWG, CPSEAG	Non- Personal	AstraZeneca	PhD studentships including Icase.	No
Yvonne Perrie	CHM, COVID- 19 VBREWG, CPSEAG	Non- Personal	Defence Threat Reduction Agency DTRA (administered by DSTL)	Research Grant to University of Strathclyde	No
Yvonne Perrie	CHM, COVID- 19 VBREWG, CPSEAG	Non- Personal	Janssen Pharmaceutica	Research Grant to University of Strathclyde	No
Yvonne Perrie	CHM, COVID- 19 VBREWG, CPSEAG	Non- Personal	Target Healthcare	Knowledge Transfer Partnership research Grant to University of Strathclyde	No
Yvonne Perrie	CHM, COVID- 19 VBREWG, CPSEAG	Non- Personal	Takeda / Millenium Pharmaceuticals	Knowledge exchange research contracts from company to University of Strathclyde	No
Yvonne Perrie	CHM, COVID- 19 VBREWG, CPSEAG	Non- Personal	LEON Nano Drugs GmbH	Knowledge exchange research contracts from company to University of Strathclyde	No
Yvonne Perrie	CHM, COVID- 19 VBREWG, CPSEAG	Non- Personal	Stablepharma Ltd	Knowledge exchange research contracts from company to University of Strathclyde	No
Yvonne Perrie	CHM, COVID- 19 VBREWG, CPSEAG	Non- Personal	NOF Corporation	Knowledge exchange research contracts from company to University of Strathclyde	No

Yvonne Perrie	CHM, COVID- 19 VBREWG, CPSEAG	Non- Personal	Veterna SrL	Knowledge exchange research contracts from company to University of Strathclyde	No
Yvonne Perrie	CHM, COVID- 19 VBREWG, CPSEAG	Non- Personal	Carocell Bio Limited	Knowledge exchange research contracts from company to University of Strathclyde	No
Yvonne Perrie	CHM, COVID- 19 VBREWG, CPSEAG	Non- Personal	SixFold	Knowledge exchange research contracts from company to University of Strathclyde	No
Yvonne Perrie	CHM, COVID- 19 VBREWG, CPSEAG	Non- Personal	Micropore Tech	Knowledge exchange research contracts from company to University of Strathclyde and PhD sponsorship	No
Yvonne Perrie	CHM, COVID- 19 VBREWG, CPSEAG	Additional			
Yvonne Perrie	CHM, COVID- 19 VBREWG,	Additional			

**CPSEAG** 

Controlled Release Society, President-elect Jan 2020 – Jun 2020 President Jun 2020–Aug 2021. Immediate Past President. Aug 2021 - Jun 2022. This was a nonsalaried volunteer position for a scientific society Head of Institute of

Pharmacy and Biomedical

Sciences, where a number of industrial collaborations and grants are held by members of the Institute

including staff within CMAC.

## BRITISH PHARMACOPOEIA COMMISSION, COMMISSION'S EXPERT ADVISORY GROUPS MEMBERS, WORKING PARTIES AND PANELS OF EXPERTS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

Member	Committee(s)	Interest Type	Company/Organisation/ Sponsor	Nature of Interest	Current	Additional Information
Adrian Caws	MC1 EAG	Personal	GSK	Shares	No	
Adrian Caws	MC1 EAG	Personal	Haleon	Shares	No	
Adrian Caws	MC1 EAG	Non- Personal	NIL	N/A	N/A	
Adrian Caws	MC1 EAG	Additional				Immediate family member holds shares in GSK and Haleon.
Adrian Slater	HCM EAG					
Alastair Davidson	MC1 EAG	Personal	NIL	N/A	N/A	
Alastair Davidson	MC1 EAG	Non- Personal	NIL	N/A	N/A	
Alec Kettle	WP AQbD	Personal	Waters Corporation	Shares, salary	Yes	
Alec Kettle	WP AQbD	Non- Personal	NIL	N/A	N/A	
Alex Bosley	ULM EAG	Personal	Torbay Pharmaceuticals	Employee of organisation – Declaration of interest made if relevant product discussed during meetings.	Yes	

Alex Bosley	ULM EAG	Non- Personal	NIL	N/A	N/A	
Alison Gleadle	BPC	Personal	Tesco plc	Shares	Yes	
Alison Gleadle	BPC	Non- Personal	NIL	N/A	N/A	
Alison Gleadle	BPC	Additional				Family member is currently employed by Astra Zeneca
Alistair Kippen	BIO EAG	Personal	Ipsen Biopharm Ltd	Salary	Yes	, , ,
Alistair Kippen	BIO EAG	Non- Personal	NIL	N/A	N/A	
Alistair Kippen	BIO EAG	Additional				Also Committee Member of EFPIA-MQEG, CASSS CMC Strategy Forum, Bioindustry Association (BIA)
Andrea Ruggiero	MC2 EAG	Personal	Merck KGaA	Consultancy	Yes	, tooosiation (Dirty
Andrea Ruggiero	MC2 EAG	Non- Personal	NIL	N/A	N/A	
Andrew Barnes	BPC, ULM EAG	Personal	East Suffolk and North Essex NHS Foundation Trust	Occasional employment	Yes	
Andrew Barnes	BPC, ULM EAG	Personal	Tristel plc	Shareholding	Yes	
Andrew Barnes	BPC, ULM EAG	Non- Personal	NIL	N/A	N/A	
Andrew Cairns	Panel VET	Personal	NIL	N/A	N/A	
Andrew Cairns	Panel VET	Non- Personal	NIL	N/A	N/A	

