Human Medicines Regulations 2012 Advisory Bodies

Annual Report 2021

Commission on Human Medicines

British Pharmacopoeia Commission

Medicines and Healthcare products Regulatory Agency

HUMAN MEDICINES REGULATIONS 2012
ADVISORY BODIES ANNUAL REPORT 2021

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

Commission on Human Medicines

British Pharmacopoeia Commission

Published by the Medicines and Healthcare products Regulatory Agency

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

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

ISBN 978-1-8384147-1-9

Printed on paper containing 75% recycled fibre content minimum

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

LIST OF CONTENTS

FOREWORD BY THE PARLIAMENTARY UNDER SECRETARY OF STATE FOR PATIENT SAFETY AND PRIMARY CARE

It gives me great pleasure to present the annual reports for 2021 of the Human Medicines Regulations Advisory Bodies: the Commission on Human Medicines and the British Pharmacopoeia Commission. These reports include a record of members' interests in the pharmaceutical industry and code of practice.

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

James Morris MP, on behalf of Lord Kamall

COMMISSION ON HUMAN MEDICINES ANNUAL REPORT 2021

TERMS OF REFERENCE

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

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

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

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

MEMBERSHIP

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

4. The Commission 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 2021

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

    Chemistry, Pharmacy and Standards (CPSEAG)
    Chaired by **Professor Kevin M G Taylor** *(for 4 meetings)*; **Professor Yvonne Perrie**

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

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

Infection (IEAG)
Chaired by **Professor Jonathan 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 M Patel**

Paediatric Medicines (PMEAG)
Chaired by **Dr Rebecca Mann** *(for 5 meetings)*; **Dr Guido Pieles** *(for one meeting);* **Professor Steven Cunningham**

Pharmacovigilance (PEAG)
Chaired by **Professor Jamie Coleman** *(Interim for 4 meetings)*

Working Groups 2021

COVID-19 Therapeutics Expert Working Group
Chaired by **Professor Sir Munir Pirmohamed** *(for 1 meeting)*; **Professor Jonathan S Friedland**

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

Dental Caries Stakeholder Reclassification Group
Chaired by **Professor Kevin M G Taylor**

Isotretinoin Expert Working Group
Chaired by **Professor Angela Thomas**

Real World Data Working Group
Chaired by **Professor Deborah Ashby**

MEETINGS

5. The Commission held 25 meetings during 2021. Of these, 6 were two-day meetings. One-day meetings lasted an average of three hours. All meetings were held via videoconference.

SECRETARIAT

6. The Commission's secretariat is based at the MHRA. A list of the support staff is at **Appendix IV**. The Commission also wishes to place on record its indebtedness and gratitude to the excellent professional and administrative staff of the MHRA concerned with the business of the Commission and its Expert Advisory Groups.

COSTS

7. Commissioners are entitled to claim an attendance fee of £325 per day (Chair's fee £500). Expert Advisory Group members are entitled to claim an attendance fee of £200 (Chair'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 231 applications for marketing authorisations.

Commission Advice on Applications for National Marketing Authorisations and Decentralised Applications

	Grant advised	**Grant not advised**
New Active Substances	24	13
Abridged Applications	69	57

9. The Commission considered 15 papers under the Early Access to Medicines Scheme.

10. The Commission considered an average of 20 applications at each of its 12 meetings in 2021, in addition to clinical trial applications, appeals, reclassifications, pharmacovigilance issues and other matters.

11. The Commission also convened at 13 ad hoc / extraordinary meetings in 2021.

APPEALS

12. The Commission considered a total of four pre-hearings covering 8 applications. Of these, one application was approved at the pre-hearing stage and 7 were approved on conditions.

13. The Commission considered a total of 41 written representations covering 66 applications. Of these, the Commission advised that marketing authorisations could be granted for 21, granted on conditions for 39 and granted subject to the resolution of the outstanding concerns for 1 application. For the remaining 5, the Commission advised against the grant of marketing authorisations.

EXTERNAL EXPERTS AND STAKEHOLDERS

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

Dr Kenneth Baillie MD PhD
Division of Genetics and Genomics, Roslin Institute, University of Edinburgh
(April)

Professor Kristien Boelaert
Professor of Endocrinology and Honorary Consultant Endocrinologist
University Hospitals Birmingham NHS Foundation Trust
(August)

Professor Judith Breuer
Professor of Virology, University College London (UCL), Division of Infection and Immunity, London
(August, October, November, December)

Mr Alexander Churchill
Deputy Director, Antiviral Taskforce, Therapeutics Taskforce
Department of Health & Social Care
(December)

Professor Tom Clutton-Brock FRCP FRCA FFICM
Director, Medical Devices Testing and Evaluation Centre
Clinical Director, NIHR Trauma Management MedTech Cooperative
Deputy Director, Institute of Translational Medicine, Birmingham
Chair, NICE Interventional Procedures Advisory Committee
Associate Medical Director, University Hospitals Birmingham NHS Foundation Trust, Professor of Anaesthesia & Intensive Care Medicine
(July)

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

Professor Gordon Dougan FRS
Department of Medicine, Cambridge Infectious Diseases, University of Cambridge
(March, September)

Professor Saul Faust
Professor of Paediatric Immunology & Infectious Diseases
Director of NIHR Southampton Clinical Research Facility
Clinical Director, NIHR Wessex Local Clinical Research Network
NIHR Senior Investigator
(September)

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
(March, September)

Mr Matthew Garrett
Dean of the Faculty of Dental Surgery at the Royal College of Surgeons of England
(July)

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
(March, September)

Dr Ravindra K Gupta MA MPH MBChB PhD FRCP FRCPath FMedSci
Professor of Clinical Microbiology, Wellcome Senior Fellow in Clinical Science, Cambridge Institute of Therapeutic Immunology and Infectious Diseases, Jeffrey Cheah Biomedical Centre, University of Cambridge & Honorary Consultant Physician – Infectious Diseases
Cambridge University Hospitals NHS Foundation Trust
(August)

Professor Philip Hannaford FRSE
Emeritus Professor of Primary Care, University of Aberdeen
(February, May)

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

Professor Peter C Hindmarsh
Professor of Paediatric Endocrinology, University College London
(August)

Ms Sara Hurley BDS (UBrist), MSc (UCL), MA (King's), psc(j)
Chief Dental Officer England, Honorary Professor Dentistry (University of Manchester), Honorary Doctorate of Health (University of Plymouth)
(December)

Dr Tom Irving
Head of SPI-M Secretariat and Scientific COVID-19 Modelling
(April)

Sir Michael Jacobs
Consultant & Hon. Senior Lecturer in Infectious Diseases
Royal Free London NHS Foundation Trust
(April, August, September)

Professor Matt Keeling
Professor in the Mathematics Institute and the School of Life Sciences of the University of Warwick
(April)

Dr Jonathan Leach OBE
NHS England Medical Director for COVID-19 Immunisation
(December)

Professor Andrew Lotery MD FRCOphth
Professor of Ophthalmology
(November)

Professor Hamish McAllister-Williams Ph.D, M.D, FRCPsych
Representative from the Royal College of Psychiatrists
Reader in Clinical Psychopharmacology at Newcastle University, Honorary Consultant Psychiatrist, Lead Clinician for the tertiary level Regional Affective Disorders Service in Newcastle, UK
(December)

Professor Dame Angela McLean
Co-Chair of the Scientific Pandemic Influenza Group on Modelling (SPI-M)
(April)

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

Professor Sarah Meredith
Professor of Clinical Trials, MRC Clinical Trials Unit at UCL, Institute of Clinical Trials and Methodology, University College London
(January, February, March, April, May, June, July, August, September)

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

Ms Sara Payne
Lay representative (Paediatric Medicines Expert Advisory Group member)
(April)

Professor Deenan Pillay
Professor of Virology, UCL Pro-Vice-Provost International
(October)

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
(January)

Mr Malcolm Qualie
Pharmacy Lead, Specialised Commissioning
NHS England
(June)

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

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
(November, December)

Dr Claire Shannon
Royal College of Anaesthetists
(July)

Professor Tom Solomon FRCP PhD
Chair, Neurological Science, Director, NIHR Health Protection Research Unit in Emerging and Zoonotic Infections, Associate Pro-Vice-Chancellor for Infrastructure and Environment, Faculty of Health and Life Sciences, University of Liverpool & Honorary Consultant Neurologist, Walton Centre NHS Foundation Trust
(March)

Dr Simon N. Stockley MB ChB, FRCGP, FIMC (RCSEd), DUMC
Clinical Workstream – Senior Medical Lead
National COVID-19 Vaccination Programme
NHS England and NHS Improvement (National)

(December)

Ms Josephine Tapper
Health advocate
(December)

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, February, March, April, May, November, December)

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

Professor Cheng-Hock Toh
Consultant in Haematology at the University of Liverpool and Liverpool University
(March, April)

Mrs Madeleine Wang BA (Hons)
Lay Member & Member of the Clinical Trials, Biologicals & Vaccines Expert Advisory Group (CTBVEAG)
(April, July, November)

Mrs Helen M Ward MSc, BSc (Hons), Senior Fellow HEA, RGN, RCN Nurse Practitioner, PGCEA, PG Cert NMP, Queens Nurse
Advanced Nurse Practitioner
(January, February, March, April, May, August, September, October, November, December)

Rosie Weatherley
Patient Representative - Information Content Manager, Mind
(December)

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

Dr Nick Andrews
Senior Statistician, Public Health England
(March)

Mr Luke Collet-Fenson
Private Secretary to the Chief Medical Officer – DHSC
(April)

Dr Kiren Collinson
Deputy Medical Director of Primary Care, General Practitioner
(October, December)

Ms Jenna Dilkes
The National Institute for Health and Care Excellence (NICE)
(January, March, May, July, September)

Dr Andrew Earnshaw
Head of the JCVI Scientific Secretariat, Secretary to the Joint Committee on Vaccination and Immunisation, Public Health England
(April)

Mr Hassan Iqbal
Senior Pharmacist Medicine Supply team - DHSC
(October, December)

Dr Chris Johnson
Interim Head of Vaccine Preventable Disease Programme (VPD) at Public Health Wales
(December)

Professor Anthony Kessel
Clinical Director - NHS England & Improvement
(August)

Professor Wei Shen Lim
JCVI
(March, April, September, November)

Xinxue Liu
COV-BOOST Senior Statistician
(September)

Dr Jamie Lopez Bernal
Consultant Epidemiologist, Public Health England
(September)

Ms Kate Mitchell – DHSC
Senior Pharmacist Medicine Supply team - DHSC
(October, December)

Ms Claire Potter
Head of Prescribing Policy & Legislation
Medicines & Pharmacy Directorate, DHSC
(October)

Dr Mary Ramsay
Public Health England / UKHSA
(March, April, September, December)

Dr Keith Ridge
Chief Pharmaceutical Officer, NHS England

(October, December)

Dr Richard Roberts
Head, Vaccine Preventable Disease Programme at Public Health Wales
(March, April)

Ms Natalie Spray
The National Institute for Health and Care Excellence (NICE)
(January, February, March, April, May, August, September, October, December)

Dr Laura Squire
Deputy Director - COVID-19 Vaccine Deployment, DHSC
(September)

Ms Phoebe Topping
Team Leader, Drugs and Addiction, of the Population Health Directorate at the Department of Health and Social Care (DHSC)
(April)

Professor Jonathan Van-Tam
Deputy Chief Medical Officer
(March, April, August, September)

Ms Eloisa Whiteman
Prescribing Policy Adviser
DHSC
(October)

Gary Williams
Head of Primary Care, NHS England
(October, December)

Director of Specialist Pharmacy Service Medicines Use and Safety
NHS England and NHS Improvement
(February)

CONSIDERATION OF OTHER MATTERS

16. 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:

Update on e-cigarettes and the risk of associated lung injury

17. The Commission considered an update on the risk of lung injury associated with e-cigarettes which are used as aids to give up smoking. Long-term use of these products is not recommended, and their use is not

legal for anyone under 18 years. A large number of cases of lung injury had occurred in the United States (US) associated with e-cigarette or vaping in 2019. A review of the situation in the UK at that time resulted in an article in 'Drug Safety Update[1]' in January 2020 to encourage awareness and reporting of e-cigarette or vaping associated lung injury (EVALI) through the Yellow Card Scheme.

18. The Commission considered the latest evidence at the January meeting and noted that the cases subsided very rapidly in the US, and there have been very few cases of possible or probable EVALI in the UK in the context of a relatively high number of e-cigarette users. The Commission considered, however, that based on the seriousness of the issue, it would be important to continue monitoring for new reports of EVALI and other serious respiratory reactions, with close attention paid to any reports in adolescents given the potential for long-term damage to health.

SAFETY OF MARKETED MEDICINES

Reassessment of the use of valproate in the treatment of women of childbearing potential for bipolar disorder

19. The Commission considered and advised on a reassessment of the use of valproate in the treatment of women of childbearing potential for bipolar disorder at the February meeting. This consideration is ongoing at the time of the report.

Naloxone – proposals for widening availability to outreach services for homelessness and accommodation services

20. The Commission considered a proposal to allow wider access to naloxone, an antidote in opioid overdose, at the April meeting. This proposal, which was aimed at reducing deaths from opioid overdose, was be taken forward through a public consultation[2]. The responses to the consultation are under consideration.

Review of the insomnia indication for chloral hydrate and chloral betaine products

21. At the April meeting, the Commission reviewed the available data for chloral hydrate and chloral betaine and advised that the indication should be restricted to the treatment of severe sleeplessness (insomnia) in children and adolescents with suspected or definite disorders that affect the development of the neurological system and brain (neurodevelopmental disorders), only when the insomnia is interfering with normal daily life, and other therapies (behavioural and pharmacologic) have failed. Any use of chloral betaine and chloral hydrate (including in adults) should not exceed 2 weeks. The Commission advised that the

[1] E-cigarette use or vaping: reporting suspected adverse reactions, including lung injury - GOV.UK (www.gov.uk)
[2] Expanding access to naloxone - GOV.UK (www.gov.uk)

product information should contain a statement that the use of chloral hydrate and chloral betaine in children and adolescents is not generally recommended and if used should be under the supervision of a medical specialist. An article was published in Drug Safety Update[3].

Assessment of the MAH submission on the relevance of preclinical findings of reduction in testicular size in juvenile rats to humans exposed to valproate

22. The Commission considered an assessment of preclinical findings in juvenile rats exposed to valproate at the August meeting. This consideration is ongoing at the time of the report.

Management of overdose of beta-blockers – proposed updates to product information

23. The Commission considered and discussed proposed changes to the product information on the management of overdose for the beta-blocker class of medicines at the April meeting. Beta blockers slow heart rate and force and are used to treat conditions including angina, heart failure some heart rhythm disorders, and after a heart attack. Beta blockers are also sometimes prescribed for glaucoma, anxiety and migraine. The Commission discussed the different pharmaceutical properties within the beta-blocker class which impact on the effects seen in overdose. The Commission noted effects on the central nervous system were seen with lipid-soluble but not water-soluble beta-blockers; a sotalol-specific effect of QT prolongation in overdose was also noted. The Commission advised that the wording on management of overdose should reflect the symptoms of overdose of individual beta blockers; should highlight the need to seek medical attention if an overdose of beta-blocker is taken and should signpost clinicians to consult national clinical guidance on the management of overdose. Product information for health professionals and patients is being updated and communication of the updates via Drug Safety Update is planned.

COVID-19 vaccines

24. The Commission also advised on the safety of COVID-19 vaccines following their administration, based on reviews of reported suspected side effects through the Yellow Card Scheme, epidemiological analysis and international safety data, as well as any relevant clinical trial or non-clinical data. Major topics of discussion and decisions reached by the Commission of vital clinical importance included:
    - Safety of the vaccines in pregnancy and breastfeeding.
    - Changes to the recommended age groups for the authorisations of COVID-19 Pfizer/BioNTech and COVID-19 Vaccine Moderna vaccines.

[3] Chloral hydrate, cloral betaine (Welldorm): restriction of paediatric indication - GOV.UK (www.gov.uk)

- Extension of the dosing interval between doses for COVID-19 Vaccine Moderna.
- Review of potential safety signals following administration of the vaccines and appropriate regulatory action where required. Ad-hoc meetings were convened to discuss individual topics, including: the risk of anaphylaxis with the mRNA COVID-19 vaccines, the risk of thrombosis with thrombocytopenia syndrome (TTS) with COVID-19 Vaccine AstraZeneca, and 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 reporting published weekly.
- Review and authorisation of booster doses of vaccines.
- Review of proposals of post-authorisation studies to monitor the effectiveness of the vaccines in real world settings, including data from public health bodies.

Medicines available without prescription

Applications

25. The Commission considered three applications for change of legal classification during the year.

26. Firstly, in relation to an application to reclassify from Prescription Only Medicine (POM) to Pharmacy Only (P), a medicine for the relief of symptoms associated with chronic idiopathic urticaria the Commission advised that, subject to certain points being addressed, the application was approvable.

27. Secondly, the Commission gave preliminary advice against an application to reclassify from POM to P a medicine for the prevention of dental caries.

28. Finally, the Commission advised on an application to reclassify from P to General Sales (GSL) availability, a medicine for the temporary relief of mild to moderate pain which has not been relieved by ibuprofen or paracetamol individually such as migraine, headache, backache, period pain, dental pain, rheumatic and muscular pain, cold and flu symptoms, sore throat and fever. The Commission advised that, subject to certain points being addressed, the application was approvable.

Ad hoc stakeholder group for reclassification of a product for dental caries

29. 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. 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 comprises representatives from: the medical and pharmacy professional organisations, practising healthcare professionals, patients, and patient representatives.

30. In 2021 one reclassification ad hoc stakeholder group was established and met to consider a POM to P reclassification application for a medicine indicated for the prevention of dental caries.

THE COMMISSIONER'S EXPERT ADVISORY GROUPS (EAGs)

31. The remit and membership of the Expert Advisory Groups and Working Groups are listed in **Appendices II & III**.

32. 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)

33. In 2021, the CDRRA EAG convened twice, in March and September, and provided advice by written correspondence on an additional 5 occasions.

34. In February, the EAG provided written comments on:
    - The interim findings from a multiplatform randomised controlled trial on the use of anticoagulants in the management of patients hospitalised with COVID-19

35. In March, the EAG met, discussed and made recommendations on:
    - Broadening the indications of an antidiabetic medicine to treat chronic kidney disease in adults
    - The product information of the beta-blocker class of medicines, to review proposed changes to the advice on managing overdose. The EAG considered that the proposed wording would highlight the signs and symptoms of overdose and would signpost clinicians towards national clinical guidance on managing overdose. The EAG noted the pharmaceutical properties of beta-blockers, including whether they are lipid-soluble or water-soluble, and their effect when taken in overdose. The EAG considered that the proposed changes took account of these differences to ensure that the overdose effects included in the product information were accurate.

36. Also in March, the EAG provided written comments on:
    - An injectable medicine proposed for use in adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in adults with an

initial Body Mass Index (BMI) of ≥30 kg/m^2 (obese), or ≥27 kg/m^2 to <30 kg/m^2 (overweight) in the presence of at least one body weight-related comorbidity.