Andrew Sully	ULM EAG	Personal	NIL	N/A	N/A
Andrew Sully	ULM EAG	Non- Personal	NIL	N/A	N/A
Angela McFarlane	PCN EAG	Personal	NIL	N/A	N/A
Angela McFarlane	PCN EAG	Non- Personal	NIL	N/A	N/A
Anna-Maria Brady	BPC, BIO EAG, WP BIO- DPS	Personal	Glaxo	Immediate family member holds shares	Yes
Anna-Maria Brady	BPC, BIO EAG, WP BIO- DPS	Personal	Astra Zeneca	Immediate family member holds shares	Yes
Anna-Maria Brady	BPC, BIO EAG, WP BIO- DPS	Non- Personal	NIL	N/A	N/A
Anna-Maria Brady	BPC, BIO EAG, WP BIO- DPS	Additional			
Anna-Maria Brady	BPC, BIO EAG, WP BIO- DPS	Additional			
Anthony Booker	HCM EAG	Personal	Herbprime UK	Consultancy	No
Anthony Booker	HCM EAG	Personal	Su Wen Herbs	Consultancy	No
Anthony Booker	HCM EAG	Personal	Phoenix medical	Consultancy	No
Anthony Booker	HCM EAG	Non- Personal	NIL	N/A	N/A

I act as a section editor and reviewer for the journal Biologicals. This is an unpaid position.
I am a panel member for the HS2 "need to sell scheme." I receive a fee for panel attendance.

Archie Lovatt	WP ATMP	Personal	SGS	Employee	Yes	
Archie Lovatt	WP ATMP	Non- Personal	NIL	N/A	N/A	
Ash Ramzan	WP BIO-DPS	Personal	NIL	N/A	N/A	
Ash Ramzan	WP BIO-DPS	Non- Personal	NIL	N/A	N/A	
Barbara Rellahan	WP BIO-DPS	Personal	AMGEN	SHARES	Yes	
Barbara Rellahan	WP BIO-DPS	Non- Personal	NIL	N/A	N/A	
Barry Moore	HCM EAG	Personal	Pukka Herbs	Salary	Yes	
Barry Moore	HCM EAG	Non- Personal	NIL	N/A	N/A	
Barry Moore	HCM EAG	Additional				British Ayurvedic Medical Council – member of product committee
Beata Surmacz- Cordle	WP ATMP	Personal	GSK	Salary, shares	Yes	
Beata Surmacz- Cordle	WP ATMP	Non- Personal	NIL	N/A	N/A	
Brent Harrington	WP AQbD					
Brian Alexander	Panel MIC					
Brij Patel	BIO EAG	Personal	Variety of pharmaceutical companies - list provided	Consultancy	Yes	
Brij Patel	BIO EAG	Non- Personal	NIL	N/A	N/A	

Brian Ward	Panel VET	Personal	NIL	N/A	N/A
Brian Ward	Panel VET	Non- Personal	NIL	N/A	N/A
Carl Mroz	CX Panel				
Carlo Emanuele Giartosio	BPC, WP BIO- DPS	Personal	Merck KGaA	Salary	Yes
Carlo Emanuele Giartosio	BPC, WP BIO- DPS	Non- Personal	NIL	N/A	N/A
Carol Iverson	Panel MIC	Personal	Merck KGaA	Salary	Yes
Carol Iverson	Panel MIC	Non- Personal	NIL	N/A	N/A
Cassandra Braxton	BIO EAG	Personal	Biogen Inc.	Salary and Shares	Yes
Cassandra Braxton	BIO EAG	Non- Personal	NIL	N/A	N/A
Chris Etheridge	HCM EAG	Personal	ВНМА	Chair of the BHMA – receive monthly honorarium.	No
Chris Etheridge	HCM EAG	Personal	Puressentiel	Independent consultancy.	No
Chris Etheridge	HCM EAG	Personal	UK TIA	Independent consultancy.	No
Chris Etheridge	HCM EAG	Non- Personal	NIL	N/A	N/A
Chris Goddard	MC2 EAG, MC3 EAG, Panel IGC	Personal	NIL	N/A	N/A
Chris Goddard	MC2 EAG, MC3 EAG, Panel IGC	Non- Personal	NIL	N/A	N/A

Chris Jones	BIO EAG	Personal	NIL	N/A	N/A
Chris Jones	BIO EAG	Non- Personal	NIL	N/A	N/A
Christine Leon	HCM EAG	Personal			
Clare Blue	WP ATMP	Personal	Biogen	Salary, Shares	No
Clare Blue	WP ATMP	Non- Personal	NIL	N/A	N/A
Clive Welham	HCM EAG	Personal	Ransom Naturals Ltd	Salary	Yes
Clive Welham	HCM EAG	Non- Personal	NIL	N/A	N/A
Daniel Kirby	ULM EAG	Personal	NIL	NIL	No
Daniel Kirby	ULM EAG	Non- Personal	Colorcon Ltd.	Financial support for PhD students	No
Daniel Kirby	ULM EAG	Non- Personal	Proveca Ltd.	Financial support for PhD students	No
Daniel Kirby	ULM EAG	Non- Personal	Catalent Pharma Ltd.	Knowledge transfer partnership grants	No
Daniel Kirby	ULM EAG	Non- Personal	Quest Pharm Ltd	Knowledge transfer partnership grants	No
Daniel Kirby	ULM EAG	Non- Personal	Max Biotech Ltd.	Commission of research, support for research associate post	No
Dave Malpas	MC1 EAG	Personal	GSK	Shareholder	Yes
Dave Malpas	MC1 EAG	Personal	Sanofi	Shareholder	Yes

Dave Malpas	MC1 EAG	Non- Personal	NIL	N/A	N/A
David Caulfield	WP ATMP	Personal	Caulfield Pharma Consulting	Owner, director, shareholder and employee	Yes
David Caulfield	WP ATMP	Personal	Autolus	Shareholder	Yes
David Caulfield	WP ATMP	Personal	Autolus	Consultancy	Yes
David Caulfield	WP ATMP	Personal	GSK	Consultancy	Yes
David Caulfield	WP ATMP	Personal	Pfizer	Consultancy	Yes
David Caulfield	WP ATMP	Personal	West Pharma	Consultancy	Yes
David Caulfield	WP ATMP	Personal	Regeneron	Consultancy	Yes
David Caulfield	WP ATMP	Personal	Kings University Vector manufacturing facility	Consultancy	Yes
David Caulfield	WP ATMP	Personal	Kings College Hospital	Consultancy	Yes
David Caulfield	WP ATMP	Personal	Newcastle Advanced Therapies	Employment	Yes
David Caulfield	WP ATMP	Non- Personal	NIL	N/A	N/A
David Elder	PCN EAG	Personal	CMC	Providing paid consultancy for CMC (Chemistry, Manufacturing & Controls) issues	Yes

David Elder	PCN EAG	Personal	GlaxoSmithKline	Shareholding	Yes
David Elder	PCN EAG	Personal	Astra Zeneca	Shareholding	Yes
David Elder	PCN EAG	Personal	AbbVie	Shareholding	Yes
David Elder	PCN EAG	Conferenc e/Scientific Meetings	Catalent	Expenses paid	No
David Elder	PCN EAG	Non- Personal	Catalent	Annual fee for organising conferences	Yes
David Evans	Panel VET			Comercines	
David Graham	Panel RAD				
Davide Grandolfo	WP ATMP	Personal	NIL	N/A	N/A
Davide Grandolfo	WP ATMP	Non- Personal	NIL	N/A	N/A
Donald Cairns	MC1 EAG	Personal	NIL	N/A	N/A
Donald Cairns	MC1 EAG	Non- Personal	NIL	N/A	N/A
Eamon Flahive	AIM EAG, Panel VET	Personal	Eli Lilly & Co	Salary (employee to Sep 2018) and shares	Yes
Eamon Flahive	AIM EAG, Panel VET	Personal	Elanco Animal Health	Salary (to Mar 2021) and shares	Yes
Eamon Flahive	AIM EAG, Panel VET	Personal	Aenorasis S.A.	Consultancy	Yes
Eamon Flahive	AIM EAG, Panel VET	Non- Personal	NIL	N/A	N/A

Edward Bush	BPC, MC1 EAG	Personal	AstraZeneca Pharmaceuticals	Salary from employment	Yes
Edward Bush	BPC, MC1 EAG	Personal	AstraZeneca Pharmaceuticals	Personal holding of a limited number of ordinary shares	Yes
Edward Bush	BPC, MC1 EAG	Non- Personal	NIL	N/A	N/A
Eike Reich	HCM EAG	Personal	NIL	N/A	N/A
Eike Reich	HCM EAG	Non- Personal	NIL	N/A	N/A
Elizabeth Williamson	HCM EAG, Panel VET	Personal	NIL	N/A	N/A
Elizabeth Williamson	HCM EAG, Panel VET	Non- Personal	NIL	N/A	N/A
Elliot Hook	MC2 EAG	Personal	GlaxoSmithKline	Salary, shares	Yes
Elliot Hook	MC2 EAG	Personal	Haleon	shares	Yes
Elliot Hook	MC2 EAG	Non- Personal	NIL	N/A	N/A
Emre Amirak	BPC, BIO EAG	Personal	Orphazyme A/S	Salary	No
Emre Amirak	BPC, BIO EAG	Personal	Vionelix Pharmaceuticals	Shares	No
Emre Amirak	BPC, BIO EAG	Personal	Sanofi	Shares	No
Emre Amirak	BPC, BIO EAG	Non- Personal	NIL	N/A	N/A
Franz Schnetzinger	WP ATMP	Personal	Gyroscope Therapeutics Ltd (a Novartis company)	Salary - Shares - Pension entitlement	Yes

Franz Schnetzinger	WP ATMP	Non- Personal	NIL	N/A	N/A
Friederike Plath	WP BIO-DPS	Personal	F Hoffmann-La Roche Ltd., Basel/Switzerland	Salary	Yes
Friederike Plath	WP BIO-DPS	Non- Personal	NIL	N/A	N/A
George Bou- Assaf	WP ATMP				
Gerard Lee	ULM EAG				
Gerry Moss	PCN EAG	Personal	NIL	N/A	N/A
Gerry Moss	PCN EAG	Non- Personal	NIL	N/A	N/A
Gillian Clarke	AIM EAG	Personal	NIL	N/A	N/A
Gillian Clarke	AIM EAG	Non- Personal	NIL	N/A	N/A
Graham Cook	AIM EAG, MC2 EAG, WP AQbD, New Analytical Technologies Ad Hoc Group	Personal	Pfizer	Shares, Salary	No
Graham Cook	AIM EAG, MC2 EAG, WP AQbD, New Analytical Technologies Ad Hoc Group	Personal	Viatris	Shares	No
Graham Cook	AIM EAG, MC2 EAG, WP AQbD, New	Non- Personal	NIL	N/A	N/A