37. In May, the EAG provided written comments on:
    - A generic medicine proposed for treating patients with life- threatening cardiac arrhythmias (an abnormal heart rhythm). The EAG considered the available evidence, discussed the expected benefits against the potential risks for patients taking this medicine and advised that the MHRA requires further information before considering the application approvable.

38. In July, the EAG provided further written advice on:
    - A previously considered application for a medicine proposed for use in adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI) of ≥30 kg/m2 (obesity), or ≥27 kg/m2 to <30 kg/m2 (overweight) in the presence of at least one weight-related comorbidity.

39. Also in July, the EAG also provided written comment on:
    - An assessment of lung toxicity in association with use of amiodarone related to a recent Coroner's Regulation 28 Report. Amiodarone is a medicine that helps to regulate the heartbeat. It is used to treat serious and life-threatening arrythmia, including atrial fibrillation, ventricular fibrillation and supraventricular tachycardia. The Group considered the need for risk management activities informed by an assessment of the Coroner's concerns in the context of other safety information for amiodarone. These included data from the UK Yellow Card Scheme, published literature, data on prescribing patterns of amiodarone in the UK, recent updates to National Institute for Health and Care Excellence (NICE) clinical guidance, and warnings present in the product information for amiodarone medicines.

40. In September, the EAG met, discussed and made recommendations on:
    - Reports of leakages in one brand of an insulin pump used by people in the UK with type 1 diabetes. People with type 1 diabetes require insulin; without it, even for short periods of time, they risk developing life-threatening ketoacidosis. Injecting insulin many times per day, or receiving it continuously, both beneath the skin, are the two ways to receive insulin. The MHRA has identified concerns associated with the Accu-Chek Insight Pump which uses an insulin cartridge containing insulin (the NovoRapid PumpCart).

      The EAG was presented with an assessment of the safety data from UK reports of leakage of insulin, including cases of cracked cartridges causing leakage. The Group's view was sought on the assessment of this safety concern and did not consider the actions

proposed by the manufacturer to reduce the occurrence of leakage leading to inadequate supply of insulin were adequate.

Given the potentially serious risk to public health, the Group recommended that advice on this issue be sought from the Commission on Human Medicines.

- The potential impact of the withdrawal of an oral medicine to treat type 1 diabetes.

Chemistry, Pharmacy and Standards Expert Advisory Group (CPSEAG)

41. In 2021, the CPSEAG convened 10 times and provided advice by written correspondence on 5 occasions.

42. In January, the EAG discussed and made recommendations on:
    - two medicines indicated for the treatment of documented life-threatening ventricular arrhythmias, such as sustained ventricular tachycardia. This medicine can also be used for the treatment of patients with documented symptomatic ventricular arrhythmias when the symptoms are of sufficient severity to require treatment
    - a medicine for the treatment and prevention of influenza (flu)
    - a medicine indicated for the treatment of genital warts, rough skin due to exposure to too much sun and for a form of skin cancer
    - a medicine indicated for the treatment of feeling sick (nausea)
    - a medicine indicated to treat adults and adolescents 12 years of age and older with severe atopic dermatitis, also known as atopic eczema
    - a medicine indicated for the relief of rheumatoid arthritis, osteoarthritis, and pain including muscular, traumatic and dental pain, headaches of most causes, postoperative and post-partum pain and pyrexia in children
    - a medicine indicated for the treatment of inflammation in the eye (uveitis or iritis) and before certain eye examinations; also to diagnose eye problems such as blurred vision (refraction) in children below 6 years and children with cross-eyes or squint (convergent strabismus)
    - a medicine indicated for the treatment of chronic lung disease allowing patients to breath more easily
    - a medicine indicated for the treatment of seasonal allergic conjunctivitis such as from hay fever

43. Also in January, the EAG provided written comments on:
    - a medicine for the treatment of active tuberculosis caused by Mycobacterium tuberculosis
    - a medicine for the treatment of conditions associated with inflammation or an overactive immune system

44. In February, the EAG did not meet, but they provided written comments on:
    - a medicine indicated for the treatment of various types of infections such as skin, bone, lung (pneumonia) or central nervous system.

45. In March, the EAG did not meet, but they provided written comments on:
    - a medicine indicated for the treatment of breast cancer
    - a medicine indicated for the treatment of urge incontinence and/or increased primary frequency and urgency as may occur in patients with overactive bladder syndrome
    - a medicine for the treatment of psychosis and Parkinson's disease
    - a medicine for the long-term treatment of adult patients with confirmed diagnosis of late-onset Pompe disease (acid α-glucosidase deficiency)

46. In April, the EAG discussed and made recommendations on:
    - a medicine used for the treatment of lung cancer
    - a medicine used for the treatment of cancer
    - a medicine used for weight loss and weight maintenance
    - a medicine used as an additional pain reliever in patients not responding to opioid pain killers
    - a medicine indicated for the treatment of feeling sick (nausea)
    - a medicine indicated for the treatment of high blood pressure (hypertension) or certain types of chest pain called angina

47. In May, there were 2 meetings, the EAG discussed and made recommendations on:
    - two medicines used for the treatment of lung cancer
    - a medicine used to replace the thyroxine that the thyroid gland does not produce sufficiently in a condition termed hypothyroidism
    - a medicine indicated for the treatment of Vitamin D deficiency
    - a medicine indicated for the treatment of various cancers
    - a medicine indicated for the treatment of chronic obstructive pulmonary disease (COPD) to breathe more easily. COPD is a chronic lung disease that causes shortness of breath and coughing
    - a medicine indicated for the treatment of chronic obstructive pulmonary disease (COPD) to breathe more easily. COPD is a chronic lung disease that causes shortness of breath cancer
    - a medicine indicated for the treatment of irregular heartbeat
    - a medicine indicated for the treatment of severe sleeplessness (insomnia)
    - a medicine indicated for the treat of premature puberty
    - a medicine used for the treatment of kidney cancer
    - a medicine indicated for the replacement of hormones produced by glands attached to kidneys, to treat a condition called Salt Losing Adrenogenital syndrome and also for the treatment of severe blood pressure disorders)
    - a medicine indicated for the treatment of various fungal infections

- a medicine indicated for the treatment of infections of the respiratory tract, urinary and genital tracts, including inflammation of the lining of the heart and to treat infected burns and blood infections

48. In June, the EAG discussed and made recommendations on:
    - a medicine indicated for the treatment of adults and adolescents (12 years and older) with chronic graft-versus-host disease (GVHD) when cells are transplanted from the donor (the graft) attack the body (the host). This most commonly causes damage to the skin, liver or digestive system
    - a medicine indicated to treat adults and adolescents 12 years of age and older with severe atopic dermatitis, also known as atopic eczema
    - an aid for smokers wishing to quit or reduce smoking prior to quitting
    - a medicine indicated for use in sedation of mechanically ventilated adult patients
    - a medicine used for the treatment of high blood pressure (also known as 'hypertension') in adults and in children and adolescents aged 6 to less than 18 years
    - a combination medicine to treat cystic fibrosis in patients aged 12 years and older who have at least one change in the cystic fibrosis gene
    - a medicine used to lower lipids known as cholesterol and triglycerides in the blood when a low fat diet and life style changes on their own have failed
    - a medicine indicated for use during 'assisted reproductive techniques'
    - to encourage pregnancy
    - a medicine indicated for the treatment of microbial infections
    - two medicines indicated for the treatment of high blood pressure (known as hypertension)
    - a medicine indicated for the treatment of high blood pressure (known as hypertension)
    - a medicine indicated for the treatment of an underactive thyroid
    - a medicine for the treatment of Human Immunodeficiency Virus (HIV) infection in adults, adolescents and children weighing at least 25 kg
    - a medicine to treat adults with advanced stages of a type of lung cancer called non-small cell lung cancer (NSCLC) that has spread to other parts of the body
    - A framework for point of care (POC) manufacture: regulatory proposal

      Proposals were presented for a new regulatory framework for medicinal products manufactured at point of care (POC) developed from stakeholder meetings. The development of this framework is a commitment in the 'innovative regulation' projects in Sector Deal 2 of the Life Sciences Industrial Strategy in order to extend the range of manufacturing and supply options to enable patients to get new products. The framework is proposed to be implemented through a

statutory instrument, SI, made under powers in the Medicines and Medical Devices Act 2021, with a public consultation which commenced in August 2021 and closed in September 2021.
Under the proposals, the framework would adapt current regulatory requirements to ensure that safety, quality and efficacy of POC product will be in line with products manufactured in current factory-based locations. The framework would cover all medicinal product types including Advanced Therapy Medicinal Products, 3D printed products, blood products and medicinal gases manufactured at POC. The core regulatory concepts for the framework includes:

- a Control Site – this will oversee all aspects of the POC manufacturing system, this will be subject to routine GMP inspections along with an appropriate number of POC sites.
- a POC Master File - the key source of information on the state of control over the POC system and used to support clinical trial and marketing authorisation applications.

49. In August, there were 2 meetings, the EAG discussed and made recommendations on:
    - a medicine indicated for treatment of atopic dermatitis, also known as atopic eczema
    - a medicine to treat a condition known as primary hypercholesterolaemia (when cholesterol in the blood is elevated) in adults
    - a medicine indicated for the treatment of overactive bladder symptoms when other treatments have not worked
    - a medicine indicated for the treatment of endometriosis (painful symptoms due to displaced tissue of the lining of the womb)
    - a medicine used for weight loss and weight maintenance
    - 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 use treatment of metastatic (advanced) or unresectable (unremovable), well or moderately differentiated neuro-endocrine tumours of pancreatic origin in adults with progressive disease
    - a medicine indicated for use to replace a hormone that the thyroid gland
    - a medicine indicated for use treatment of fungal infections
    - a medicine indicated for the treatment of muscle cramps in the stomach, gut and bladder (irritable bowel syndrome)
    - a medicine indicated for the short-term symptomatic treatment of indigestion (dyspepsia) and of metabolic acidosis (a condition where the body fluids and tissues are unusually acidic).

50. In September, 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 use treatment of skin and soft tissue infections such as boils, ulcers, infected burns, respiratory infections such as pneumonia, sinusitis and tonsilitis, other infections such as osteomyelitis (affecting the bone and bone marrow), enteritis (infections of the intestinal tract, especially the small intestine). endocarditis (inflammation of the lining of the heart and its valves), urinary tract infection, meningitis (a serious disease characterised by inflammation of the membranes around the brain or spinal cord), and septicaemia (blood poisoning) It is also used to prevent infections during major surgery
- a medicine indicated for the treatment of serious bacterial infections
- two medicines indicated for the treatment of a condition where the thyroid does not produce enough thyroxine (hormone)

51. In October, the EAG discussed and made recommendations on:
    - a medicine used to treat adults with kidney cancer and a disease called Von Hippel-Lindau
    - a medicine used to treat adults with Philadelphia chromosome-positive 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 indicated for the treatment of haemolytic anaemia (haemoglobin ≤ 10.5 g/dL) due to sickle cell disease in adults and paediatric patients 12 years of age and older as monotherapy or in combination with hydroxycarbamide
    - a medicine indicated for use treatment of various types of breast cancer
    - a medicine indicated for the treatment of serious bacterial infections
    - a medicine indicated for the treatment of osteoporosis in adults. Osteoporosis is a disease that causes your bones to become thin and fragile.
    - a medicine used to treat certain types of cancer such as multiple myeloma (a type of cancer that develops from cells in the bone marrow called plasma cells), advanced cancer of the ovaries, childhood neuroblastoma (a type of cancer affecting the nervous system), malignant melanoma (a type of skin cancer), soft tissue sarcoma (cancer of the muscle, fat, fibrous tissue, blood vessels, or other supporting tissue of the body)
    - a medicine used to treat severe infections such as typhoid and meningitis, when other antibiotics do not help or are unsuitable
    - a medicine for the treatment of patients aged 6 years and older with cystic fibrosis (CF) (production of abnormally thick mucus, leading to the blockage of the pancreatic ducts, intestines, and bronchi and often resulting in respiratory infection)
    - A medicine for the treatment for certain endocrine (hormone secreting gland) and non-endocrine disorders in certain cases of cerebral oedema (swelling of brain); and for diagnostic testing of

adrenocortical hyperfunction (hyperfunction is a condition where there is an over-production of products of the adrenal cortex

- The CPS were informed that in light of the recent EFSA statement (May 2021) that titanium dioxide can no longer be considered safe as a food additive, the UK Food Standards Agency (FSA) is independently assessing the safety of titanium dioxide in foods. The UK Committee on Mutagenicity (COM) and the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) are assessing the evidence. Removal of titanium dioxide from the EU list of permitted food colourings is likely but use in medicines in Europe will continue, at least on a temporary basis. MHRA continues to liaise closely with the FSA on any actions required
- The CPS discussed whether the ICH Q3D guideline (control of elemental impurities in drug substances and finished products) permitted daily exposure (PDE) limits set for products administered by parenteral routes were appropriate for products administered by the intrathecal route. It was generally agreed that given the clinical need of intrathecally administered medicinal products no action on currently marketed products is warranted at the moment, and further investigation on the safe level of heavy metals in the cerebrospinal fluid should be conducted
- The CPS were informed of a new azido impurity, 5-[4'-((5-(azidomethyl)-2-butyl-4-chloro-1H-imidazole-1-yl) methyl) [1,1'-biphenyl]-2-yl)-1H-tetrazole has been found in a number of losartan containing products. The impurity is potentially mutagenic, and a strategy was proposed to ensure that patients are not unduly exposed whilst ensuring that losartan products remain available to patients

52. In December, the EAG discussed and made recommendations on:

- a medicine for diagnostic use in adult patients with prostate cancer
- a medicine used for the treatment of patients with prostate-specific membrane antigen (PSMA) who have prostate cancer
- a medicine used to treat adults with Philadelphia chromosome-positive 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 to treat adults with Philadelphia chromosome-positive 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 indicated for use in the treatment of severe blood loss after childbirth
- a medicine indicated for the treatment of retention of water in body
- a medicine indicated for the treatment of blood clots
- a medicine indicated for the treatment of severe rheumatoid arthritis, severe inflammation of the gut (Crohn's disease), some diseases

where the body's immune system reacts against itself (auto immune disease), and after organ transplantation
- a medicine indicated for the relief of symptoms of nausea and vomiting
- a medicine indicated for the prevention of influenza
- a medicine indicated for the treatment for malignant pleural mesothelioma (a form of cancer that affects the lining of the lung), to patients who have not received prior chemotherapy and to treat advanced stage lung cancer either alone or in combination with other drugs
- a medicine indicated for the treatment of an overactive bladder (difficulty in controlling or a frequent need to empty the bladder)
- a medicine for the treatment of urinary tract infections
- a medicine for the treatment of certain bacterial infections, post-operative infections, and severe established abdominal and gynaecological infections
- a medicine indicated for the treatment of infections of the bladder, kidney and other parts of the urinary tract
- a medicine used to lower lipids known as cholesterol and triglycerides in the blood when a low-fat diet and lifestyle changes on their own have failed

53. Also in December, the EAG provided written comments on:
    - a Drug Safety Update (DSU) concerning albumin-bound paclitaxel formulations

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

54. In 2021, the CTBVEAG convened, virtually, five times and provided advice by written correspondence on 43 occasions.

55. In January, the EAG provided written comments on:
    - a paper on the evaluation of the responses provided by Eli Lilly after questions from the initial assessment of a product for the treatment of mild to moderate COVID-19 illness
    - a paper on the use of antivirals and other agents for the treatment of COVID-19
    - a paper on clinical trial applications for the treatment of COVID-19
    - an approved (not in the UK or EU) antiparasitic medicine used for the treatment of cryptosporidiosis and giardiasis diarrhoea and also has reported activity against anaerobic bacteria, protozoa and other viruses.

56. In February, the EAG provided written comments on:
    - a Phase IV, open-label, event-driven clinical trial with 1:1 allocation to Direct oral anticoagulants (DOAC) or no additional therapy (usual care) with the objective of testing the hypothesis that DOACs, now

commonly used in the NHS for older patients with AF, are effective and cost-effective at reducing major adverse clinical events in younger patients at low or intermediate risk of stroke, and can reduce the high rate of cognitive decline.
- papers on the use of antivirals and other agents for the treatment of COVID-19
- clinical trial applications for the treatment of COVID-19

57. In March, the EAG discussed and made recommendations on:
    - a medicine indicated for the long-term treatment of adult patients with confirmed diagnosis of late-onset Pompe disease (acid α- glucosidase [GAA] deficiency)
    - a paper on the risk of escape variants in patients treated with COVID-19 therapies and how this was being monitored. This relates to both nucleoside analogue antivirals (e.g. remdesivir) and anti-SARS-CoV-2 monoclonal antibodies, especially when used in immunocompromised patients where prolonged viral replication occurs. The EWG reflected that viraemia is mainly a problem early in disease in the community setting/outpatients so this is where monitoring would need to be focused. The EWG heard that this had been one of the main concerns discussed in the Covid-19 therapeutics EWG, especially when the first monoclonal antibody had been discussed. The Chair concluded that he would raise this issue at the next C-19 EWG meeting.

58. In March, the EAG provided written comments on:
    - clinical trial applications for the treatment of COVID-19
    - papers on the use of antivirals and other agents for the treatment of COVID-19.

59. In April, the EAG discussed and made recommendations on:
    - a medicine indicated for the treatment of adult patients who have advanced triple-negative breast cancer (a type of breast cancer that does not have any of the receptors commonly found in breast cancer) and progressed on prior treatment.
    - a paper on the finalised MHRA biosimilar guidance, following a public consultation for the draft guidance in October/November last year.

60. In April, the EAG provided written comments on:
    - clinical trial applications for the treatment of COVID-19

61. In May, the EAG discussed and made recommendations on:
    - a clinical trial application to evaluate the efficacy and safety of a new drug substance in patients with glaucoma.
    - a medicine indicated for the treatment of a type of lung cancer that is advanced or has 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.

62. In May, the EAG provided written comments on:
    - a paper on the use of antivirals and other agents for the treatment of COVID-19
    - clinical trial applications for the treatment of COVID-19

63. In June, the EAG provided written comments on:
    - a paper on the use of antivirals and other agents for the treatment of COVID-19
    - clinical trial applications for the treatment of COVID-19

64. In July, the EAG provided written comments on:
    - clinical trial applications for the treatment of COVID-19.

65. In August, the EAG provided written comments on:
    - a paper concerning a clinical trial aimed at informing JCVI recommendations regarding COVID19 vaccination in 12 to 16 year old subjects.

66. In September, the EAG provided written comments on:
    - a paper regarding creation of CAR T-cell manufacture via CRISPR technology to treat acute myeloid leukaemia
    - an advanced cancer indication, using a gene therapy treatment derived from a novel vaccinia virus backbone.

67. In October, the EAG discussed and made recommendations on:
    - a product indicated for the treatment and prevention of recurrence of non-muscle-invasive bladder cancer (NMIBC)
    - a product indicated for the pre-exposure prophylaxis and post-exposure prophylaxis against rabies in all age groups

68. In October also, the EAG provided written comments on:
    - a paper on the use of antivirals and other agents for the treatment of COVID-19.