	Analytical Technologies Ad Hoc Group				
Greg Blake	AIM EAG	Personal	GSK	Salary and Shareholder	Yes
Greg Blake	AIM EAG	Non- Personal	NIL	N/A	N/A
Hannah Batchelor	CX Panel, MC1 EAG	Personal	NIL	N/A	N/A
Hannah Batchelor	CX Panel, MC1 EAG	Non- Personal	UCB	Grant awarded to support a PhD student under my supervision	Yes
Hannah Batchelor	CX Panel, MC1 EAG	Non- Personal	GSK	Grant awarded to support a PhD student under my supervision	Yes
Huimin (Helen) Tao	WP ATMP	Personal	Novartis	Salary, shares, stock	Yes
Huimin (Helen) Tao	WP ATMP	Personal	Select bio	Stock holding	Yes
Huimin (Helen) Tao	WP ATMP	Non- Personal	NIL	N/A	N/A
lan Anderson	WP ATMP				
lan Williams	AIM EAG, MC3 EAG	Personal	Pfizer	Shares	No
lan Williams	AIM EAG, MC3 EAG	Non- Personal	NIL	N/A	N/A
Ilaria Santeramo	WP ATMP	Personal	NIL	N/A	N/A
Ilaria Santeramo	WP ATMP	Non- Personal	NIL	N/A	N/A
Isobel Searing	WP ATMP	Personal	Oxford Biomedica	Salary, share options	Yes

Isobel Searing	WP ATMP	Non- Personal	NIL	N/A	N/A
Istvan Boros	Panel RAD	Personal	Jazz Pharmaceuticals	Salary	Yes
Istvan Boros	Panel RAD	Personal	Jazz Pharmaceuticals	ECA Annual QP Forum - Expenses and Fees	No
Istvan Boros	Panel RAD	Non- Personal	NIL	N/A	N/A
Jacqueline Barry	WP ATMP	Personal	NIL	N/A	N/A
Jacqueline Barry	WP ATMP	Non- Personal	NIL	N/A	N/A
James Birchall	MC2 EAG	Personal	Astrazeneca	Small shareholding	No
James Birchall	MC2 EAG	Personal	Quadmedicine	Member advisory board	No
James Birchall	MC2 EAG	Personal	Avaxzipen	Member advisory board	Yes
James Birchall	MC2 EAG	Personal	Latch Medical	Consultancy	No
James Birchall	MC2 EAG	Personal	Abbvie	Consultancy	No
James Birchall	MC2 EAG	Non- Personal	Astrivax	Grant	Yes
James Birchall	MC2 EAG	Non- Personal	Latch Medical	Grant	No
James Brain	Panel RAD	Personal	GE Healthcare	Salary, Shares	Yes
James Brain	Panel RAD	Non- Personal	NIL	N/A	N/A

James Cowie	MC2 EAG	Personal	Novartis	Salary and Shares	No
James Cowie	MC2 EAG	Personal	Dove Analytica Ltd and Novartis Pharma AG Switzerland	Consultancy	Yes
James Cowie	MC2 EAG	Non- Personal	NIL	N/A	N/A
James Norton	WP ATMP	Personal	Meiragtx	Salary, bonus, shares, pension, private medical insurance, travel insurance, expenses for conference and business travel.	Yes
James Norton	WP ATMP	Non- Personal	NIL	N/A	N/A
James Rickard	BPC, MC2 EAG	Personal	Biotherapy Services Ltd	Shares, Share Options & Salary	Yes
James Rickard	BPC, MC2 EAG	Personal	Dechra Pharmaceuticals plc	Shares	Yes
James Rickard	BPC, MC2 EAG	Non- Personal	NIL	N/A	N/A
Jasbir Rattu	WP ATMP	Personal	Ceutiqus Ltd	Directorship	Yes
Jasbir Rattu	WP ATMP	Personal	Vegavcet	Consultant ATMP QP	No
Jasbir Rattu	WP ATMP	Personal	Santen	Consultant ATMP QP	No
Jasbir Rattu	WP ATMP	Non- Personal	NIL	N/A	N/A
Jeff Aronson	PCN EAG	Personal	NIL	N/A	N/A

Jeff Aronson	PCN EAG	Non- Personal	NIL	N/A	N/A	
Jeff Aronson	PCN EAG	Additional				I have earned publishers' royalties from edited books about aspects of clinical pharmacology.
Jeff Aronson	PCN EAG	Additional				I have received fees for preparing expert reports on adverse drug reactions, but none from any pharmaceutical company or other relevant industry.
Jenny McIntosh	WP ATMP	Personal	Freeline	Shares, consultancy	Yes	other relevant industry.
Jenny McIntosh	WP ATMP	Personal	NBioMarin	Royalties	Yes	
Jenny McIntosh	WP ATMP	Non- Personal	NIL	N/A	N/A	
Joao Inacio Silva	Panel MIC	Personal	NIL	N/A	N/A	
Joao Inacio Silva	Panel MIC	Non- Personal	NIL	N/A	N/A	
Joaquim Ramada-	ULM EAG	personal	Ascend GCTX	Salary, shares	Yes	
Magalhaes Joaquim Ramada- Magalhaes	ULM EAG	personal	GSK	Ex-employee shares	Yes	
Joaquim Ramada- Magalhaes	ULM EAG	personal	Barts NHS Trust	Consultancy/Bank Staff	Yes	
Joaquim Ramada- Magalhaes	ULM EAG	Non- Personal	NIL	N/A	N/A	
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John Berridge	MC1 EAG	Personal	NIL	N/A	N/A
John Berridge	MC1 EAG	Non- Personal	NIL	N/A	N/A
John Campbell	WP ATMP	Personal	Resolution Therapeutics Ltd.	Shares, consultancy	Yes
John Campbell	WP ATMP	Non- Personal	NIL	N/A	N/A
John Lough	MC1 EAG, WP AQbD	Personal	Rokshaw Laboratories	Supervise part-time PhD student (developing fast, alternative LC assays and related substances methods (nil financial interest)	Yes
John Lough	MC1 EAG, WP AQbD	Non- Personal	NIL	N/A	N/A
John McGuire	PCN EAG	Personal	Astra Zeneca	Salary, Shares	Yes
John McGuire	PCN EAG	Non- Personal	NIL	N/A	N/A
John Miller	AIM EAG, MC2 EAG	Personal	NIL	N/A	N/A
John Miller	AIM EAG, MC2 EAG	Non- Personal	NIL	N/A	N/A
John More	BLP Panel	Personal	NIL	N/A	N/A
John More	BLP Panel	Non- Personal	NIL	N/A	N/A
Jon Beaman	BPC, MC3 EAG	Personal	Pfizer Ltd	Salary and shares	Yes

Jon Beaman	BPC, MC3 EAG	Non- Personal	NIL	N/A	N/A
Josefina Nilsson	WP ATMP	Personal	VIRONOVA BIOANALYTICS AB	Shares and Salary	Yes
Josefina Nilsson	WP ATMP	Non- Personal	NIL	N/A	N/A
Juan Miguel Sánchez Nieto	WP ATMP	Personal	Orchard Therapeutics	Salary and Shares	Yes
Juan Miguel Sánchez Nieto	WP ATMP	Non- Personal	NIL	N/A	N/A
Julian Smith	ULM EAG	Personal	JCS Pharma Consulting Ltd	Director, Consultant and Shareholder	Yes
Julian Smith	ULM EAG	Personal	GSK Plc	Shares	Yes
Julian Smith	ULM EAG	Non- Personal	NIL	N/A	N/A
Kaicun Zhao	HCM EAG	Personal	NIL	N/A	N/A
Kaicun Zhao	HCM EAG	Non- Personal	NIL	N/A	N/A
Karen Foster	MC2 EAG, MC3 EAG	Personal	Procter & Gamble	Sole salaried occupation	Yes
Karen Foster	MC2 EAG, MC3 EAG	Non- Personal	NIL	N/A	N/A
Katja Strohfeldt	HCM EAG	Personal	NIL	NIL	N/A
Katja Strohfeldt	HCM EAG	Non- Personal	NIL	NIL	N/A
Keith Chidwick	BIO EAG, BLP Panel				
Keith Redhead	Panel VIP				

Kevin Taylor	BPC, PCN EAG	Personal	NIL	N/A	N/A
Kevin Taylor	BPC, PCN EAG	Non- Personal	NIL	N/A	N/A
Kimber Barnett	WP AQbD	Personal	Pfizer	Salary, shares	Yes
Kimber Barnett	WP AQbD	Non- Personal	NIL	N/A	N/A
Kimberly Gilmour	WP ATMP	Personal	NIL	N/A	N/A
Kimberly Gilmour	WP ATMP	Conferenc e/Scientific Meetings	Moderna	ESID 2023 - Expense and fees	No
Kimberly Gilmour	WP ATMP	Conferenc e/Scientific Meetings	Moderna	Educational talk (online) - Fee for talk	No
Kimberly Gilmour	WP ATMP	Non- Personal	NIL	N/A	N/A
Kimberly Gilmour	WP ATMP	Additional			
Laurent Duhau	WP BIO- DPS	Personal	Sanofi	Salary and shares	Yes
Laurent Duhau	WP BIO- DPS	Non- Personal	NIL	N/A	N/A
Leonard Pattenden	WP ATMP	Personal	Acsend GCTx	COO and co-founder. Salary and shares.	No
Leonard Pattenden	WP ATMP	Personal	CMC Biopharma Ltd	Managing Director, Dividends. Consultancy. Fee-for- service.	Yes

Involved in trials of gene therapy for primary immunodeficiency and CAR T cell trials based at Great Ormond Street Hospital.

Leonard Pattenden	WP ATMP	Non- Personal	NIL	N/A	N/A
Lily Li	WP ATMP	Personal	Aviadobio	Salary	Yes
Lily Li	WP ATMP	Personal	Catapult	Salary	No
Lily Li	WP ATMP	Non- Personal	NIL	N/A	N/A
Lincoln Tsang	BIO EAG	Personal	Ropes & Gray LLP	Full-time legal practice as a partner and head of life sciences based in the London office of a global law firm headquartered in Boston, Massachusetts, United States, specialising in advising the life sciences sector on both non-contentious and contentious matters. Legal services rendered by the firm are regulated by relevant bar rules including the Solicitors Regulation Authority's professional code of conduct.	Yes
Lincoln Tsang	BIO EAG	Personal	BioIndustry Association	Advisor to BIA's Regulatory Affairs Advisory Committee. Non-remunerated.	No