69. In November, the EAG provided written comments on:
    - a clinical trial application for the treatment of COVID-19.

70. Also in November, the EAG provided written comments on:
    - a medicine indicated for the treatment of neovascular age-related macular degeneration; Diabetic macular oedema; Wet age-related macular degeneration.

71. In December, the EAG provided written comments on:
    - a clinical trial application for the treatment of COVID-19.

72. Also in December, the EAG provided written comments on:
    - a cell therapy product indicated for the treatment of Relapsed/refractory T cell malignancies

COVID-19 Therapeutics Expert Working Group

73. 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 is 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 here.

74. The Expert Working Group brings together a range of formidable experts from the fields of infectious diseases, immunology, clinical pharmacology, genetics, paediatric infections, etc and inviting additional expertise as needed. Collective expertise enables the MHRA to meet a critical item on the public health agenda, that of regulating COVID-19 therapeutics.

75. The Expert Working Group met on 13 occasions in 2021, and discussed many items, some of the more high-profile topics included: Ronapreve, molnupiravir, sotrovimab, Ivermectin, ISARIC 4C remdesivir study findings, discussions on escape variants, and consideration of a surveillance strategy for COVID-19 therapeutics for monitoring safety and effectiveness post-authorisation.

76. The reviews and positive assessments of some of the products listed above led to the first authorisations in Great Britain, those for a monoclonal antibody therapy (sotrovimab), a combination antibody therapy (Ronapreve), and the first anti-viral in COVID-19 (molnupiravir). And, in late December 2021 the Expert Working Group considered an application for (Paxlovid).

77. The Expert Working Group considered the potential risk of escape variants on public health. This phenomenon was discussed on multiple occasions, in order to evaluate and compare risks in a manner that was tailored to the available data for a given product. To thoroughly interrogate the risk and potential implications of escape variants, the group relied heavily on their expert knowledge of SARS-CoV-2 in conjunction with a product's mechanism of action. The group also considered the target population/s, and other relevant biological & clinical factors in a methodical manner, to ensure that risks were suitably minimised or mitigated. The EWG's advice was shared with the CHM where a range of regulatory options for managing risk as well as how best to capture data on use of the products post-authorisation were considered. The CHM agreed with the recommendations and subsequently 'escape variants' became a key facet of the COVID-19 Therapeutics Surveillance Strategy.

78. The CHM noted the Expert Working Group's advice on Ivermectin.

79. The Expert Working Group regularly invite representatives from other public and private bodies to furnish them with the latest information, this interaction is integral to the group's ability to effectively fulfil their remit. For example, representatives from the REMAP-CAP platform trial gave a presentation on the immunomodulatory treatments included in their trial.

80. In order to foster a more comprehensive understanding of the topics discussed, the expert group includes a diverse membership spanning many clinical and public health disciplines. A diverse membership also facilitates appropriate public health responses to new COVID-19 therapies, and also as our understanding of COVID 19 evolves, it enables potential and realised public health implications to be appropriately addressed.

81. The Expert Working Group works closely with the other expert advisory groups, including the COVID-19 Vaccines Benefit-Risk Expert Working Group and Clinical Trials, Biologicals and Vaccines Expert Advisory Group, and the Commission on Human Medicines.

COVID-19 Vaccines Benefit Risk Expert Working Group

82. The COVID-19 Vaccines Benefit-Risk Expert Working Group was convened following the emergence of COVID-19 as a global pandemic. The group's remit is primarily to advise Commission of Human Medicines (CHM) on the quality, safety and efficacy of COVID-19 vaccines and on the balance of benefit and risks prior to and post authorisation. The complete list of the group's objectives can be found here.

83. The COVID-19 Vaccines Benefit-Risk Expert Working Group met on 52 occasions in 2021 and will continue having regular as well as ad-hoc meetings as needed. Significant events advised on by the group included the authorisation under Regulation 174 of the Human Medicines Regulations 2012 of a further two vaccines shown to be effective against SARS-CoV-2, COVID-19 Vaccine Moderna and COVID-19 Vaccine Janssen. The group also advised on the safety of authorised COVID-19 vaccines following their administration, based on reviews of suspected side effects reported through the Yellow Card Scheme, epidemiological analysis and international safety data, as well as any relevant clinical trial or non-clinical data.

84. Outcomes of the Expert Working Group's discussions were provision of advice to the MHRA assessment team and making recommendations to the Commission on Human Medicines (CHM) on the licensure and conditions for licensure of the COVID-19 vaccines, based on safety, quality and efficacy of the vaccines. Major topics of discussion and decisions reached by the group included:
    - Safety of the vaccines in pregnancy and breastfeeding.

- Changes to the recommended age groups for the authorisations of COVID-19 Pfizer/BioNTech and COVID-19 Vaccine Moderna vaccines.
- Extension of the dosing interval between doses for COVID-19 Vaccine Moderna.
- Advice on batch testing of the vaccines.
- Review of potential safety signals following administration of the vaccines and appropriate regulatory action where required. Ad-hoc meetings were convened to discuss individual topics, including: the risk of anaphylaxis with the mRNA COVID-19 vaccines, the risk of thrombosis with thrombocytopenia syndrome (TTS) with COVID-19 Vaccine AstraZeneca, and 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 reporting published weekly.
- Review and authorisation of booster doses of vaccines.
- Review of proposals of post-authorisation studies to monitor the effectiveness of the vaccines in real world settings, including data from public health bodies.

85. Experts from various public health organisations and academic institutions were invited to the Expert Working Group and presentations were heard from the COVID-19 Genomics UK (COG-UK) consortium, Public Health England (PHE), the Wellcome Trust, Office of National Statistics, and representatives from NHS England.

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

86. In 2021, the GRIDEAG convened 2 times and provided advice by written correspondence on 2 occasions.

87. In March there was no meeting, but the EAG provided written comments on:
    - a medicine for the treatment of rheumatoid arthritis, psoriatic arthritis and ulcerative colitis (unpredictable, non-infectious inflammatory disease of the gastrointestinal tract) in adult

88. In May, the EAG discussed and made recommendations on:
    - The EAG were presented with a summary of a recent publication discussing ocular surface disease: presentation, management and long-term sequelae, in relation to a monoclonal antibody (a type of specialised protein) used for the treatment of moderate to severe atopic dermatitis (also known as atopic dermatitis) in adults and adolescents 12 years or older. The article advocated involvement of an ophthalmologist prior to treatment in those with a history of ocular surface disease.

The EAG discussed the growing understanding of specific monoclonal antibodies associated ocular side effects, and the current management of these in the UK clinical setting. The EAG did not support adding a recommendation in the product information that there should be a mandatory assessment by an ophthalmologist prior to treatment initiation, as this has the potential to delay initiation of treatment in the UK setting, potentially impacting patients with severe atopic dermatitis in need of further treatment options. However, the EAG noted that there may be scope for developing clinical pathways to facilitate prompt assessment of patients treated with - monoclonal antibodies - who experience ocular symptoms.

The EAG recommended that dry eye should be listed as an adverse event in section 4.8 the Summary of Product Characteristics and an appropriate warning included in Section 4.4. The EAG heard that eye dryness is currently listed in the Patient Information Leaflet which also advises patients to talk to their doctor if they have any new or worsening eye problems, including eye pain or changes in vision.

- The EAG discussed a medicine for the treatment of rheumatoid arthritis, psoriatic arthritis and ulcerative colitis in adult patients who have responded inadequately to, or who are intolerant to one or more alternative treatments. The EAG noted that UK usage is fairly low, and in 2020 usage was estimated as just over 3200 patient-years, using IMS MIDAS data.

  The EAG was presented with an assessment of the responses to additional questions raised by the UK and the PRAC relating to new safety signals of cardiac events and malignancies with this drug.

  In relation to cardiovascular risk, the EAG agreed that the data shows an increased risk and that the RMP and product information should be updated accordingly. It was agreed that the risk factors of age ≥ 65 years and smoking should be included. It was noted that as the risk increases with age, this would not exclude a possible risk in younger patients. The EAG also noted that general risk factors for cardiovascular events are well known and understood and are easily communicated to prescribers and patients.

  The EAG noted that there is not sufficient evidence to conclude whether there is a dose relationship with respect to the cardiovascular risk, but that this requires further investigation.

  In relation to risk of malignancy, the EAG agreed that the data shows an increased risk and that the RMP and product information should be updated accordingly. It was agreed that the risk factors of age ≥ 65 years and smoking should be included. The EAG also noted that general risk factors for malignancy are not well defined

and as such any risk factors should be clearly specified in the product information.

The EAG noted that the sub-type of lymphoma had not been discussed in the data presented, and that the MAH should be asked to discuss this further. Rheumatoid arthritis is associated with an increased risk of B cell lymphomas, so an increase in other types of lymphoma with tofacitinib would be particularly concerning.

- The EAG heard that, in November 2020, a new monoclonal antibody treatment for psoriatic arthritis was approved, and that a recommendation had been added in the product information to monitor liver enzymes, according to routine patient management, in psoriatic arthritis patients treated with this medicine every 4 weeks.

  The EAG commented that rheumatologists and dermatologists are accustomed to performing regular monitoring blood tests for established treatments, including psoriatic arthritis patients treated with methotrexate. It further noted that the British Association of Dermatology and the British Society for Rheumatology periodically publish guidelines on monitoring.

  The EAG recommended that it was not necessary for MHRA or professional bodies to disseminate further communications to raise awareness of the new monitoring requirements.

89. Also in May, the EAG provided written comments on:
    - a medicine for the treatment of moderate to severe atopic dermatitis

90. In December, the EAG discussed and made recommendations on:
    - The EAG considered a paper discussing the results of the Febuxostat versus Allopurinol Streamlined Trial (FAST) in the context of the results from the Cardiovascular Safety of Febuxostat and Allopurinol in Patients with Gout and Cardiovascular Morbidities (CARES) trial.

      The EAG considered proposed changes to the existing cardiovascular safety warning in the product information.

      The EAG noted that there are differences in the patient populations and study protocols of the CARES and FAST studies. The EAG was of the view that allopurinol would continue to be used as a first choice of treatment in preference to febuxostat.

Infection Expert Advisory Group (IEAG)

91. In 2021, the IEAG provided advice by written correspondence on 44 occasions.

92. In January, the EAG provided written comments on a medicine indicated for the treatment and prevention of influenza

93. Also in January, the EAG provided written comments on six clinical trial applications for the treatment of COVID-19

94. In February, the EAG provided written comments on seven clinical trial applications for the treatment of COVID-19

95. In March, the EAG provided written comments on 10 clinical trial applications for the treatment of COVID-19

96. In April, the EAG provided written comments on medicine indicated for the treatment of herpes infections

97. Also in April, the EAG provided written comments on two clinical trial applications for the treatment of COVID-19

98. In May, the EAG provided written comments on a medicine indicated for the treatment of fungal infections

99. Also in May, the EAG provided written comments on three clinical trial applications for the treatment of COVID-19

100. In June, the EAG provided written comments on three clinical trial applications for the treatment of COVID-19

101. In July, the EAG provided written comments on three clinical trial applications for the treatment of COVID-19

102. In August, the EAG provided written comments on a medicine indicated for the treatment of HIV infection

103. Also in August, the EAG provided written comments on a clinical trial application for the treatment of COVID-19

104. In October, the EAG provided written comments on two clinical trial applications for the treatment of COVID-19

105. In November, the EAG provided written comments on a clinical trial application for the treatment of COVID-19

106. In December, the EAG provided written comments on two clinical trial applications for the treatment of COVID-19.

Isotretinoin Expert Working Group (IEWG)

107. In September 2019, the CHM reconvened the Isotretinoin Expert Working Group (IEWG) to evaluate the latest information on the risks of psychiatric

adverse reactions and sexual dysfunction suspected to be associated with the use of isotretinoin.

108. The IEWG held six meetings in 2021 to consider the available information. The importance of direct input from patients and other stakeholders was recognised as of paramount important to this review. In addition to consideration of the information received in the 659 responses to the call for information, 3 of the 6 meetings were held where patients, their families and healthcare professionals were able to present evidence directly to the IEWG.

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

109. The MWHEAG met on 5 occasions during the year. Summary reports based on the minutes of each meeting are published on the GOV.UK website.

110. The MWHEAG considered the latest evidence and made recommendations on the following issues with marketed medicines:
    - Menstrual disorders reported following vaccination against COVID- 19
    - the risk of venous thromboembolism with extended use regimens of low dose combined hormonal contraception

111. The MWHEAG considered and made recommendations on applications related to new uses of existing medicines or new medicinal products for diabetes and prevention of premature birth.

112. The MWHEAG provided comments on points to consider to inform design of long-acting contraceptives based on use of modelling of pharmacokinetics.

Safety of Medicines during pregnancy

113. 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 1073 new reports of suspected ADRs associated with use of medicines in pregnancy received from October 2020 to September 2021. The majority of reports received during this period did not raise any new concerns. The EAG considered reports related to the use of COVID-19 vaccines during pregnancy throughout the year and considered that the reports did not raise any safety concerns.

114. The MWHEAG reviewed potential safety signals following use of NSAIDs in later trimester pregnancy and advised that no regulatory action was warranted.

115. The MWHEAG considered that further review and/or regulatory action should be taken for use of the following medicines related to fertility or use during pregnancy or breastfeeding:
    - Sodium valproate and reversibility of male infertility
    - Nipple pain and suppressed lactation with labetalol

Neurology, Pain & Psychiatry Expert Advisory Group (NPPEAG)

116. In 2021, the NPPEAG convened virtually one time and provided advice by written correspondence on two occasions.

117. In March, the EAG provided written comments on:
    - a medicine indicated for the treatment of psychosis and Parkinson's disease.
    - a review of the insomnia indication for chloral hydrate and chloral betaine products.

118. In April, the EAG discussed and made recommendations on:
    - a medicine indicated for the short-term treatment of anxiety associated with depression.
    - a paper to review the indication of a drug used for sleep disorders in children.
    - a paper to review the safety of anti-epileptic drugs during pregnancy: results of the confidential enquiry into maternal deaths.

Oncology and Haematology Expert Advisory Group (OHEAG)

119. In 2021, the OHEAG convened virtually 9 times and provided advice by written correspondence on three occasions.

120. In March, the EAG discussed and made recommendations on:
    - a medicine indicated for the treatment of patients with advanced non-small cell lung cancer with a specific gene defect (called KRAS G12C) and had received prior treatment.
    - a medicine indicated for the treatment of adult patients who have advanced triple-negative breast cancer (a type of breast cancer that does not have any of the receptors commonly found in breast cancer) and progressed on prior treatment.

121. In April, the EAG discussed and made recommendations on:
    - a medicine indicated for the treatment of adult patients who have had advanced non-small cell lung cancer with a gene defect called METex14.

122. Also in April, the EAG made recommendations on Early Access to Medicines Scheme (EAMS) procedures for:

- a medicine indicated in combination with chemotherapy for the treatment of adults with cancer of the stomach or oesophagus that has spread to other parts of the body
- a medicine indicated for the treatment of adult patients who have advanced non-small cell lung cancer with a gene defect called METex14.

123. Also in April, the EAG provided written comments on how best to communicate to healthcare professionals the risk of certain side effects associated with a number of products indicated for the treatment of some breast cancers.

124. In May, the EAG discussed and made recommendations on:
    - a medicine indicated for the treatment of adult patients who have von Hippel-Lindau disease.
    - a medicine indicated for the treatment of a type of lung cancer that is advanced or has 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 12 years of age and older and adults with graft-versus-host disease.

125. In June, the EAG discussed and made recommendations on:
    - a medicine indicated for the treatment of patients aged 12 years and older with chronic graft versus host disease who have received at least one prior treatment.
    - a medicine indicated for the treatment of patients with non-small cell lung cancer.
    - a medicine indicated for the treatment of cancer of the oesophagus or the junction of the oesophagus and the stomach, to be used after chemotherapy, radiotherapy, and surgery to remove the tumour.

126. In July, the EAG made recommendations on an Early Access to Medicines Scheme (EAMS) procedure for a medicine indicated in combination with chemotherapy for the treatment of adults with cancer of the stomach or oesophagus that has spread to other parts of the body.

127. In August, 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.

128. In September, the EAG discussed and made recommendations on Early Access to Medicines Scheme (EAMS) procedures for:
    - a medicine indicated for the treatment of adult patients who have advanced non-small cell lung cancer.
    - a medicine indicated for the treatment of lung cancer following surgery and chemotherapy.

129. Also in September, the EAG discussed and made recommendations on:
    - a medicine indicated for the treatment of lung cancer following surgery and chemotherapy.
    - a medicine proposed for the treatment of acute and chronic graft versus host disease in patients 12 years of age and older.

130. In October, the EAG discussed and made recommendations on:
    - a medicine indicated for the treatment of adult patients who have von Hippel-Lindau disease.
    - a medicine indicated for the treatment of a type of blood cancer called acute myeloid leukaemia.

131. Also in October, the EAG made recommendations on an Early Access to Medicines Scheme (EAMS) procedure for a medicine indicated for the treatment of a type of blood cancer called chronic myeloid leukaemia that has not responded to previous treatments.

132. Also in October, the EAG provided written comments on an application for a new formulation of a medicine intended to prevent bleeding in patients with certain conditions who undergo a dental procedure.

133. In December, the EAG discussed and made recommendations on:
    - a medicine indicated for the treatment of HLA-A*02:01-positive adult patients with a cancer of the eye (uveal melanoma) that cannot be removed with surgery or has spread to other parts of the body.
    - a medicine indicated for the treatment of a type of blood cancer called chronic myeloid leukaemia that has not responded to previous treatments.
    - a medicine indicated for the treatment of lung cancer following surgery and chemotherapy.

134. Also in December, the EAG made recommendations on Early Access to Medicines Scheme (EAMS) procedures for:
    - a medicine indicated for the treatment of a type of blood cancer called chronic myeloid leukaemia that does not have a gene defect called T315I mutation and has not responded to previous treatments.
    - a medicine indicated for the management of patients with prostate-specific membrane antigen (PSMA)-positive metastatic castrate-resistant prostate cancer.
    - a medicine indicated for the treatment of patients with prostate-specific membrane antigen (PSMA)-positive metastatic castrate-resistant prostate cancer.
    - a medicine indicated for the treatment of lung cancer following surgery and chemotherapy.

135. Also in December, the EAG provided written comments on a Drug Safety Update (DSU) concerning an anti-cancer drug when it is produced using a method called albumin-bound.

Paediatric Medicines Expert Advisory Group (PMEAG)

136. 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.

137. The PMEAG met eleven times in 2021 and provided advice through written correspondence for additional ten papers. Below the papers discussed during the meetings are summarised.

Paediatric Investigation Plans (PIPs)

138. The PMEAG advised on 10 PIP applications in a range of therapeutic areas including prevention and treatment of COVID-19, oncology, prevention of Diabetes type 1, treatment of Hypercholesterinaemia and treatment of Duchenne Muscular Dystrophy (an inherited progressive muscle wasting condition).

New Paediatric Drugs

139. The PMEAG considered an application for a new medicinal product with an indication for the treatment of moderate-to-severe atopic dermatitis (an allergic condition that causes the skin to become itchy or dry) in adolescents and adults.

Marketing authorisation applications supported by paediatric data

140. The PMEAG advised on 8 applications to add paediatric indications to existing products. The products covered a range of indications in paediatric patients including, a vaccine for prevention of COVID-19 in adolescents, two medicines intended for the treatment of insomnia, two medicines intended for the treatment of seizures, a medicine intended for treatment of virus infection, a medicine for procedural analgesia and lastly a medicine intended for the treatment of severe pain.

Safety of medicines in children

141. In 2021 the PMEAG reviewed monthly statistics on suspected adverse drug reactions in paediatric patients reported to MHRA, and an overview of all identified paediatric signals. The PMEAG advised on paediatric signals and paediatric safety reviews such as a review of the use of antibiotic eye products in young children, and the risk of accidental exposure to a medicine used for the treatment of common colds in young children.

142. The PMEAG considered the scope of a review of the effects of NSAIDs in later pregnancy on the risk of oligohydramnios and neonatal renal dysfunction. Lastly, the experts discussed and advised on a paper on

Yellow Card reports related to exposure in association with breastfeeding for COVID-19 vaccines.

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

143. The PMEAG considered additional quality information provided by Marketing Authorisation Holders of a medicine for the treatment of low blood pressure in new-born babies. The information suggested the quality of the drug was not affected by the higher temperatures used when babies are warmed in special care cots (neonatal incubators).

144. The PMEAG discussed a paper concerning the conduct of clinical trials for coronavirus vaccines in children.

145. The PMEAG advised on the clinical issues associated with two the potential discontinuations, one for a medicine used in asthma and a medicine used for uncontrolled seizures in children.

146. The PMEAG discussed a paper on future ways of working due to the UK's exit from the EU and new arrangements post transition. The PMEAG heard a presentation on orphan drugs and the new approaches for orphan designation following the UK's exit from the EU. The presentation covered the criteria for orphan designation in Great Britain and the considerations for determining the orphan condition. Lastly the PMEAG heard a presentation on the introduction of Innovative Licensing and Access Pathway, a new regulatory pathway supporting innovative approaches to the safe, timely and efficient development of medicines to improve patient access.

Pharmacovigilance Expert Advisory Group (PEAG)

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

148. During 2021, a new Chair and four new members were appointed to the PEAG.

149. The PEAG met six times by teleconference in 2021 and provided advice by written procedure on 5 further occasions.

150. During 2021, the PEAG considered papers and advised on the following:
    - Risk of acute kidney injury with remdesivir, an antiviral treatment for COVID-19

- The design of a pregnancy registry to capture data on the use of COVID-19 antiviral medicines in pregnancy and safety outcomes in the mother and child
- An update on the magnitude of the risks of major congenital malformations and neurodevelopmental delay with the use of valproate alone and with other antiepileptic medicines in pregnancy
- Valproate and effects on male fertility
- The first report from the Valproate Registry and an update on the work of the NHS England / NHS Improvement Valproate Safety Implementation Group
- Results of a confidential enquiry into maternal deaths with anti-epileptic drugs
- Risk of major cardiac adverse events and malignancies with tofacitinib, a treatment for rheumatoid arthritis, psoriatic arthritis and ulcerative colitis
- Risk of acute myeloid leukaemia and myelodysplastic syndrome with Zynteglo, a gene therapy for treatment of transfusion dependent beta-thalassaemia
- A review of the use of haloperidol in elderly patients with delirium
- Proposed updates to warnings in the product information regarding cardiovascular risk for febuxostat, a treatment for gout
- Risk of psychiatric disorders with doxycycline
- Risk of sudden cardiac death when ibrutinib, a treatment for mantle cell lymphoma, chronic lymphocytic leukaemia and Waldenstrom's macroglobulinaemia, is used with angiotensin converting enzyme (ACE) inhibitors, used to treat hypertension and heart failure
- Homocysteine elevations with givosiran, a treatment for acute hepatic porphyria
- Withdrawal reactions with topical corticosteroids

151. The PEAG also considers matters raised by Coroners under Regulation 28 of the Coroners (Investigations) Regulations 2013 to prevent future deaths. In 2021, the PEAG considered one Coroner's Report relating to the need for lung imaging for patients taking amiodarone long term to prevent lung toxicity.

152. The PEAG considered and gave advice on Risk Management Plans for new medicines that are now approved through Project Orbis, a programme co-ordinated by the US Food and Drug Administration (FDA) involving the UK MHRA and the medicines regulatory authorities of Australia, Canada, Singapore, Switzerland and Brazil to review and approve promising cancer treatments. These included the RMPs for Trodelvy (sacituzumab govitecan) for locally advanced or metastatic triple-negative breast cancer and Rybrevant (amivantamab) for locally advanced or metastatic lung cancer.

153. The PEAG also considered the proposed RMP for belzutifan for the treatment of renal cell carcinoma associated with von Hippel-Lindau

disease, the first drug to be awarded an innovation passport under the UK's Innovative Licensing Access Pathway (ILAP).

154. The PEAG's advice on these issues was subsequently taken forward for further discussion at CHM and implementation.

155. In accordance with its responsibility for oversight of the UK Yellow Card Scheme, the PEAG considered Yellow Card reporting statistics including reporting statistics for the COVID-19 vaccines at each of its meetings in 2021. In addition the PEAG considered data from the Yellow Card Vaccine Monitor which is part of the MHRA's COVID-19 Vaccine Safety Surveillance Strategy.

156. The PEAG's advice underpins key medicines safety advice provided to UK healthcare professionals in MHRA's monthly Drug Safety Update newsletter (www.mhra.gov.uk/drug-safety-update).

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

Real World Data Ad Hoc Working Group

158. The remit of the group was to review the guidance produced by MHRA internal group on Real-World Data (RWD) to guide development of protocols for novel clinical trial research to collect real world data; to advise on the potential role for such trials to be included in regulatory submissions to support marketing authorisations or variations; review and advise on issues around deriving evidence from RWD that is acceptable to support regulatory submissions, and points that will need to be considered when making a clinical trial application for a RWD based study; to advise on the types of regulatory decisions/situations in which each of the different trial types could be used.

159. In 2021, the Real World Data Ad Hoc Group met twice.

160. In July, the ad hoc group discussed the responses received from the external consultation on the draft guideline on randomised controlled trials generating real-world evidence to support regulatory decisions. One of the reactions to the comments received in the consultation was that the content of the original draft guideline was split into two documents; "MHRA guidance on the use of real-world data in clinical studies to support regulatory decisions" and "MHRA guideline on randomised controlled trials using real-world data to support regulatory decisions". The new draft documents produced by the internal group were discussed in detail by the ad hoc group. Proposals for revisions to the new draft guidelines were made, which were to be incorporated into the documents to produce revised drafts.

161. In October, the group discussed the revised guidelines and subject to further revisions recommended that they should be finalised and published. The group also discussed a document summarising the responses received from the consultation and the actions taken based on them. It was also agreed that this document could be published. The finalised documents were published in December 2021.

REPORTING OF SUSPECTED ADVERSE DRUG REACTIONS 2021

Yellow Card data (excluding for COVID-19 vaccines)

162. 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. Prior to the UK's exit from the EU, pharmaceutical companies submitted reports via the European Medicines Agency (EMA). Since the UK's exit in 2021, pharmaceutical companies now submit reports directly to the MHRA. 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.

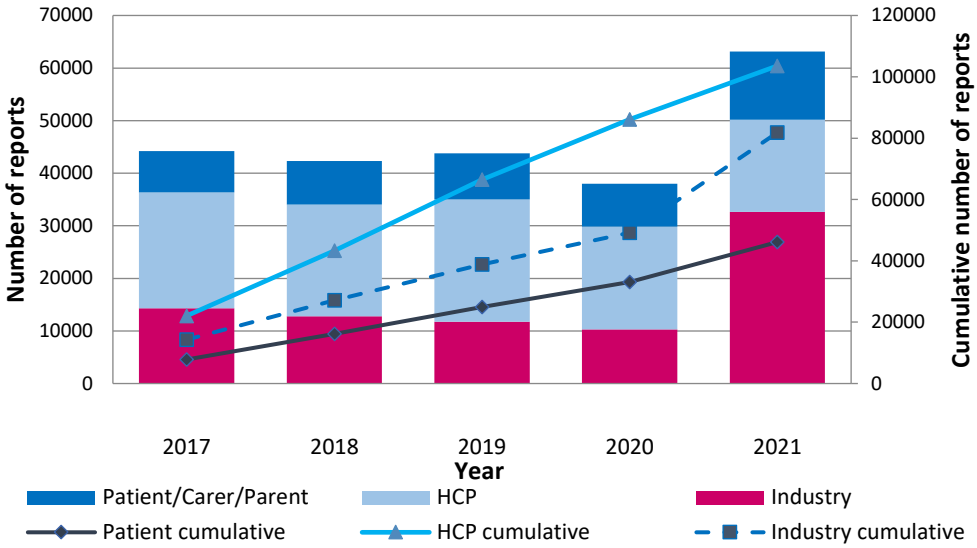
163. The total number of UK spontaneous suspected ADR reports received from all sources over the last five years shows a stable and robust system with an average of 46,296 reports as shown in Figure 1 below. As expected with social distancing measures introduced across the UK in March 2020 due to the COVID-19 pandemic, total numbers of Yellow Card reports decreased by 13% in 2020 compared to 2019. This trend has reversed in 2021 with overall ADR reporting increasing again. The total number of suspected ADR reports received in 2021 is 63,170 which is a 66% increase (25,180 reports) compared to 2020, and a 44% (19,405 reports) increase compared to 2019.

164. Overall, direct Yellow Card reporting from healthcare professionals accounted for 28% (17,484 reports) of all suspected ADR reports received in 2021 and 21% (13,027 reports) of all suspected ADR reports were received from members of the public (including patients, parents and carers). Yellow Card reports from members of the public increased by 60% and 48% compared to 2020 and 2019, respectively. Reporting rates from healthcare professionals has decreased in 2021 compared to 2020 and 2019 by 11% and 25%, respectively. This is unsurprising considering the considerable pressures the NHS has seen through the pandemic in 2021.

165. In 2021, suspected ADR reports from the pharmaceutical industry accounted for 52% (32,659 reports) of all reports received by the MHRA. This represents an increase of 218% (22,385 reports) and 178% (20,892

reports) compared to 2020 and 2019, respectively. The increase in ADR reporting from industry over the last year is linked to the MHRA receiving non-serious UK cases directly from Marketing Authorisation Holders where these were not received from EudraVigilance previously.

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



Year	2017	2018	2019	2020	2021
Total number of UK spontaneous ADR reports	44,213	42,340	43,765	37,990	63,170

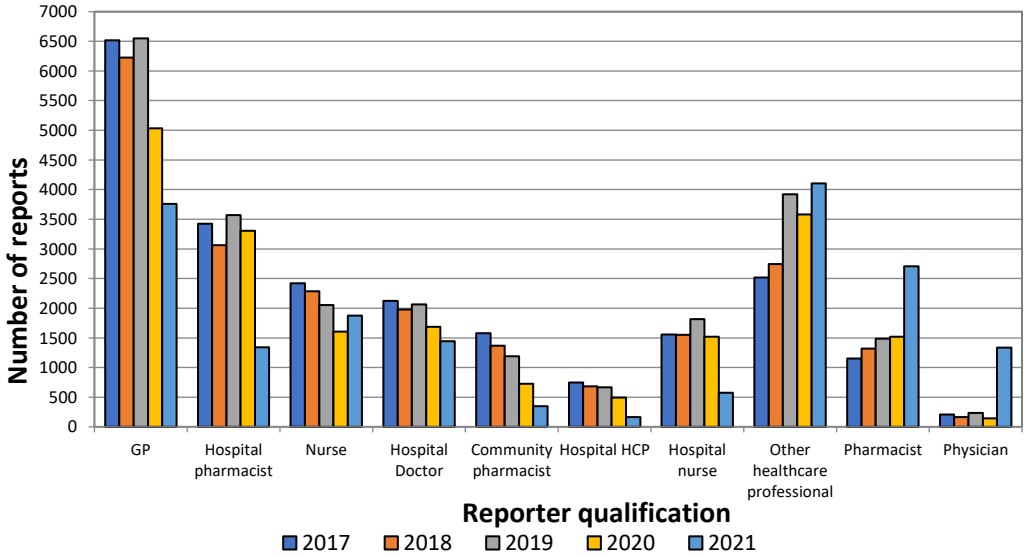
Patient ADR Reporting

166. In 2021, 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 13,027 suspected ADR reports received which represent 21% of all reports. Reports from members of the public increased by 66% (5,192 reports) over the last five years, since 2017. This is in part due to the MHRA's Yellow Card strategy work and its 5 Yellow Card Centres where significant efforts continue to be made to proactively encourage the reporting of suspected ADRs from patients or their families. The sharp increase in 2021 (60%) for non-COVID-19 vaccines is largely 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

167. Yellow Card reporting received directly from healthcare professionals in 2021 decreased by 11% (2,067 reports) compared to 2020 and 25% (5,739 reports) compared to 2019 largely due to the pandemic. A breakdown of direct healthcare professional reports by reporter qualification between 2017 and 2021 is shown in Figure 2.

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



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

168. As in previous years, GPs were the highest reporting group compared to all other healthcare professionals to the Yellow Card scheme accounting for 21% of all direct healthcare professional reports. For the majority of healthcare professional reporter groups, reporting to the scheme decreased in 2021 due to the continued effects of the pandemic. GP reporting decreased by 25% (1,277 reports) compared to 2020 and 43% (2,794 reports) compared to 2019.

169. However, Figure 2 also shows a significant increase in reporting for the Physician group in 2021 compared to previous years which may account for the declining overall trend seen in other groups e.g. GPs/hospital doctors. This is due to a process change being implemented in 2021 which saw the start of reports being auto-committed to the database to address the increased volumes of ADR reports the MHRA received in association with the COVID-19 vaccines. The change means that reporter qualifications are no longer updated individually with more specific information.

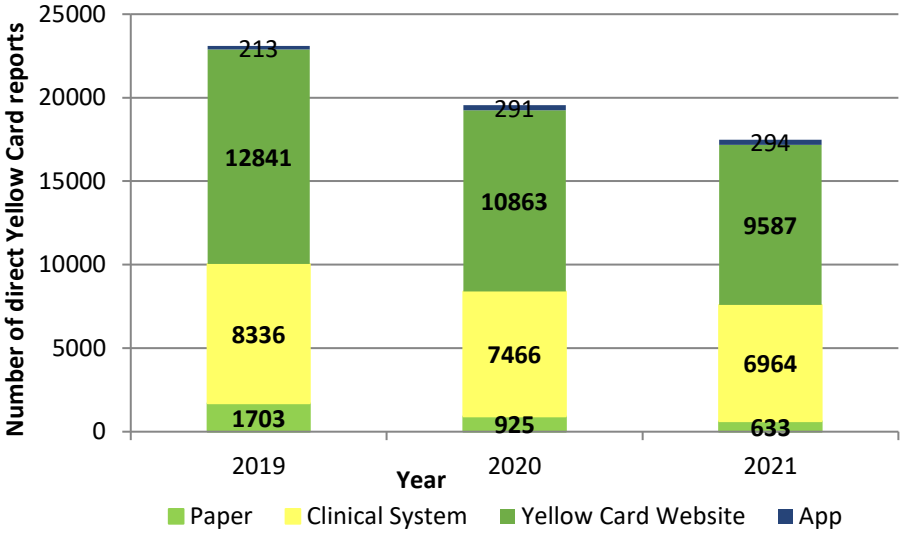
170. Figure 2 shows an increase in reporting from pharmacists and other healthcare professionals in 2021 compared to 2020, with increases of 78% and 15%, respectively. Similar increases were seen in these reporting groups when compared to 2019, of 82% and 5%, respectively.

171. Reporting from 'other healthcare professionals' has increased again following a decrease in 2020. In 2021, other healthcare professionals accounted for 23% (4,105 reports) of all direct healthcare professional reports. The most frequently reported professions within this group were unspecified other healthcare professionals (61%), radiographers (11%), pharmacy assistants (10%) and pre-registration pharmacists (10%).

Electronic ADR Reporting

172. Electronic reporting is the most popular method of reporting for both healthcare professionals and members of the public; however, it should be noted that the MHRA requested that reports be submitted electronically during the pandemic, due to lockdown measures. In 2021 95% (12,368 reports) of all ADR reports from the public were reported electronically, with a 46% (3,233 reports) increase in reports via the Yellow Card website compared to 2020. A breakdown of the main methods of reporting from healthcare professionals can be found in Figure 3.

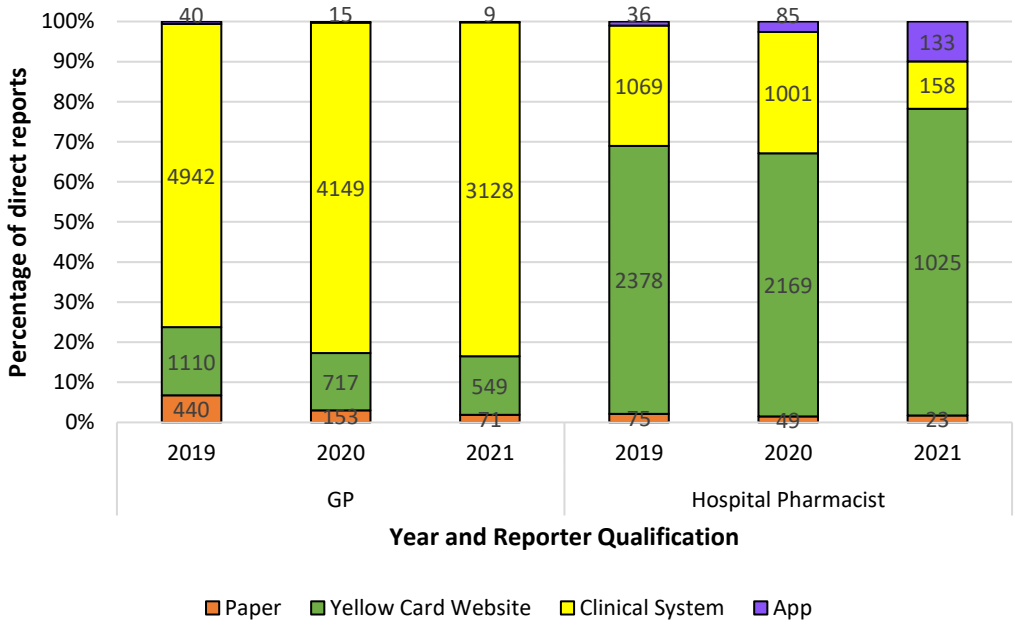
Figure 3 - Graph showing the breakdown of the main ways in which healthcare professionals reported suspected ADRs directly to the Yellow Card scheme over the last 3 years.



173. The number of suspected ADR reports received directly from the Yellow Card form being integrated into clinical IT systems has decreased by 7% (502 reports) compared to 2020 and 16% (1,372 reports) compared to 2019. Reports from all clinical systems formed 39% of all direct reports from healthcare professionals.

174. Figure 4 shows the ways in which suspected ADR reports are submitted to the Yellow Card scheme from GPs and hospital pharmacists over the last 3 years.