Lincoln Tsang	BIO EAG	Personal	Association for the British Healthtech Industries	Advisor to ABHI Legal Issues and Compliance Committee. Non-remunerated.	No
Lincoln Tsang	BIO EAG	Personal	Association for the British Pharmaceutical Industry	Member of its Legal Affairs and Regulatory Affairs Networks	No
Lincoln Tsang	BIO EAG	Non- Personal	NIL	N/A	N/A
Lionel Randon	BIO EAG	Personal	Merck KGaA	Salary	Yes
Lionel Randon	BIO EAG	Non- Personal	NIL	N/A	N/A
Lionel Randon	BIO EAG	Additional			
Lionel Randon	BIO EAG	Additional			
Mandy Godber	ULM EAG	Personal	NIL	N/A	N/A
Mandy Godber	ULM EAG	Non-	NIL	N/A	N/A
Marius Brits	MC2 EAG	Personal			
Mark Lowdell	WP ATMP				
Mark Santillo	UM EAG	personal	Fresnius Kabi	Commissioned and paid products research	No

EDQM Expert in the MAB Working Party since 2016 and General Method Working

Member of EFPIA since 2009 involved in the Manufacturing & Quality, Biomanufacturing and Pharmacopoeia's expert

Party since 2018.

Groups.

Mark Santillo	UM EAG	personal	Baxter Healthcare (Australia)	Review of papers	No
Mark Santillo	UM EAG	personal	BBraun	Consultancy on new technology	No
Mark Santillo	UM EAG	Non- Personal	NIL	N/A	N/A
Martin llott	Panel VIP	Personal	NIL	N/A	N/A
Martin llott	Panel VIP	Non- Personal	NIL	N/A	N/A
Matthew Almond	MC3 EAG, Panel IGC	Personal	NIL	N/A	N/A
Matthew Almond	MC3 EAG, Panel IGC	Non- Personal	NIL	N/A	N/A
Matthew Almond	MC3 EAG, Panel IGC	Additional			
Matthew Collis	WP ATMP				
Mellisa Hanna- Brown	WP AQbD				
Michael Rowan	HCM EAG	Personal	NIL	N/A	N/A
Michael Rowan	HCM EAG	Non- Personal	NIL	N/A	N/A
Michelle Johnson	Panel VIP				
Monica Pianella	WP ATMP	Personal	NIL	N/A	N/A
Monica Pianella	WP ATMP	Non- Personal	NIL	N/A	N/A

Family member held shares in GlaxoSmithKline until October 2022. They have now all been sold.

Monique Simmonds	BPC, HCM EAG	Personal	NIL	N/A	N/A
Monique Simmonds	BPC, HCM EAG	Non- Personal	DEFRA Darwin initiative advisory committee	Member no financial etc interest	Yes
Monique Simmonds	BPC, HCM EAG	Personal	DEFRA group evidence science and analysis committee (GESAC)	Member no financial etc interest	Yes
Monique Simmonds	BPC, HCM EAG	Non- Personal	Garden Africa Advisory Board	Member no financial etc interest	Yes
Monique Simmonds	BPC, HCM EAG	Non- Personal	Grantham Centre for Sustainable Futures	Member no financial etc interest	Yes
Monique Simmonds	BPC, HCM EAG	Non- Personal	Good Practice Traditional Chinese Medicine Research Association	Chair no financial etc interest	Yes
Monique Simmonds	BPC, HCM EAG	Non- Personal	Hilliers Gardens Trust Advisory Board	Chair no financial etc interest	Yes
Monique Simmonds	BPC, HCM EAG	Non- Personal	Hong Kong Dept of Health, Pharmacopoeia International Advisory Committee	Member no financial etc interest	Yes
Monique Simmonds	BPC, HCM EAG	Non- Personal	Polypharmakos Limited	Director no financial etc interest	Yes
Monique Simmonds	BPC, HCM EAG	Non- Personal	Responsible Beauty Advisory Council (P&G)	Member no financial etc interest	Yes
Monique Simmonds	BPC, HCM EAG	Non- Personal	Royal Holloway University of LONDON Department of Health Advisory Board	Member no financial etc interest	Yes
Neil Wynne	MC2 EAG	Personal	CP Pharmaceuticals	Salary	Yes
Neil Wynne	MC2 EAG	Non- Personal	NIL	N/A	N/A

Paul Fleming	MC1 EAG	Personal	BGMA	Fees, as Technical Director to a trade association	No
Paul Fleming	MC1 EAG	Non- Personal	NIL	N/A	N/A
Paul Getty	WP ATMP	Personal	Pharmon Biologics	Current employer	Yes
Paul Getty	WP ATMP	Non- Personal	NIL	N/A	N/A
Paul Marshall	BPC, MC1 EAG	Personal	Jazz Pharmaceuticals	Salary & shares	No
Paul Marshall	BPC, MC1 EAG	Personal	Reckitt Benckiser Plc	Shares	No
Paul Marshall	BPC, MC1 EAG	Personal	Individior Plc	Shares	No
Paul Marshall	BPC, MC1 EAG	Personal	Sims Marshall Consultancy Ltd	Shares	No
Paul Marshall	BPC, MC1 EAG	Conferenc es/Scientifi c Meetings	TOPRA	Expenses paid - Event "Getting the CMC Dossier Right"	No
Paul Marshall	BPC, MC1 EAG	Non- Personal	NIL	N/A	N/A
Paul Varley	BIO EAG, BLP Panel, WP BIO-DPS	Personal	Alchemab Therapeutics	Salary and Share options	Yes
Paul Varley	BIO EAG, BLP Panel, WP BIO-DPS	Personal	Numerous small biotech companies	Consulting fees	Yes
Paul Varley	BIO EAG, BLP Panel, WP BIO-DPS	Non- Personal	NIL	N/A	N/A
Peng Wang	WP ATMP	Personal	Lonza Houston	Salary	Yes