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



175. In 2021, 98% of all GP reports were received electronically, with GP reports via clinical systems accounting for 83% (3,128 reports) of all reports from GPs. Of this, SystmOne accounted for 77% (2,421 reports) of suspected ADR reports from GPs. Reports from Vision accounted for 18% (565 reports) of all GP reports and reports from EMIS accounted for 5% (142 reports) of all GP reports in 2021.

176. Reports received from hospital pharmacists via clinical systems (MI Databank) decreased by 84% (840 reports) compared to 2019, as well as through the Yellow Card website with a decrease of 55% (1,190 reports).

177. The increase in electronic reporting compared to paper reporting across all reporter groups is anticipated due to limited access to paper Yellow Card reports received via the post as a result of remote working during the pandemic.

The Yellow Card App

178. The Yellow Card App is designed with both healthcare professionals and patients as target users; reporting trends have shown that the app is particularly used by patients as a route of reporting. Suspected ADR reporting through the app has continued to increase with 1,008 reports received in 2021, representing a 7% increase (65 reports) in reporting

since 2020 and 54% increase (354 reports) since 2019. Of these reports, 71% (717 reports) were from members of the public.

179. Following enhancements made in 2020, the COVID-19 reporting form for both vaccines and medicines used to treat coronavirus symptoms has proved to be a popular reporting option for both patient and healthcare professionals.

UK Yellow Card Centres

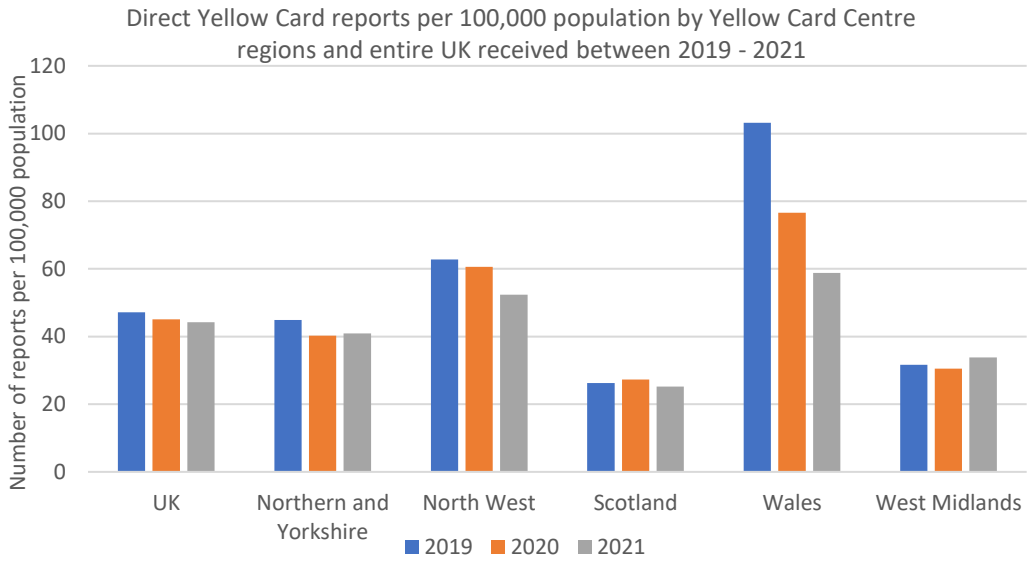
180. The MHRA works with five Yellow Card Centres (YCCs) based in the United Kingdom to increase awareness of the Yellow Card scheme and increase ADR reporting rates within their regions. The YCCs operate in Wales, Scotland, Northern & Yorkshire, North West and the West Midlands. The YCCs are involved in various programmes which improve awareness and ADR reporting rates.

181. During the pandemic, the YCCs continued promoting the Yellow Card scheme by adapting and developing online training to be delivered virtually ensuring the education of both undergraduate and postgraduate healthcare students, as well as qualified healthcare professionals. The YCCs also play an important part in our social media campaigns by supporting through their YCC social media pages.

182. Many events and conferences were able to go ahead virtually and YCCs were able to discuss the importance of ADR reporting with attendees. YCC Northern and Yorkshire conducted a range of training sessions which included remote lectures to Newcastle University medical students. YCC North West carried out training remotely to various health care professionals and also lectured at the Czech Hospital Pharmacy Conference, which covered areas such as pharmacovigilance activities and the COVID-19 vaccines. YCC Scotland have carried out patient group engagement and delivered training to medical, pharmacy and podiatry groups. YCC West Midlands have created a YouTube channel to share Webex content which has been delivered to healthcare professionals as well as their ADR champions. YCC Wales expanded their social media presence by creating a YCC Wales Instagram page to help promote the Yellow Card scheme further.

183. The YCCs dedication and continued support of the Yellow Card scheme has continued through 2021, in spite of the complexities of working during the peak of the pandemic. The reporting rates for YCCs compared to the rest of the UK can be seen in Figure 5. It is important to note this graph is based on the number of reports received directly for non-COVID-19 vaccine related ADR reports. Overall, for 2021 the reporting rate is similar or slightly lower for some YCCs compared to last year. This could be due to the additional workload pressures and changing priorities for healthcare professionals. In 2021 two YCCs had a higher reporting rate per 100,000 people than the UK average (44): North West (52) and Wales (58).

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



Signal Detection

184. The MHRA signal management system is designed for the timely detection of new and changing drug safety issues. Changes in the frequency of ADRs already known to be associated with medicines are also closely monitored through the MHRA's signal detection process. The drug-event combinations from Yellow Card reports are assessed on a weekly basis to identify potential safety signals.

185. In 2021, there were a total of 70 validated signals – potential signals that have been identified by a statistical algorithm or from external sources which subsequently require additional detailed investigation and review. Once evaluated, these validated signals can result in regulatory action, such as updates to product information, or may contribute to wider reviews alongside other sources of data. Each signal is prioritised and assigned a timeframe during which a regulatory position on the action required is reached. A breakdown of the signals and assigned priorities is provided in Table 1.

Table 1: Number of signals assessed in 2021

	Signal Priority		
	Top	**Increased**	**Standard**
Number of signals	2	16	52

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

186. The number of validated signals identified by the MHRA decreased in 2021 compared with 2020. The decrease in signals can be attributed to the

change in review processes of signals identified from other international regulators (detailed below) and a focus on COVID-19 Vigilance.

187. In 2021, information (ADR reports, enquiries) received directly from members of the public contributed towards multiple signals being detected. Of these signals 11 were initiated for investigation from information from members of the public. Pharmacovigilance Information received from healthcare professionals also contributed to a number of safety signals, of which 18 reports were the index case.

188. Further signals were identified from other sources of information, including information directly from the medical literature and directly from marketing authorisation holders (MAH) as standalone signal notifications or emerging safety issues.

189. Some examples of signals which stimulated regulatory action in 2021 include metronidazole use and vertigo, which was reviewed following receipt of a patient report. This review found that this appeared a distinct reaction to dizziness (already listed in product information) and caused significant disability and incapacity. The review resulted in product information updates. A further example is of Olbas Oil and accidental exposure to the product. This signal was raised following a case report of a child accidentally exposed to the oil and getting the product in their eyes. Information from the National Poisons Information Service was requested to support this signal and after review by the Paediatric Medicines Expert Advisory Group, the MAH was requested to conduct a review with a view updating the warnings in the product information.

190. Additionally, the signal of topical corticosteroid and the risk of topical steroid withdrawal reactions was completed in 2021. This signal was triggered by an enquiry from a patient representative to the Yellow Card scheme. A comprehensive review was completed of Yellow Card reports, published literature and information from other regulators. Independent advice was also received from experts. Information about these reactions will be added to the product information provided to healthcare professionals and patients. A Drug Safety Update article was published in September 2021.

191. The Pregnancy Signal Meeting continued in 2021 with the aim of the meeting to review all reports of drug exposures in pregnancy received each week as well as all reports of abnormal pregnancy outcomes to develop a safety profile of the medicines use during pregnancy. The meetings have generated several validated signals that have been taken forward for discussion at Signal Management Review Meetings. All validated signals and reports of interest identified through the Pregnancy Signal Detection meetings are highlighted to the Medicines for Women's Health EAG (MWHEAG) for comment or advice. Further details of this process can be seen in the MWHEAG section of the report.

192. Following the MHRA's exit from the EU, the signal management processes were amended to ensure that new signals reviewed by the European Pharmacovigilance Risk Assessment Committee (PRAC) and other international regulators were also incorporated into the MHRA's routine signal detection activities. This was to ensure that the MHRA is aware of any ongoing or potential safety issues occurring globally and were in a position to take action, if necessary. Marketing Authorisation Holders are also obliged to notify the MHRA directly of signals arising from any data source. The changes in these processes account for the increase in the number of validated signals that required evaluation by the MHRA in 2021. The MHRA assessed 54 signals that were also reviewed by the PRAC.

Table 2: Number of signals assessed in 2021 from other international regulators

	Signal Priority		
	Top	**Increased**	**Standard**
Number of signals	0	11	43

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, this is due to as if the signal was identified by other sources it will be included in Table 1*

193. In 2021, 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 has the opportunity to propose topics to the other agencies for discussion, who subsequently provide written responses, followed up with a telephone conference if required. In general, the topics relate to potential drug safety issues, but may also entail more general pharmacovigilance questions. The MHRA have proposed a number of topics in 2021, through which further information and worldwide evidence has been obtained to aid the assessment of signals. For example, the MHRA has used the network to further gather information on COVID-19 vaccine adverse events following immunisation.

E-Cigarette Reporting

194. The MHRA is the competent authority in Great Britain and Northern Ireland for the regulation of nicotine-containing e-cigarettes and refills under the terms of the Tobacco and Related Product Regulations (TRPR) and the Tobacco Products and Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2020. All nicotine containing products have to be notified to the MHRA. During 2021 there were 24 adverse reaction reports (ADRs). We also received 2 reports of product quality concerns relating to nicotine containing e-cigarettes.

195. The rate of Yellow Card reporting has decreased compared to 2020 where we received 149 adverse reaction reports. As a result of the emerging

news relating to e-cigarette or vaping associated lung injury (EVALI) in the United States, towards the end of 2019 we requested all reports of respiratory reactions reported to industry to be shared with the MHRA; we received 125 reports which were uploaded on our database. These additional reports explain the decrease since the previous year. The rate of Yellow Card reporting in 2021 is broadly consistent with the rates of 2019, 2018 and 2017 (27, 17 and 24 reports respectively). We continue 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

196. In 2021 the MHRA received 424,436 spontaneous Yellow Card reports in association with the COVID-19 vaccines. The MHRA saw an increase in the number of reports associated with COVID-19 vaccines throughout 2021. Overall, direct Yellow Card reports from the public account for 82% all spontaneous reports for the COVID-19 vaccines. 15% of all reports were received directly from healthcare professionals and less than 3% were reported by pharmaceutical companies. The low direct reporting from companies was expected as we encouraged the Yellow Card Scheme to be the central reporting system for COVID-19 vaccines.

197. Similar to usual Yellow Card reporting, GPs are one of the highest reporting healthcare professional reporters for adverse reactions to COVID-19 vaccines, accounting for 21% of all direct healthcare professional reports. The other healthcare professional group accounted for 35% of all direct healthcare professional reports. The most frequently reported professions within this group were unspecified other healthcare professionals (53%), healthcare assistants (20%) and pharmacy assistants (6%).

198. Electronic reporting is the most popular method of reporting as reports were requested to be submitted electronically during the pandemic through the dedicated COVID-19 Yellow Card reporting website or the app. The website was the most common reporting route for both healthcare professional and patient reporting, with 90% and 94%, respectively.

COVID-19 vaccine signal detection

199. The MHRA has continued to adapt its signal management system in response to the COVID-19 pandemic. The pharmacovigilance strategy that was developed for medicines and vaccines, to manage the response to the COVID-19 pandemic continued to be followed in 2021. 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 which started in December 2020 and new authorised COVID-19 therapeutics. The MHRA has assessed the COVID-19 vaccines and medicines continually throughout each stage of the vaccination rollout and pandemic. Please note that the statistics presented above do not represent the entirety of the MHRA's COVID-19 vaccine signal assessment. Further

detail on the MHRA's response to the pandemic can be seen in the COVID-19 EWG section of the report.

200. In addition, the MHRA have regularly published the weekly summary of Yellow Card reporting which summarises 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 Professor Kevin Park who had served on various CHM's Expert Advisory Groups for 30 years and more recently on the Clinical Trials, Biologicals & Vaccines, COVID-19 Vaccines Benefit Risk and COVID-19 Therapeutics Expert Working Groups until 2020.

MEMBERSHIP OF THE COMMISSION ON HUMAN MEDICINES

Chair

Professor Stuart Ralston[1] MB ChB MD FRCP FMedSci FRSE FFPM (Hon)
Professor of Rheumatology, University of Edinburgh, Western General Hospital, Edinburgh

Professor Sir Munir Pirmohamed[2] MB ChB (Hons) PhD 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[3] MA PhD FRCP FRCPE FRCPI FESCMID FMedSci
Deputy Principal, St. George's, University of London

Members

Professor Amanda Adler[4]
Professor of Diabetic Medicine and Health Policy, University of Oxford

Ms Susan Bradford
Lay Representative

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

Professor Steven Cunningham[5]
Professor of Paediatric Respiratory Medicine, University of Edinburgh and Honorary Consultant, Royal Hospital for Children and Young People, NHS Lothian, Edinburgh

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

[1] End of appointment 11/02/2021
[2] Appointed 12/02/2021
[3] Since 01/04/2021
[4] Appointed 01/05/2021
[5] Appointed 01/05/2021

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

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

Dr Rebecca Mann[6] BMBS FRCPCH
Consultant Paediatrician, Taunton and Somerset NHS Foundation Trust

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

Professor Sandosh Padmanabhan[7]
Professor of Cardiovascular Genomics and Therapeutics, University of Glasgow

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

Professor Yvonne Perrie[8]
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 MBPharmacol Soc
Emerita Professor of Toxicology, University of Surrey
Visiting Professor of Toxicology, University of Hertfordshire

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

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

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

[6] Stepped down 30/04/2021
[7] Appointed 01/05/2021
[8] Appointed 01/05/2021

Invited Experts to CHM Meetings

Dr Kenneth Baillie MD PhD
Division of Genetics and Genomics, Roslin Institute, University of Edinburgh

Professor Kristien Boelaert
Professor of Endocrinology and Honorary Consultant Endocrinologist
University Hospitals Birmingham NHS Foundation Trust

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

Professor Tom Clutton-Brock FRCP FRCA FFICM
Director, Medical Devices Testing and Evaluation Centre
Clinical Director, NIHR Trauma Management MedTech Cooperative
Deputy Director, Institute of Translational Medicine, Birmingham
Chair, NICE Interventional Procedures Advisory Committee
Associate Medical Director, University Hospitals Birmingham NHS Foundation Trust, Professor of Anaesthesia & Intensive Care Medicine

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

Professor Gordon Dougan FRS
Department of Medicine, Cambridge Infectious Diseases, University of Cambridge

Professor Saul Faust
Professor of Paediatric Immunology & Infectious Diseases
Director of NIHR Southampton Clinical Research Facility
Clinical Director, NIHR Wessex Local Clinical Research Network
NIHR Senior Investigator

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

Mr Matthew Garrett
Dean of the Faculty of Dental Surgery at the Royal College of Surgeons of England

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

Dr Ravindra K Gupta MA MPH MBChB PhD FRCP FRCPath FMedSci
Professor of Clinical Microbiology, Wellcome Senior Fellow in Clinical Science, Cambridge Institute of Therapeutic Immunology and Infectious Diseases, Jeffrey Cheah Biomedical Centre, University of Cambridge & Honorary Consultant Physician – Infectious Diseases
Cambridge University Hospitals NHS Foundation Trust

Professor Philip Hannaford FRSE
Emeritus Professor of Primary Care, University of Aberdeen

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 C Hindmarsh
Professor of Paediatric Endocrinology, University College London

Dr Tom Irving
Head of SPI-M Secretariat and Scientific COVID-19 Modelling

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

Professor Matt Keeling
Professor in the Mathematics Institute and the School of Life Sciences of the University of Warwick

Dr Jonathan Leach OBE
NHS England Medical Director for COVID-19 Immunisation

Professor Andrew Lotery MD FRCOphth
Professor of Ophthalmology

Professor Dame Angela McLean
Co-Chair of the Scientific Pandemic Influenza Group on Modelling (SPI-M)

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

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

Ms Sara Payne
Lay representative (Paediatric Medicines Expert Advisory Group member)

Professor Deenan Pillay
Professor of Virology, UCL Pro-Vice-Provost International

Mr Malcolm Qualie
Pharmacy Lead, Specialised Commissioning
NHS England

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

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

Dr Claire Shannon
Royal College of Anaesthetists

Professor Tom Solomon FRCP PhD
Chair, Neurological Science, Director, NIHR Health Protection Research Unit in Emerging and Zoonotic Infections, Associate Pro-Vice-Chancellor for Infrastructure and Environment, Faculty of Health and Life Sciences, University of Liverpool & Honorary Consultant Neurologist, Walton Centre NHS Foundation Trust

Dr Simon N. Stockley MB ChB, FRCGP, FIMC (RCSEd), DUMC
Clinical Workstream – Senior Medical Lead
National COVID-19 Vaccination Programme
NHS England and NHS Improvement (National)

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

Professor Cheng-Hock Toh
Consultant in Haematology at the University of Liverpool and Liverpool University

Mrs Madeleine Wang BA (Hons)
Lay Member & Member of the Clinical Trials, Biologicals & Vaccines Expert Advisory Group (CTBVEAG)

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

Observers of CHM Meetings

Dr Nick Andrews
Senior Statistician, Public Health England

Mr Luke Collet-Fenson
Private Secretary to the Chief Medical Officer – DHSC

Dr Kiren Collinson
Deputy Medical Director of Primary Care, General Practitioner

Ms Jenna Dilkes
The National Institute for Health and Care Excellence (NICE)

Dr Andrew Earnshaw
Head of the JCVI Scientific Secretariat, Secretary to the Joint Committee on Vaccination and Immunisation, Public Health England

Mr Hassan Iqbal
Senior Pharmacist Medicine Supply team - DHSC

Dr Chris Johnson
Interim Head of Vaccine Preventable Disease Programme (VPD) at Public Health Wales

Professor Anthony Kessel
Clinical Director - NHS England & Improvement

Professor Wei Shen Lim
JCVI

Xinxue Liu
COV-BOOST Senior Statistician

Dr Jamie Lopez Bernal
Consultant Epidemiologist, Public Health England

Ms Kate Mitchell – DHSC

Dr Mary Ramsay
Public Health England

Dr Keith Ridge
Chief Pharmaceutical Officer, NHS England

Dr Richard Roberts
Head, Vaccine Preventable Disease Programme at Public Health Wales

Ms Natalie Spray
The National Institute for Health and Care Excellence (NICE)

Ms Phoebe Topping
Team Leader, Drugs and Addiction, of the Population Health Directorate at the Department of Health and Social Care (DHSC)

Professor Jonathan Van-Tam
Deputy Chief Medical Officer

Gary Williams
Head of Primary Care, NHS England

Director of Specialist Pharmacy Service Medicines Use and Safety
NHS England and NHS Improvement

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[9] MD PhD FRCP
Professor of Diabetic Medicine and Health Policy, University of Oxford

Members

Dr John Firth[10] BA BM ChB DM FRCP
Deputy Medical Director, Cambridge University Hospitals FT, Consultant Physician and Nephrologist, Addenbrooke's Hospital, Cambridge

Professor Andrew Grace[11] MB PhD FRCP
Honorary Professor of Experimental Cardiology, Department of Biochemistry, University of Cambridge; Consultant Cardiologist, Royal Papworth Hospital, Cambridge University Health Partners

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

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

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

[9] Appointed in 2021 and in line with CHM post 01/05/2021
[10] End of Appointment 09/12/2021
[11] End of Appointment 11/11/2021
[12] Reappointed 20/01/2021

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[13] BSc Hons MRPharmS FAPS FSB PhD
Chair in Drug Delivery, Strathclyde Institute of Pharmacy and Biomedical Sciences, University of Strathclyde, Glasgow. Scotland

Professor Kevin M G Taylor[14] BPharm PhD FRPharmS
Chair of the British Pharmacopoeia Commission and Professor of Clinical Pharmaceutics, UCL School of Pharmacy, London

Members

Professor Hannah Batchelor[15] 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 Conway[16] BSc (Pharm) PhD FRPharmS CMgr FCMI
Head of Pharmacy and Professor of Pharmaceutics, University of Huddersfield, Huddersfield

Professor Geoffrey W Hanlon[17] BSc PhD
Emeritus Professor of Pharmaceutical Microbiology, School of Pharmacy & Bio-Molecular Sciences, University of Brighton

Mr V'lain G Fenton-May[18] BPharm MIPharm FRPharmS
Pharmaceutical Microbiologist

Professor Ben Forbes BPharm, PhD
Joint Head of School, School of Cancer & Pharmaceutical Sciences

[13] Appointed in line with CHM post 01/06/2021
[14] End of Appointment 31/05/2021
[15] Appointed 30/08/2021
[16] Appointed 30/08/2021
[17] End of Appointment 16/09/2021
[18] End of Appointment 11/11/2021

Dr Gillian M Hawksworth[19] MBE PhD FFRPS FRPharmS (Hon) DSc
Academic Community Pharmacist, Visiting Fellow at University of Huddersfield & Past President of the RPSGB

Mr Robert Lowe[20] BPharms FRPharmS
Practising Hospital Pharmacist, Specialist Pharmacy Services -East of England

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

Professor Afzal Mohammed[21] BPharm, PhD
Professor of Pharmaceutics Aston Pharmacy School, Aston University

Professor Darragh Murnane PhD BSc (Pharm) MRPharmS
University of Hertfordshire, Hatfield, Hertfordshire

Mrs Ruth Paulin[22] BPharma MRPharmaS
Lay Member

Professor Kevin M G Taylor[23] BPharm PhD FRPharmS
Chair of the British Pharmacopoeia Commission and Professor of Clinical Pharmaceutics, UCL School of Pharmacy, London

Professor Michael D Threadgill[24] 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
Associate Head School of Pharmacy, Professor of Pharmaceutical Microbiology, Leicester School of Pharmacy, De Montfort University, Leicester

Mr Hadar Zaman[25] MPharm, MFRPSII, IPresc, FHEA
Associate Professor in Pharmacy Practice and Head of School for Pharmacy and Medical Sciences, University of Bradford, Consultant Mental Health Pharmacist at Alternative Futures Group, Associated Non-Executive Director Barnsley Hospital.

[19] End of Appointment 10/11/2021
[20] End of Appointment 10/11/2021
[21] Appointed 30/08/2021
[22] Appointed 01/11/2021
[23] Appointed 01/06/2021
[24] Reappointed 14/11/2021
[25] Appointed 01/11/2021

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

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

Members

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

Professor Chris Goldring[26] BSc, PhD, PGCert, FBPhS
Professor of Pharmacology, Department of Pharmacology and Therapeutics, The University of Liverpool

Professor Helen J Lachmann[27] MD FRCP FRCPath **(Vice Chair)**
Reader and Honorary Consultant in Amyloidosis and Renal Medicine, University College London

[26] Appointed 06/08/2021
[27] End of Appointment 11/11/2021

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

Dr Robin Thorpe[28] PhD FRCPath
Retired, Head, Division of Biotherapeutics, National Institute for Biological Standards and Control (NIBSC)

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

Mrs Madeleine Wang[29] BA (Hons)
Lay Representative. Patient Advocate

Professor Christina Yap[30] 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

[28] Reappointed 13/04/2021
[29] End of Appointment 11/11/2021
[30] Appointed 06/08/2021

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

Members

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

Professor Qasim Aziz[31] MRCP PhD FRCP
Professor of Neurogastroenterology, Director Wingate Institute of Neurogastroenterology, Centre for Neuroscience, Trauma and Surgery, Blizard Institute, Barts and the London School of Medicine and Dentistry, Queen Mary University of London

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

Professor Anjan Dhar[32] 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[33] BMSc, MBChB, PhD, FRCP (Edin)
Consultant Gastroenterologist & NRS Clinician, NHS Lothian
Honorary Senior Clinical Lecturer, University of Edinburgh

Professor Kevin Moore[34] BSc MB BS PhD FRCP
Professor of Hepatology, Royal Free Hospital, London

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

[31] Stepped down 19/02/2021
[32] Appointed 01/07/2021
[33] Appointed 01/11/2021
[34] End of Appointment 13/10/2021

Professor Stuart Ralston[35] MB ChB MD FRCP FMedSci FRSE FFPM (Hon)
Professor of Rheumatology, University of Edinburgh

Dr Ravishankar Sargur[36] MD, FRCPath, FRCP, MBA
Consultant Clinical Immunologist and Clinical Lead for Laboratory Immunology, Northern General Hospital, Sheffield

Professor Nidhi Sofat[37] PhD MBBS FRCP PGCert FHEA
Professor of Rheumatology, St Georges University London

[35] Appointed 18/02/2021
[36] Appointed 18/02/2021
[37] Appointed 22/01/2021

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

Members

Dr Michael Brown[38] 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[39] 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 B.A M.B,B.Chir M.A M.D FRCP FRCP Reader in Infectious Diseases, Cardiff University School of Medicine/ Hon. Consultant Physician, University Hospital of Wales

Professor 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

Dr Louis Grandjean[40] MBBS BSc MSc PhD MRCPCH Associate Professor Paediatric Infectious Diseases Great Ormond Street Hospital and University College London

Dr Richard Hobson[41] MB BS MRCP (UK) FRCPath PhD LLM Consultant Microbiologist and Honorary Senior Lecturer, Harrogate & District NHS Foundation Trust/University of Leeds

Dr Susan Hopkins MB ChB BAO (Hons) BA FRCPI Consultant in Infectious Diseases and Microbiology, Royal Free Hampstead NHS Trust, Healthcare Epidemiologist, Health Protection Agency, Honorary Senior Lecturer, University College London

[38] Appointed 01/11/2021
[39] Appointed 01/08/2021
[40] Appointed 01/08/2021
[41] End of Appointment 17/04/2021

Dr Lim S Jones[42] 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

Professor Kevin Moore[43] BSc MB BS PhD FRCP Professor of Hepatology, Royal Free Hospital, London

Dr Matthias Schmid MD FRCP DTMH Consultant Physician, Head of Department of Infection & Tropical Medicine, Director 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

[42] Appointed 01/11/2021
[43] Stepped down 29/10/2021

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 FRSE
Emeritus Professor of Primary Care, University of Aberdeen

Members

Dr Amparo Alvarez-Llobell[44]
GP at Higherland Surgery
GPwSI in Women's Health
Speciality Dr in GUM

Professor Lucy Chappell[45] PhD FRCOG FMedSci
NIHR Research Professor in Obstetrics, King's College London

Dr Caitlin Dean[46] RGN, MSc, PhD
Lay member. Chair Trustee, Pregnancy Sickness Support

Dr Kenneth Hodson[47] MD MBChB MRCP(UK) MRCOG
Head of UK Teratology Information Service
UK Teratology Information Service

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

Professor Stuart Ralston[48] MB ChB MD FRCP FMedSci FRSE FFPM (Hon)
Professor of Rheumatology, University of Edinburgh, Western General Hospital, Edinburgh

[44] Appointed 11/03/2021
[45] Appointed 11/03/2021; Resigned 30/07/2021
[46] Appointed 11/03/2021
[47] Appointed 11/03/2021
[48] Appointed 11/03/2021

Mr Ertan Saridogan[49] PhD MRCOG
Consultant in Gynaecology, Reproductive Medicine and Minimal Access Surgery, University College London Hospitals (UCLH) Elizabeth Garrett Anderson Wing

Professor Jonathan H Tobias[50] BA (Cantab) MBBS (London) MD (London) PhD (London) FRCP (London)
Professor of Rheumatology, University of Bristol; Honorary Consultant Rheumatologist, North Bristol Trust

Dr Laurie Tomlinson[51] MBBS MSc PhD
Department of Non-communicable Disease Epidemiology
Faculty of Epidemiology and Population Health
London School of Hygiene & Tropical Medicine

Dr Diana Wellesley FRCP **(Vice Chair)**
Head of Prenatal Genetics, Consultant and Honorary Senior Lecturer in Clinical Genetics, Wessex Clinical Genetics Service, Princess

[49] Appointed 11/03/2021
[50] End of Appointment 12/03/2021
[51] Appointed 11/03/2021

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 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

Members

Dr Lisa Brownell[52] 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 Adult Psychiatry, Hertfordshire Partnership NHS

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

Dr Barry Mark Miller[53] 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[54] MD (Hons) FRCP FRCPsych
Professor of Clinical Psychiatry, Edinburgh University

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

Professor Andrew Rice[55] 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

[52] Appointed 11/03/2021
[53] Appointed 09/12/2021
[54] Appointed 11/03/2021
[55] Appointed 11/03/2021

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

Dr Aditya Sharma[56] 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 Catherine F Stannard[57] MB ChB FRCA FFPMRCA
Consultant in Complex Pain/Pain Transformation Programme Clinical Lead, NHS Gloucestershire CCG

Dr Hoo Kee Tsang[58] 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

[56] Reappointed 14/07/2021
[57] End of Appointment 08/12/2021
[58] Appointed 09/12/2021

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

Members

Professor David Bowen[59] 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[60] FRCP, MD,MSc, BMedSci, MBBS
Academic Unit of Clinical Oncology, Department of Oncology and Metabolism, Weston Park Hospital, University of Sheffield.

Professor Stephen Devereux PhD FRCP FRCPath
Consultant Haematologist, Kings College Hospital

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

Dr Rebecca Kristeleit[61] BSc MBChB PhD FRCP FRSB
Consultant Medical Oncologist, Guy's and St Thomas' NHS Foundation Trust.

Professor Siow Ming Lee[62] PhD FRCP
Professor of Medical Oncology, Consultant Medical Oncologist

Dr Robert Marcus[63]
Consultant Haematologist at Kings College Hospital London, UK

Professor James Spicer[64] FRCP, PhD
Professor of Experimental Cancer Medicine, King's College London; Consultant in Medical Oncology, Guy's & St Thomas' NHS Foundation trust

[59] Reappointed 16/06/2021
[60] Appointed 18/02/2021
[61] Appointed 18/02/2021
[62] Appointed 11/03/2021
[63] Resigned 04/05/2021
[64] Appointed 11/03/2021

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[65] MBChB PhD FRCPCH Professor of Paediatric Respiratory Medicine, University of Edinburgh and Honorary Consultant, Royal Hospital for Children and Young People, NHS Lothian, Edinburgh

Dr Rebecca Mann[66] BMBS FRCPCH
Consultant Paediatrician, Taunton and Somerset NHS Foundation Trust

Members

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

Dr Jayesh Mahendra Bhatt[67] MBBS, MD, DCH, FRCPCH
Consultant Respiratory Paediatrician, Nottingham Childrens Hospital

Miss Elinor Burrows[68] RGN RSCN MSc
Respiratory Lead Nurse & Nurse Consultant Cystic Fibrosis

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

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

Dr 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

[65] Appointed in line with CHM post 01/05/2021
[66] End of Appointment 30/04/2021
[67] Appointed 18/02/2021
[68] Appointed 18/02/2021

Professor Meriel Jenney[69] MBChB MRCP MD FRCPCH
Consultant Paediatric Oncologist, Clinical Board Director, Clinical Diagnostics and Therapeutics Clinical Board, Assistant Medical Director (Cancer Services), University Hospital of Wales

Dr Kathryn Johnson[70] MBChB FRCPCH
Consultant Neonatologist, Leeds Teaching Hospitals NHS Trust and Honorary Senior Lecturer, Leeds University

Dr Caroline Jones[71] MB ChB FRCPCH MD
Consultant Paediatric Nephrologist, Alder Hey Children's NHS Foundation Trust

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

Dr Rubin Minhas MB ChB MBA, GP Principal

Dr Clare Pain[72] 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 BA CPE LPC
Lay Representative. Solicitor

Dr Guido Pieles PhD MD **(Vice Chair)**
Consultant Congenital Cardiologist, Congenital Hear Unit, Bristol Heart Institute

Professor Heather M Wallace PhD FRCPath FRSC FRSB FBTS FBPhS European Registered Toxicologist ERT Professor of Biochemical Pharmacology and Toxicology, School of Medicine, Medical Sciences and Nutrition, Institute of Medical Sciences, University of Aberdeen

Dr William John Watkins[73] BSc PhD
Senior Statistician/Lecturer, College of Biomedical & Life Sciences, Cardiff University

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

[69] Reappointed 16/01/2021
[70] Appointed 18/02/2021
[71] Reappointed 17/02/2021
[72] Appointed 18/02/2021
[73] Appointed 18/02/2021

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

Members

Mrs Alana Adams[75] BPharm (Hons) MSc MRPharmS IP
Principal Pharmacist, Welsh Medicine Information Service and Advice, University Hospital of Wales, Cardiff

Professor Darren Ashcroft[76] BPharm, MSc, PhD, FRPharmS
Professor of Pharmacoepidemiology, University of Manchester

Professor Ann Daly[77] 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[78] MD MBChB PhD FRCP
CRF Director - NIHR Royal Liverpool and Broadgreen Clinical Research Facility; Consultant Physician, Clinical Pharmacology & Therapeutics/ General Medicine; Honorary Senior Lecturer, University of Liverpool

[74] Appointed in line with CHM post in 2021
[75] Appointed 22/01/2021
[76] Reappointed 11/12/2021
[77] Reappointed 11/12/2021
[78] Appointed 22/01/2021

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

Dr Daniel Hawcutt[79] BSc (Hons), MB ChB (Hons), MD, MRCPCH **(Vice chair)**
Senior Lecturer in Paediatric Clinical Pharmacology, Women's and Children's Health, Institute of Translational Medicine, University of Liverpool

Ms Susan Hunneyball[80] BSc (Hons) Lay Member

Dr Patricia McGettigan[81] MD, BSc, MB, BCh, BAO, BA
Reader in Clinical Pharmacology and Medical Education and Consultant Physician, Barts Health Trust

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

Dr Rupert Payne[82] MB ChB MRCP PhD MRCGP FRCP Consultant Senior Lecturer in Primary Care, University of Bristol

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

Mrs Madeleine Wang[83] BA (Hons)
Lay Representative and Patient Advocate

[79] Reappointed 11/12/2021
[80] Reappointed 11/12/2021
[81] Appointed 22/01/2021
[82] Reappointed 14/07/2021
[83] Appointed 22/01/2021

Appendix III

MEMBERSHIP OF THE COVID-19 THERAPEUTICS EXPERT WORKING GROUP

Chair

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

Members

Professor Kenneth Baillie MD PhD MBChB PhD FRCA FRCP FFICM
Professor of Experimental Medicine, 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
Consultant & Hon. Senior Lecturer in Infectious Diseases
Royal Free London NHS Foundation Trust

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

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 MRC Centre for Drug Safety Science

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

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 MRC 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

Sir Michael Jacobs MA PhD MB BS 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 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 & Vice-chair of the Clinical Trials, Biologicals & Vaccines Expert Advisory Group (CTBVEAG)

Professor Paul J Lehner PhD FRCP FMedSci
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 & Member of the Commission on Human Medicines (CHM) & Chair of the Clinical Trials, Biologicals & Vaccines Expert Advisory Group (CTBVEAG)

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 and Member of the Commission on Human Medicines (CHM)

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 Tom Solomon FRCP PhD
Chair, Neurological Science, Director, NIHR Health Protection Research Unit in Emerging and Zoonotic Infections, Associate Pro-Vice-Chancellor for Infrastructure and Environment, Faculty of Health and Life Sciences, University of Liverpool & Honorary Consultant Neurologist, Walton Centre NHS Foundation Trust

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)

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

Professor Susannah Walsh BSc PhD MBA
Associate Head School of Pharmacy, Professor of Pharmaceutical Microbiology, Leicester School of Pharmacy, De Montfort University, Leicester

Mrs Madeleine Wang BA (Hons)
Lay Member & Member of the Clinical Trials, Biologicals & Vaccines Expert Advisory Group (CTBVEAG)

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 DENTAL CARIES STAKEHOLDER RECLASSIFICATION GROUP

Chair

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

Members

Regina Ahmed
Pharmacy Profession (RPS)

Martin Duerden
Medical Profession (RCGP)

Invited Experts

Raymond Anderson
Practising Community Pharmacist

Mick Armstrong
Practising Dentist

Tony Benford
Dental Nurse

Dr Arianne Matlin
Dental Professional Body Representative

Patient 1
Patient

Jancy Pope
Practising Dentist

Ms Juliette Reeves
Dental Hygienist

Kamini Shah
Dental Consultant

Rebecca Shepherd
Practising Community Pharmacist

Vijay Sudra
Practising Dentist

Catherine White
Patient Representative

MEMBERSHIP OF ISOTRETINOIN EXPERT WORKING GROUP

Chair

Professor Angela Thomas OBE MB BS PhD FRCPE FRCPath
University of Edinburgh

Members

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)

Dr Susannah Baron
Consultant Dermatologist, St Thomas' Hospital

Professor Amanda (Mandy) Drake FRCPE
Personal Chair of Epigenetics and Metabolism, Academic Director, Academic Foundation Programme, Associate Director, Edinburgh Clinical Academic Training Programme

Professor Nicol Ferrier BSc MB ChB MD FRCP FRCPsych
Professor of Psychiatry and Honorary Consultant Psychiatrist, University of Newcastle

Dr Arianna Di Florio
Clinical Senior Lecturer, Cardiff University
Honorary Consultant Psychiatrist, Cardiff and Vale University Health Board, Adjunct Assistant Professor, University of North Carolina at Chapel Hill

Dr Clive Grattan BA MA MB BChir FRCP MD ILT
Consultant Dermatologist, St John's Institute of Dermatology, Guy's Hospital, London

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

Professor Peter C Hindmarsh
Professor of Paediatric Endocrinology, University College London

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)

Professor Rod Mitchell
Professor of Developmental Endocrinology, Honorary Consultant Paediatric Endocrinologist, UKRI Future Leaders Fellow/Academic Lead for Public Engagement MRC Centre for Reproductive Health, Queens Medical Research Institute, Edinburgh