Peng Wang	WP ATMP	Non- Personal	NII	N/A	N/A
Peter Hamilton	WP AQbD	Personal	AstraZeneca	Salary, Shares	Yes
Peter Hamilton	WP AQbD	Non- Personal	NIL	N/A	N/A
Peter Henrys	Panel IGC	Personal	BOC Ltd.	Salary	Yes
Peter Henrys	Panel IGC	Non- Personal	NIL	N/A	N/A
Peter Henrys	Panel IGC	Additional			

Chairman of EDQM European Pharmacopoeia Medical Gas 9G Working Group Chairman of British **Compressed Gas Association** (BCGA) Medical Gas Committee (TSC7) Member of European Industrial Gas Association (EIGA) Medical Gas Committee (WG7) and Medical Gas Equipment Committee (WG15) Chairman of BSI CH 121 / SC6 Standards Committee (Medical Gas Supply Systems) Member of ISO TC 121 / SC6 **Standards Committee** (Medical Gas Supply Systems) Member of the Association of **Anaesthetists Safety** Committee

Financial Director (Non-Paid) of BAREMA (British Anaesthetic and Respiratory Equipment Manufacturing Association

Phil Borman	WP AQbD	Personal	GSK	Shares	Yes
Phil Borman	WP AQbD	Non- Personal	NIL	N/A	N/A
Phil Hampshire	MC3 EAG	Personal	Accord Healthcare	Salary	Yes
Phil Hampshire	MC3 EAG	Non- Personal	NIL	N/A	N/A
Phil Nethercote	WP AQbD	Personal	NIL	N/A	N/A
Phil Nethercote	WP AQbD	Non- Personal	NIL	N/A	N/A
Philip Weir	ULM EAG	Personal	NIL	N/A	N/A
Philip Weir	ULM EAG	Non- Personal	NIL	N/A	N/A
Raffaella Balocco	PCN EAG	Personal	NIL	N/A	N/A
Raffaella Balocco	PCN EAG	Non- Personal	NIL	N/A	N/A
Ralph Woodland	Panel VIP	Personal	NIL	N/A	N/A
Ralph Woodland	Panel VIP	Non- Personal	NIL	N/A	N/A
Rhona Banks	Panel VIP	Personal	Zoetis	Consultancy (including fees)	Yes

Rhona Banks	Panel VIP	Personal	LETI Laboratories	Consultancy (including fees)	Yes
Rhona Banks	Panel VIP	Personal	Ceva Phylaxia	Consultancy (including fees)	Yes
Rhona Banks	Panel VIP	Personal	Intervacc	Consultancy (including fees)	Yes
Rhona Banks	Panel VIP	Personal	ABIC (PHIBRO)	Consultancy (including fees)	Yes
Rhona Banks	Panel VIP	Personal	Galvmed	Consultancy (including fees)	Yes
Rhona Banks	Panel VIP	Personal	ECO Animal Health	Consultancy (including fees)	Yes
Rhona Banks	Panel VIP	Personal	IDRC (Canada)	Consultancy (including fees)	Yes
Rhona Banks	Panel VIP	Personal	DECHRA	Consultancy (including fees)	Yes
Rhona Banks	Panel VIP	Personal	GlaxoSmithKline	Shares	Yes
Rhona Banks	Panel VIP	Non- Personal	NIL	N/A	N/A
Richard Cawthorne	Panel CX	Personal	Croda International	Shares and salary	Yes
Richard Cawthorne	Panel CX	Non- Personal	NIL	N/A	N/A
Richard Middleton	HCM EAG	Personal	Herbal Medicines Regulatory Services Ltd	Regulatory Consultancy related to general herbal medicine regulation	Yes
Richard Middleton	HCM EAG	Personal	Diapharm UK Ltd	UK Responsible Person for Medical Devices held by Diapharm GmbH	Yes

Richard Middleton	HCM EAG	Personal	British Herbal Medicine Association	Director of Trade Association representing herbal medicine manufacturers	Yes
Richard Middleton	HCM EAG	Non- Personal	NIL	N/A	N/A
Rickard Nordstrom	WP ATMP	Personal	Vironova Bioanalytics AB	Shares and Salary	Yes
Rickard Nordstrom	WP ATMP	Non- Personal	NIL	N/A	N/A
Rita Tendeiro Rego	WP ATMP	Personal	Virocell Biologics Ltd	Salary and Shares	Yes
Rita Tendeiro Rego	WP ATMP	Personal	Qualis Pharma Solutions Ltd	Director of the Company	Yes
Rita Tendeiro Rego	WP ATMP	Non- Personal	NIL	N/A	N/A
Robert Lowe	BPC, PCN EAG	Personal	NIL	N/A	N/A
Robert Lowe	BPC, PCN EAG	Non- Personal	NIL	N/A	N/A
Robin Thorpe	BIO EAG, PCN EAG	Personal	NIL	N/A	N/A
Robin Thorpe	BIO EAG, PCN EAG	Non- Personal	NIL	N/A	N/A
Rodney Horder	AIM EAG, PCN EAG	Personal	G&L Scientific	Consultancy	No
Rodney Horder	AIM EAG, PCN EAG	Personal	Blackrock Pharmaceuticals	Consultancy	No
Rodney Horder	AIM EAG, PCN EAG	Non- Personal	NIL	N/A	N/A