Professor Gudrun Moore
Professor of Clinical and Molecular Genetics, Genetics and Genomic Medicine, UCL Great Ormond Street Institute of Child Health

Mr Giangiacomo Ollandini FRCS MD
Milton Keynes Hospital NHS Foundation Trust - Urology
Urologist, Andrologist, MSc in andrological surgery and gender disorder

Ms Linda Pepper BA MA (Education)
Independent Consultant: patient and public involvement in healthcare & Member of the Medicines for Women's Health Expert Advisory Group (MWHEAG)

Dr Sara Pruneddu
Dermatology Consultant, Kings College Hospital NHS trust, London

Dr Amr Abdel Raheem MB BCh, MSc, DipSurg, PhD, FECSM, FEAA
University College London Hospitals NHS Foundation Trust
infertility & contraception, Peyronies Disease, Erectile Dysfunction and male Hypogonadism

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

Professor Allan Young
Vice Dean, Academic Psychiatry (Interim), Director, Centre for Affective Disorders
NIHR Senior Investigator, Academic Director, Psychological Medicine and Older Adults Clinical Academic Group, Immediate Past President of International Society for Affective Disorders, President British Association for Psychopharmacology, Institute of Psychiatry, Psychology & Neuroscience (IoPPN), King's College London

MEMBERSHIP OF THE REAL WORLD DATA WORKING GROUP

Chair

Professor Deborah Ashby OBE FMedSci
Director of the School of Public Health, Imperial College London

Members

Ms Susan Bradford
Lay Representative, Member of the Commission on Human Medicines (CHM)

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

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

Dr Peter Hall MB ChB MRCP PhD
Reader in Cancer Informatics and Health Economics, University of Edinburgh

Professor Andrew Hattersley CBE FRCP FMedSci FRS
Gillings Chair of Precision Medicine and Professor of Molecular Medicine & Consultant Physician, University of Exeter

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 of Pharmacovigilance Expert Advisory Group (PEAG) and Member of Paediatric Medicines Expert Advisory Group (PMEAG)

Professor Sarah Meredith
Professor of Clinical Trials, MRC Clinical Trials Unit at UCL, Institute of Clinical Trials and Methodology, University College London, Invited Expert of the Commission on Human Medicines (CHM)

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, Chair of the Commission on Human Medicines (CHM)

Professor Christopher Weir BSc (Hons) PhD MSc FRSS C.Stat
Personal Chair in Medical Statistics and Clinical Trials, Usher Institute, University of Edinburgh, Member of the Commission on Human Medicines (CHM)

COMMISSION ON HUMAN MEDICINES STAFF

Commission on Human Medicines (CHM)

Dr Krishna Prasad
Principal Assessor, Licensing

Ms Ebru Agca
Secretary

Chemistry, Pharmacy and Standards Expert Advisory Group (CPSEAG)

Dr Keith Pugh
Principal Assessor, Licensing (Pharmaceutical)

Mrs Munise Guler
Secretary

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

Dr Zoran Simic
Principal Assessor, Licensing (Biologicals)

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

Ms Pauline Edwards
Secretary

Pharmacovigilance Expert Advisory Group (PEAG)

Ms Claire Davies
Principal Assessor, VRMM

Mrs Munise Guler
Secretary

Paediatric Medicines Expert Advisory Group (PMEAG)

Dr Angeliki Siapkara
Principal Assessor, Paediatric Care

Mrs Munise Guler
Secretary

Glossary of Acronyms and Abbreviations

AAV	Adeno-Associated Virus
ABS	Antibiotics
ADR	Adverse Drug Reaction
AQbD	Analytical Quality by Design
ATMP	Advanced Therapy Medicinal Products
BP	British Pharmacopoeia
BPCRS	British Pharmacopoeia Chemical Reference Substances
CAR T-cell	Chimeric Antigen Receptor T-cell
CDRRA	Cardiovascular, Diabetes, Renal, Respiratory and Allergy
CF	Cystic fibrosis
CHM	Commission on Human Medicines
COG-UK	COVID-19 Genomics UK
COM	The UK Committee on Mutagenicity
COPD	Chronic obstructive pulmonary disease
COT	the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment
CPS	Chemistry, Pharmacy and Standards
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
CTBV	Clinical Trials, Biologicals & Vaccines
DHSC	Department of Health and Social Care
DOAC	Direct oral anticoagulants
DSU	Drug Safety Update
EAG	Expert Advisory Group
EC	European Commission
EDQM	European Directorate for the Quality of Medicines and HealthCare
EGFR	Epidermal growth factor receptor
EMA	European Medicines Agency
EU	European Union
EVALI	E-cigarette or vaping associated lung injury
EWG	Expert Working Group
FDA	Food and Drug Administration (US)
FSA	Food Standards Agency (UK)
GAA	acid α-glucosidase
GP	General Practitioner
GRID	Gastroenterology, Rheumatology, Immunology & Dermatology
GSL	General Sales
GVHD	Chronic graft-versus-host disease
HCM	Herbal and Complementary Medicines

HIV	Human Immunodeficiency Virus
IEAG	Infection Expert Advisory Group
IEWG	Isotretinoin Expert Working Group
ILAP	Innovative Licensing Access Pathway
IMWP	International Meeting of World Pharmacopoeias
INN	International Nonproprietary Names
JCVI	The Joint Committee on Vaccination and Immunisation
LA	Licensing Authority
LGC	Laboratory of the Government Chemist
MAH	Marketing Authorisation Holder
MC	Medicinal Chemicals
MHRA	The Medicines and Healthcare products Regulatory Agency
MWH	Medicines for Women's Health
NHS	National Health Service
NIBSC	National Institute of Biological Standard and Control
NMIBC	Non-muscle-invasive bladder cancer
NPP	Neurology, Pain & Psychiatry
NSCLC	Non-small cell lung cancer
OH	Oncology and Haematology
P	Pharmacy Only
PCN	Pharmacy and Nomenclature
PDE	Permitted daily exposure
PEAG	Pharmacovigilance Expert Advisory Group
Ph+ CML	Philadelphia chromosome-positive chronic myeloid leukaemia
PHE	Public Health England
PMEAG	Paediatric Medicines Expert Advisory Group
POC	Point of care
POM	Prescription Only Medicine
PSMA	Prostate-specific membrane antigen
Q&A	Questions and Answers
RWD	Real World Data
SI	Statutory instrument
TTS	Thrombosis with thrombocytopenia syndrome
UK	United Kingdom
ULM	Unlicensed Medicines
US	United States
USAN	United States Adopted Names
USP	the United States Pharmacopeia
VMD	Veterinary Medicines Directorate
WHO	World Health Organization
YCC	Yellow Card Centre

BRITISH PHARMACOPOEIA COMMISSION ANNUAL REPORT FOR 2021

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. During the year, the British Pharmacopoeia has maintained its high standards and levels of service, keeping users updated and working at both national and international levels to support the public health response to the COVID-19 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 relating to items that could potentially be used in the treatment of COVID-19 (monographs, general chapters, Appendices and Supplementary Chapters); (iii) providing additional access to the online BP for NHS users; (iv) enhanced monitoring and supply management of British Pharmacopoeia Chemical Reference Substances (BPCRS) to ensure the availability of reference substances supportive to the medicines supply chain. The BP has worked with other pharmacopoeias across the globe to support the public health response through the World Health Organization's International Meeting of World Pharmacopoeias. This has included identifying existing monographs for medicinal substances and products under investigation for the treatment of COVID-19, the publication of a

comprehensive list of such monographs on the WHO website (WHO/IMWP) and the production of non-mandatory monographs for Favipiravir and Favipiravir Tablets. Regular updates have been provided via the dedicated COVID-19 page on the BP website.

MEMBERSHIP

4. A list of members of the British Pharmacopoeia Commission during 2021 is shown in **Appendix I**. Professor Kevin Taylor's second term as Chair was extended for one year with effect from 1st October 2021.

5. The final term of office for five members of the BP Commission ended on 31st December 2021. A campaign to identify new members was carried out in collaboration with the Department of Health and Social Care Appointments Team during the year and the appointment of new members will be finalised in early 2022.

6. A list of members of the supporting Expert Advisory Groups, Panels of Experts and Working Parties for 2021 is given in **Appendix II**. During the year the Working Party on Advanced Therapy Medicinal Products, which had been established to support the work arising from the MHRA strategy for pharmacopeial standards for biological medicines, identified further subject areas for which the provision of non-mandatory guidance in the British Pharmacopoeia would be useful. Two new sub-groups of the Working Party were established on Empty Capsids for AAV (Adeno-Associated Virus) Products and on T Cell and NK Cell Characterisation Assays.

CODE OF PRACTICE

7. Members of the British Pharmacopoeia Commission are required to comply with a Code of Practice on Declaration of Interests in the Pharmaceutical Industry. With the exception of the Chair, members are permitted to hold personal interests in the pharmaceutical industry. Members of the Expert Advisory Groups, Panels of Experts and Working Parties are also required to comply with the Code of Practice.

MEETINGS

8. The British Pharmacopoeia Commission met three times during 2021. Eighteen 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 WP ATMP sub-groups. Due to the continuing impact of the COVID-19 pandemic, all meetings were held remotely by videoconference rather than in person.

9. 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

10. 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. A list of members of the Secretariat is shown in **Appendix III**.

LABORATORY

11. The Laboratory is based at the Laboratory of the Government Chemist (LGC) (Teddington) and is managed under a collaboration agreement with LGC. The Laboratory remained operational throughout the year ensuring that essential testing work could be carried out and the supply of BPCRS could be maintained. The Laboratory Management Board is shown in **Appendix III.**

COSTS

12. 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 2021

13. Following publication of the British Pharmacopoeia 2021, three online updates were issued providing users with the text of Supplements 10.3, 10.4 and 10.5 of the 10th Edition of the European Pharmacopoeia.

British Pharmacopoeia 2022

14. The British Pharmacopoeia 2022 was published in August 2021. This new edition is available as a package containing the five volumes of the British Pharmacopoeia 2022, the one volume of the British Pharmacopoeia (Veterinary) 2022 and access to the electronic versions of both publications (online BP and offline download format).

15. 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 2022 is 1st January 2022.

16. All monographs published within the 10th Edition of the European Pharmacopoeia, as amended by Supplements 10.1 to 10.5, are included either in this edition of the British Pharmacopoeia or, where appropriate, in the associated edition of the British Pharmacopoeia (Veterinary). Monographs of the European Pharmacopoeia are clearly distinguished from those of national origin by means of a chaplet of stars that appears alongside the monograph title. Where appropriate, statements of relevance to UK usage, such as Action and use and the list of BP preparations, have been added to the European Pharmacopoeia monographs.

17. The British Pharmacopoeia 2022 contains 20 new monographs of national origin which were not published in previous editions. These include one new monograph for Traditional Herbal Medicines and four new monographs for unlicensed formulations. 130 monographs were amended in respect of technical or editorial content. In addition, several texts were updated to replace references to EU legislation by references to the relevant UK legislation.

18. The titles of nine monographs were amended in the British Pharmacopoeia 2022. In accordance with established policy, the former titles have been retained as subsidiary titles, which have the same legal weight as the main title.

19. One new Appendix was added to harmonise with the European Pharmacopoeia: Appendix VIII U – Tetrabutylammonium in Radiopharmaceutical Preparations. Appendix XIV C – Bacterial endotoxins was updated to incorporate the European Pharmacopoeia Test for Bacterial Endotoxins using Recombinant Factor C.

20. Three new Supplementary Chapters were added to harmonise with the European Pharmacopoeia (IV T: Depyrogenation of Items Used in the Production of Parenteral Preparations; IV U: Multivariate Statistical Process Control; VII E: Methods of Pretreatment for Preparing Traditional Chinese Drugs – General Information). Supplementary Chapter I N: Particulate Contamination was updated to incorporate the European Pharmacopoeia Recommendations on Testing of Particulate Contamination: Visible Particles.

21. A new Supplementary Chapter (X) was added on the Use of Analytical Quality by Design Concepts for Analytical Procedures. This Chapter provides non-mandatory guidance for analysts applying the principles of Analytical Quality by Design to the development of analytical testing methods and the use of these methods throughout the product lifecycle to provide assurance of quality.

22. The Supplementary Chapter on Aseptic Preparation of Unlicensed Medicines (V F) was updated to include a new section on Ready-to-Administer Injections.

These products are prepared in aseptic preparation units and are stored in a ready-to-administer form until they are administered to the patient.

British Pharmacopoeia (Veterinary) 2022

23. The British Pharmacopoeia (Veterinary) 2022 was published as a companion volume to the British Pharmacopoeia 2022 in August 2021. 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) 2022 is 1st January 2022.

24. The British Pharmacopoeia (Veterinary) 2022 contains five new monographs of national origin which were not published in previous editions. Two monographs were amended in respect of technical content in this edition.

25. Appendix XV J (Vet) 3 – Principles for the Detection of Extraneous Viruses in Immunological Veterinary Medicinal Products using Culture Methods was updated to reflect changes in the European Pharmacopoeia.

British Approved Names 2022

26. British Approved Names 2022 was published in August 2021. This new edition consolidates British Approved Names 2017 and its four Supplements and additionally defines 38 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

27. The BP 2022 publications can be accessed through the online version (pharmacopoeia.com) and the offline download edition. Both of these formats are updated to include the European Pharmacopoeia Supplement updates.

28. Following the regular public consultation schedule for new and revised monographs, four three-month consultation periods were held during 2021. This provides users with the opportunity to contribute to the monograph development and revision process, thereby helping to ensure that published monographs are relevant and robust.

29. A new section of the BP website for BP Consultations was introduced in 2021, which includes details of both live and closed consultations and will promote public engagement and transparency of the work of the BP. As a result of the positive responses received to consultations undertaken in 2020, the use of LC/UV Identification tests using diode array detection was included in several national monographs in the BP 2022 and there will be a gradual introduction of numerical limits in Related substances tests from the BP 2023 onwards.

30. A regular programme of user research has continued to further support development of the BP website and products. Following the implementation of the Tracked Changes functionality, a new Revision History functionality has been implemented which enables users to understand why a monograph has been revised.

Prices and Availability

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

32. 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

33. By the end of 2021 work was progressing on the preparation of the next editions of the British Pharmacopoeia and British Pharmacopoeia (Veterinary). These will be published during 2022 and will have an effective date of 1st January 2023.

34. A digital update to the British Pharmacopoeia 2022 was issued in September 2021 providing users with the text of Supplement 10.6 to the 10th Edition of the European Pharmacopoeia which came into effect on 1st January 2022. Efficiencies introduced into the publication process during the year allowed this Supplement to be incorporated in the online version three months ahead of implementation. A further update was issued in January 2021 providing users with the text of Supplement 10.7 which will come into effect on 1st April 2022. Supplement 10.8 will be available in advance of its implementation on 1st July 2022. These updates will only be available via the online BP and the offline download. The texts will subsequently be included in the BP 2023 publications as appropriate.

OTHER PHARMACOPOEIAL MATTERS

Biological Medicines

35. While continuing to maintain quality standard monographs for Biological products, the main focus during the year has been the development of guidance for cell and gene therapy products as well as the exploration and assessment of innovative approaches for monoclonal antibody standards.

36. The Advanced Therapy Medicinal Products (ATMP) Working Party continues to develop non-mandatory guidance documents that support quality and innovation in these medicines. The first text developed by the Working Party, related to the Application of Flow Cytometry, was published in the online

version of the BP 2022 in December. Substantial progress had been made towards the completion of draft guidance relating to Vector Copy Number Quantification and this is expected to be published in Spring 2022. Both guidance documents underwent public consultations, where the value of the texts was recognised across the product lifecycle by those participating in the consultations. Responses were received from the private sector, academic researchers and trade associations. 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 new topics and is working to produce further non-mandatory guidance documents for the ATMP community.

37. 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.

38. In addition to the work related to standards development, the MHRA has also recognised and continued to support broader engagement across the biopharmaceutical and ATMP landscape. The MHRA and BP remains active within the international regulatory and pharmacopoeial community, for example through continued engagement with colleagues in the US FDA Office for Tissue and Advanced Therapies (OTAT), the US National Institute for Standards and Technology (NIST) and the US Standards Coordinating Body for Regenerative Medicines (SCB).

Unlicensed Medicines

39. 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. In addition to the general guidance published on Ready-to-Administer Injections, where there is a clinical need for unlicensed formulations the Expert Advisory Group on Unlicensed Medicines will prepare monographs for ready-to-administer injections used in the Outpatient Parenteral Antibiotic Therapy Service.

Herbal and Complementary Medicines

40. The Expert Advisory Group on Herbal and Complementary Medicines carried out a strategic review of their work programme during the year to identify future candidate monographs that will provide the most value to users. This review considered the possible target user groups, barriers to monographs being used, how to engage with users and the practicalities of sourcing samples and technical information. Three key target user groups were identified: (1) Traditional Herbal Registration (THR) holders,
(2) manufacturers of herbal products that did not utilise the THR scheme and (3) herbal practitioners. The EAG concluded that a strategy whereby the BP Secretariat would look into herbal extracts that are used by (or potentially used by) all these groups would give the most potential value to users and this approach was subsequently endorsed by the BP Commission.

41. In parallel, the ongoing work of maintaining and updating the existing monographs for herbal medicines which are still used and would benefit from modernisation is continuing.

Nomenclature

42. The BP continued to provide advice and comments to the World Health Organization (WHO) Committee on International Nonproprietary Names (INN). Recommended INN (rINN) for products licensed in the UK are 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 (85 and 86) were published by WHO during the year.

43. 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

44. The Analytical Quality by Design (AQbD) Working Party achieved a key milestone through the publication of the “Supplementary Chapter on the use of Analytical Quality by Design Concepts for Analytical Procedures” in the BP 2022. This text contains guidance and supporting information for the use of AQbD concepts within a pharmacopoeial context. The Working Party are currently working on drafting additional content for a future revision in order to further aid users.

45. 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 undertaken in 2021. The outcomes of this project are currently being discussed with the relevant Expert Advisory Group for further consideration and subsequent publication in a future edition of the BP.

46. The BP has continued to enhance its global presence in AQbD, further developing collaborative relationships with peer organisations and delivering presentations at national and international conferences. Two webinars were jointly hosted with the United States Pharmacopeia in February and in September. These were both well attended and involved extensive engagement through the Q&A panel sessions.

47. The Working Party has also expanded its professional membership by the appointment of five new experts who will aid in delivering the strategic objectives of the group.

Liaison with Other UK Organisations

48. The BP has continued to collaborate with academic institutions, although this work has been somewhat limited this year. Several projects are in progress with the Robert Gordon University (review of identification tests which specify the use of chloroform) and with the University of Sunderland where work is being undertaken on Baclofen formulations, Chlorphenamine formulations, Paroxetine Tablets and on Pizotifen Malate and Tablets. This work will be reflected in future revisions to BP monographs.

49. The BP and Veterinary Medicines Directorate (VMD) continue to collaborate closely on the development of monographs for veterinary medicines and on a range of regulatory and policy issues relating to veterinary medicines.

Laboratory

50. The Laboratory has continued to support the work of the British Pharmacopoeia Commission and the wider MHRA remit relating to public health throughout 2021.