Roger Pickett	Panel RAD	Personal	General Electric	Shares held through prior employment	Yes
Roger Pickett	Panel RAD	Personal	General Electric	Immediate family member held shares through prior employment	Yes
Roger Pickett	Panel RAD	Non- Personal	NIL	N/A	N/A
Ronald Torano	MC3 EAG	Personal	GSK	Salary and Shares	Yes
Ronald Torano	MC3 EAG	Non- Personal	NIL	N/A	N/A
Rory Cooney	Panel VIP	Personal	NIL	N/A	N/A
Rory Cooney	Panel VIP	Non- Personal	NIL	N/A	N/A
Rosario LoBrutto	WP AQbD				
Ryan McCoy	WP ATMP	Personal	NIL	N/A	N/A
Ryan McCoy	WP ATMP	Non- Personal	NIL	N/A	N/A
S Handa	HCM EAG				
Sarah Cockbill	Panel VET	Non- Personal	NIL	N/A	N/A
Sarah Cockbill	Panel VET	Personal	NIL	N/A	N/A
Sarah Hartley	ULM EAG	Personal	Rosemont Pharmaceuticals	Salary	Yes
Sarah Hartley	ULM EAG	Non- Personal	NIL	N/A	N/A

Seamus Boland	Panel IGC	Personal	Novartis International Pharmaceuticals	Shares	No	
Seamus Boland	Panel IGC	Personal	SGS International	Shares	Yes	
Seamus Boland	Panel IGC	Personal	SGS International	Salary	Yes	
Seamus Boland	Panel IGC	Personal	Janssen	Shares (immediate family member)	Yes	
Seamus Boland	Panel IGC	Personal	Janssen	Salary (immediate family member)	Yes	
Seamus Boland	Panel IGC	Non- Personal	NIL	N/A	N/A	
Sean Jones	BPC, WP AQbD	Personal	NIL	N/A	N/A	
Sean Jones	BPC, WP AQbD	Non- Personal	NIL	N/A	N/A	
Sean Jones	BPC, WP AQbD	Additional				Immediate family member is a QC analyst working for Catalent in Swindon. The site manufactures Zydis fast dissolving tablets.
Sharon Palser	BPC	Personal	NIL	N/A	N/A	arecoming tableto.
Sharon Palser	BPC	Non- Personal	NIL	N/A	N/A	
Simeon Gill	BIO EAG	Personal	AstraZeneca	Salary and AZ shares	Yes	
Simeon Gill	BIO EAG	Non- Personal	NIL	N/A	N/A	
Simeon Gill	BIO EAG	Additional	AstraZeneca			AstraZeneca is a contract giver to contract research and contract manufacturing organisations

Stephen Ellison	WP AQbD	Personal	LGC (Teddington) limited	Salary and some shares in LGC group	Yes
Stephen Ellison	WP AQbD	Non- Personal	NIL	N/A	N/A
Steven Nolan	MC1 EAG	Personal	NIL	N/A	N/A
Steven Nolan	MC1 EAG	Non- Personal	NIL	N/A	N/A
Tina Morris	WP AQbD				
Tishwant Kanwarjit	WP ATMP	Personal	NIL	N/A	N/A
Tishwant Kanwarjit	WP ATMP	Non- Personal	NIL	N/A	N/A
V'lain Fenton- May	ULM EAG, Panel MIC	Personal	NIL	N/A	N/A
V'lain Fenton- May	ULM EAG, Panel MIC	Non- Personal	NIL	N/A	N/A
Vicky Smith	WP ATMP	Personal	NIL	N/A	N/A
Vicky Smith	WP ATMP	Non- Personal	NIL	N/A	N/A
Victoria Vanhoutte	WP ATMP	Personal	NIL	N/A	N/A
Victoria Vanhoutte	WP ATMP	Non- Personal	NIL	N/A	N/A
Vikas Jaitely	BPC, AIM EAG, Panel MIC	Personal	Merck Group (Merck KgAa) Germany	Salary	Yes
Vikas Jaitely	BPC, AIM EAG, Panel MIC	Non- Personal	NIL	N/A	N/A

Vincent Loh	BIO EAG	Personal	NIL	N/A	N/A
Vincent Loh	BIO EAG	Non- Personal	NIL	N/A	N/A
Warren Mann	AIM EAG	Personal	NIL	N/A	N/A
Warren Mann	AIM EAG	Non- Personal	NIL	N/A	N/A
Wayne Goddard	ULM EAG	Personal	NIL	N/A	N/A
Wayne Goddard	ULM EAG	Non- Personal	NIL	N/A	N/A
Wayne Zunic	BIO EAG				
Zara Hannoun	WP ATMP	Personal	Oxford Biomedica	Shares and salary	Yes
Zara Hannoun	WP ATMP	Conferenc e/Scientific Meetings	Oxford Biomedica	ASGCT - conference fees and expenses (presented at the conference)	No
Zara Hannoun	WP ATMP	Non- Personal	Oxford Biomedica	N/A	Yes
Zheng-Tao Wang	HCM EAG				

## **Contact information about these reports:**

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

Tel: 020 3080 6000

E-mail: info@mhra.gov.uk

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