51. Activities continued throughout the year with adjustments made to support work during the COVID-19 pandemic. The Laboratory remained fully operational throughout by implementing social distancing and by adjustments to working arrangements including enhanced cleaning and laboratory protocols.

52. Despite the pandemic, laboratory work on 33 new and revised BP monographs was undertaken during the year for inclusion in future publications. The Laboratory also participated in two interlaboratory trials to validate their in-house method for the determination of cannabinoids and provided data to support several regulatory investigations during the year.

BP Reference Materials

53. Nine new British Pharmacopoeia Chemical Reference Substances (BPCRS) were established to support the British Pharmacopoeia and British Pharmacopoeia (Veterinary) publications, 55 were replaced and 170 were re-tested to ascertain their continued stability.

54. All new BPCRS that were introduced into the BP 2022 and BP (Vet) 2022 were made available to coincide with publication in August 2021, ensuring that users were ready to comply with the new and revised monographs before they came into force.

55. The demand for these reference materials remained high throughout the year. 34388 vials were sold within the UK and to countries worldwide, representing a slight decrease of about 4% from the previous year but with an overall increase of about 12% compared to the 2019 figures.

European Pharmacopoeia

56. The sixth and seventh Supplements to the 10th Edition of the European Pharmacopoeia (Supplements 10.6 and 10.7) were published in July 2021 and October 2021 respectively. Supplement 10.6 came into effect on 1st January 2022 and Supplement 10.7 will come into effect on 1st April 2022. The eighth Supplement (10.8) was published in January 2022 and will come into effect on 1st July 2022. The text of these publications will be included in the next editions of the British Pharmacopoeia or British Pharmacopoeia (Veterinary), as appropriate.

57. 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. All meetings of the European Pharmacopoeia Commission and its Expert Groups and Working Parties were held remotely during the year.

58. The European Directorate for the Quality of Medicines & HealthCare (EDQM) are investigating an appropriate limit for Aluminium in parenteral nutrition solutions. The UK had provided background information relating to the rationale behind the limit in the BP monograph for unlicensed Parenteral Nutrition Solutions. Further investigative work is being undertaken at both national and European level on this issue.

59. 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.

60. Supplementary lists of Approved Synonyms for names at the head of monographs of the European Pharmacopoeia were prepared and published on the recommendation of the British Pharmacopoeia Commission.

61. 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 2021, is included in Appendix V.

International Liaison and Collaboration

62. Liaison was maintained on a wide range of topics relating to pharmacopoeial matters and nomenclature with various international organisations and bodies including the World Health Organization (WHO), the Australian Therapeutic Goods Administration Laboratories, the Canadian Health and Food Protection Branch, the United States Pharmacopeia (USP) and the United States Adopted Names (USAN) Council.

63. Due to on-going travel restrictions imposed by the COVID-19 pandemic, all international meetings were held remotely. BP staff and experts participated in a large number of meetings either as attendees or participants.

64. BP Staff attended the twelfth International Meeting of World Pharmacopoeias (IMWP) organised by the World Health Organization in February. 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 had discussed future priorities for the IMWP, issues relating to international harmonisation, impurity control and nitrosamine contamination, together with activities to support the COVID-19 pandemic including the development of reference standards and the potential for developing vaccine monographs. These issues were discussed further during the year at the regular meetings held between representatives of the IMWP participating pharmacopoeias.

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

66. The BP attended the WHO Consultation on Screening Technology, Laboratory Tools and Pharmacopoeial Specifications for Medicines in May during which monographs and reference materials for the International Pharmacopoeia were discussed. Further discussions were held during the year relating to the development of standards for COVID-19 critical medicines.

67. BP staff attended the 72nd and 73rd 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 had also discussed policies for the safe naming of drug substances, liposomal substances and COVID-19 vaccines.

68. BP staff had held discussions with the United States Pharmacopeia to discuss areas of mutual interest including informal harmonisation projects for Finished Product monographs, Analytical Quality by Design and Monograph Lifecycle, standards for digital therapy, the USP Science and Quality Framework and the pharmacopoeial response to the global pandemic. Procedures and timelines had been agreed relating to the joint development of monographs for small chemicals and antibiotics and potential candidate monographs would be identified in due course.

69. Two successful joint webinars between the BP and the USP had been held during the year. The first webinar, held in February, had addressed Analytical Quality by Design applications and the Analytical Method Lifecycle. This had included updates from the BP and the USP and views from regulators. Following the success of the initial event a second webinar was held in September on the "Real World Application of AQbD and Analytical Procedure Lifecycle Management" which provided an opportunity to highlight the new Supplementary Chapter published in the BP 2022.

70. The BP continued to work with the Chinese Pharmacopoeia and the Indian Pharmacopoeia throughout the year. A Memorandum of Understanding between the BP and the Indian Pharmacopoeia had been finalised in February which would enable co-operation in developing harmonised standards and would facilitate the exchange of information and sharing of technical expertise between the two organisations. Further discussions had been held during the year relating to the potential for the joint development of monographs and sharing best practices for the digitisation of pharmacopoeias.

71. The Co-operation Agreement between the BP and the Croatian Agency for Medicinal Products and Medical Devices had been extended until March 2026. This agreement allowed the Croatian Pharmacopoeia to reproduce the BP general text relating to Unlicensed Medicines in their publication.

ACKNOWLEDGEMENTS

72. The Commission wishes to place on record its heartfelt thanks to the following members who retired from the British Pharmacopoeia Commission at the end of the year: Professor Alastair Davidson (Vice-Chair), Dr Graham Cook, Professor John Miller, Dr Ronald Torano and Dr Paul Varley. Professor Davidson had made a significant contribution to the work of both the British Pharmacopoeia Commission and the European Pharmacopoeia Commission for nearly 50 years. He had been a member of the BP Commission for 16 years, serving as Vice-Chair between 2014 and 2021, and had served as Chair of Expert Advisory Group MC1: Medicinal Chemicals for many years. He had been a member and Chair of several Expert Groups of the European Pharmacopoeia Commission and a member of the UK delegation to the EP Commission. Dr Cook had served as a member of the BP Commission for 12

Years and had been instrumental in establishing the Working Party on Analytical Quality by Design. Professor Miller, Dr Torano and Dr Varley had each served for 10 years and the Commission had benefitted enormously from their experience and range of expertise, particularly in the areas of reference substances, current practices within the pharmaceutical industry and biological medicines. The Commission was pleased to note that the retiring members would continue to be involved with the work of the BPC through their membership of the Expert Advisory Groups, Panels of Experts and Working Parties.

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

74. The British Pharmacopoeia Commission also wishes to record its immense gratitude to the staff of the British Pharmacopoeia and Laboratory Services Group of the Medicines and Healthcare products Regulatory Agency. Significant input to the work of the British Pharmacopoeia Commission continued to be received from members of staff from the Licensing Division, the Vigilance & Risk Management of Medicines Division, the Inspection, Enforcement & Standards Division, the Technology, Digital, Data & Delivery Division and the Communications Division of the MHRA. Significant input has also been received from the BP and MHRA Laboratories, from the Department of Health and Social Care, from the National Institute for Biological Standards and Control, from the Cell and Gene Therapy Catapult and from the Veterinary Medicines Directorate.

75. The Commission wishes to acknowledge the advice of the publishing team at The Stationery Office in the production of the British Pharmacopoeia 2022, the British Pharmacopoeia (Veterinary) 2022 and British Approved Names 2022.

OBITUARIES

76. Members were saddened to learn of the death of Mr Robert Shaw who had served on the Expert Advisory Group on Pharmacy between 2003 and 2006.

MEMBERSHIP OF THE BRITISH PHARMACOPOEIA COMMISSION DURING 2021

Chair

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

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

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

Dr Graham D Cook[1] BPharm PhD MRPharmS
Senior Director, Process Knowledge/Quality by Design, Pfizer

Professor Alastair G Davidson[1] BSc PhD FRPharmS (Vice-Chair)
Visiting Professor of Pharmaceutical Sciences, University of Strathclyde

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

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

Mr Robert Lowe BPharm FRPharmS
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

[1] Retired 31/12/2021

Professor John Miller[1] MSc PhD MRSC CChem
Visiting Professor, Strathclyde Institute of Pharmacy and Biomedical Sciences; former Head of the EDQM Laboratory

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

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

Dr Ronald Torano[1] BSc PhD MRSC CChem
Pharmacopoeial Intelligence and Advisory Specialist; GlaxoSmithKline

Dr Paul Varley[1] BSc PhD
Vice President of Biopharmaceutical Development, Kymab Limited

Secretary and Scientific Director

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

[1] *Retired, 31st December 2021.*

APPENDIX II

MEMBERSHIP OF EXPERT ADVISORY GROUPS, PANELS OF EXPERTS AND WORKING PARTIES OF THE BRITISH PHARMACOPOEIA COMMISSION DURING 2021

EXPERT ADVISORY GROUPS

ABS: Antibiotics	R L Horder (**Chair**), G D Cook (**Vice Chair**), G Blake, G Clarke, E Flahive, V Jaitely, W Mann, J Miller, M Pires, J Sumal, I R Williams
BIO: Biological and Biotechnological Products	P Varley (**Chair**), A-M Brady (**Vice-Chair**), E Amirak, L Bissett*, C Braxton*, C Burns, K Chidwick*, A Cook*, J Cook*, B Cowper, S Gill, C Jones*, A Kippen, V Loh, K Nordgren*, B Patel, A M Pickett*, T Pronce*, L Randon, I Rees*, S Schepelmann*, P Stickings*, R Thorpe, L Tsang, M Wadhwa*, W Zunic
HCM: Herbal and Complementary Medicines	M Simmonds (**Chair**), R Middleton (**Vice-Chair**), P Anderson, A Booker, C Etheridge, C Leon, B Moore, M Pires, E Reich, M Rowan, A Slater, K Strohfeldt-Venables, J Sumal*, C Welham, E Williamson, K Zhao (*Corresponding members* SS Handa, A Krauss, Z-T Wang)
MC1: Medicinal Chemicals	A G Davidson (**Chair**), D Cairns (**Vice-Chair**), S Bale[1], H Batchelor, J C Berridge, E Bush, A J Caws, D Deutsch, P Fleming, E Gray, W J Lough, D J Malpas, P Marshall, S Nolan
MC2: Medicinal Chemicals	G Cook (**Chair**), C T Goddard (**Vice-Chair**), J Birchall, K Boon, J Cowie, K Foster, E Hook, J Lim, J Miller, A Ruggiero, N Wynne (*Corresponding members* M Brits, W Sherwin)
MC3: Medicinal Chemicals	M Almond (**Chair**), J Beach (**Vice-Chair**), J Beaman, K Foster, C T Goddard, P Hampshire, W K L Pugh, B Rackstraw, R Torano, I R Williams
PCN: Pharmacy and Nomenclature	J K Aronson (**Chair**), R A Lowe (**Vice-Chair**), M Ahmed*, E Baker, J Beach, D Elder, E Gray, R L Horder, J Lim*, J MacDonald, 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, M Santillo, J Smith, A Sully, P Weir, M Westwood

PANELS OF EXPERTS

BLP: Blood Products	K Chidwick, A R Hubbard, J More, P Varley
CX: Excipients	C Mroz (**Vice-Chair**), H Batchelor, R Cawthorne, D Deutsch
IGC: Inorganic and General Chemicals	C T Goddard (**Chair**), M Almond, S Boland, P Henrys, G Lay
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 Immunological Products	A-M Brady (**Chair**), R Banks, R Cooney, M Ilott, M Johnson, K Redhead, C Stirling, R Woodland

WORKING PARTIES

AQbD: Analytical Quality by Design	G Cook (**Chair**), P Borman, M Chatfield, S Ellison, C Gray, P Hamilton, M Hanna-Brown, S Jones, A Kettle, W J Lough, P Nethercote, E Razzano, M Zaman (*Corresponding members* K Barnett, B Harrington, R LoBrutto, T Morris, W Sherwin)
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**), L Bisset, C Blue, C Burns, J Campbell, D Caulfield, M Collis, D Gilham, K Gilmour, J Glassford, D Grandolfo, Z Hannoun, T Kanwarjit, L Li, A Lovatt, M Lowdell, J Nieto, A Niewiarowska, J Norton, A Nowocin, L Pattenden, J Rattu, E Razzano, R Rego, I Santeramo, F Schnetzinger, I Searing, V Smith, B Surmacz-Cordle, V Vanhoutte, M Walsh, P Wang, S Vinter, Y Zhao

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, G Cook, J Miller, M Simmonds, R Torano

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

APPENDIX III

MEMBERS OF THE BRITISH PHARMACOPOEIA COMMISSION STAFF DURING 2021

Secretary and Scientific Director
Mr J Pound

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

Laboratory Management Board
Mr J Pound (*Secretary & Scientific Director, BP)*
Mr S Young (*Head of Analytical Science, BP)*
Mr M Whaley (*Laboratory Services Manager, BP*)
Ms I Reydellet (*Operations Manager, LGC, until August*)
Mr R Griffiths (*Customer and Infrastructure Manager, LGC, from August*)
Mr D Rutty (*Operations and Delivery Manager, LGC, from August*)
Ms L Johnson (*Accounts Manager, LGC*)
Dr P Domann (*Head of Operations, LGC*)
Dr J Braybrook (*Director, National Laboratories, LGC*)

Administrative
Ms F Chughtai
Ms N Begum
Mr B Delahunty
Miss J Paine
Ms U Rothna

DHSC Staff
Ms R Hunter (*from October*)

Secondees from the Cell and Gene Therapy Catapult
Dr M Francois (*until November*)
Dr R McCoy
Ms M Pianella (*from November*)

APPENDIX IV

BRITISH PHARMACOPOEIA COMMISSION PUBLICATIONS DURING 2021

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

British Pharmacopoeia 2022 package

Consisting of:-

British Pharmacopoeia 2022

British Pharmacopoeia (Veterinary) 2022

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
(*Price £150*)

APPENDIX V

EUROPEAN PHARMACOPOEIA COMMISSION

MEMBERS OF THE UNITED KINGDOM DELEGATION DURING 2021

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

Alternates: A Gibb, R L Horder

MEMBERS OF GROUPS OF EXPERTS FROM THE UNITED KINGDOM DURING 2021

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 (***Chair***)
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 (***Chair***), E Gray
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 2021:

Bacterial Endotoxins Test	K Nordgren[1], S Diebold
Cell Therapy Products	K Cornish
Chromatographic Separation Techniques	S Young
Extracts	M Pires
Gene Therapy Products	Y Zhao
General Methods	E Gray, O McPolin (*Specialist*)
Host-cell Proteins	A Kippen
Inhalanda	K M G Taylor
Monoclonal Antibodies	P Varley, S Prior, M Wadhwa
Mycoplasmas	R Hawkins
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	L Bisset
Rules of Procedure	A Gibb
Special Revision Programme	A Evans
Standard Terms	M Ahmed
Statistics	R Gaines Das

[1] *Retired during the year.*

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

INTRODUCTION

Purpose of the Code

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

Importance of impartiality

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

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

SCOPE

Committees and groups to which this Code applies

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

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

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

DEFINITIONS

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

Pharmaceutical Industry

3.2 "Pharmaceutical industry" means:

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

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

Immediate family

3.3 "Immediate family" means:

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

INTERESTS WHICH NEED TO BE DECLARED

Summary of interests that need to be declared

4.1 It is the responsibility of each individual to identify and to declare all relevant interests. The following types of interest must be declared by 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 be 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 Chair 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 Chair 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 Chair 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 Chair'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 Chair'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 Chair's discretion to answer questions from other members. The Chair and/or the MHRA Secretariat will advise on these matters. The Chair 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 Chair or member, the source of the interest (e.g. the company name), will not provide any financial information nor numbers (e.g. for shares) nor identify the family member or other holding the interest by name.

COMMISSION ON HUMAN MEDICINES, 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 Name	Nature of Interest	Current	Additional Information
Aditya Sharma	NPPEAG	Personal	NIL	N/A	N/A	
Aditya Sharma	NPPEAG	Non-Personal	Lundbeck	Unrestricted educational grant	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	NIL	N/A	N/A	
Alana Adams	PEAG	Non-Personal	NIL	N/A	N/A	

Allan Young	IEWG	Personal	Allegan	Paid lectures and advisory boards for the company with drugs used in affective and related disorders	Yes
Allan Young	IEWG	Personal	Bionomics	Paid lectures and advisory boards for the company with drugs used in affective and related disorders	Yes
Allan Young	IEWG	Personal	COMPASS	Paid lectures and advisory boards for the company with drugs used in affective and related disorders	Yes
Allan Young	IEWG	Personal	Janssen	Paid lectures and advisory boards for the company with drugs used in affective and related disorders	Yes
Allan Young	IEWG	Personal	Livanova	Paid lectures and advisory boards for the company with drugs used in affective and related disorders	Yes
Allan Young	IEWG	Personal	Lundbeck	Paid lectures and advisory boards for the company with drugs used in affective and related disorders	Yes
Allan Young	IEWG	Personal	Novartis	Paid lectures and advisory boards for the company with drugs used in affective and related disorders	Yes
Allan Young	IEWG	Personal	Sumitomo Dainippon Pharma	Paid lectures and advisory boards for the company with drugs used in affective and related disorders	Yes

Allan Young	IEWG	Personal	Sunovion	Paid lectures and advisory boards for the company with drugs used in affective and related disorders	Yes
Allan Young	IEWG	Non-Personal	Janssen Cilag NV	A Double-Blind, Placebo-Controlled, Multi-Center Study Investigating the Efficacy, Safety, and Tolerability of JNJ-61393215 as Adjunctive Treatment in Adults with Major Depressive Disorder with Anxious Distress with Suboptimal Response to Standard Antidepressants. Young, A.	Yes
Allan Young	IEWG	Non-Personal	Janssen Pharmaceutica N.V.	An Open-label Long-term Extension Safety Study of Intranasal Esketamine in Treatment-resistant Depression Safety and Sustenance of Esketamine Treatment Response With Repeated Doses at Intervals Determined by Symptom Severity (SUSTAIN-3) Young, A.	No
Allan Young	IEWG	Non-Personal	LivaNova plc	A Global Prospective, Multi-center, Observational post-market Study to assess short, mid and long-term effectiveness and efficiency of VNS Therapy® as adjunctive therapy in real-world patients with difficult to treat depression Young, A.	Yes

Allan Young	IEWG	Non-Personal	N/A	UK Chief Investigator for Novartis Major Depression Disorder Study MIJ821A12201	Yes	
Allan Young	IEWG	Non-Personal	N/A	UK Chief Investigator for Compass Pathways Ltd Psilocybin Clinical Trials Portfolio	Yes	
Allan Young	IEWG	Non-Personal	N/A	Principal Investigator on the following current industry sponsored clinical trials.	Yes	
Amanda Adler	CHM, CDRRA EAG	Personal	NIL	N/A	N/A	
Amanda Adler	CHM, CDRRA EAG	Non-Personal	NovoNordisk	The ISAP collaborative trail sponsored by the University of Oxford' will start in 2022'. NovoNordisk provides drug for the trail, and salary support for colleagues in the University of Oxford Diabetes Trials Unit.	Yes	The ISAP collaborative trail sponsored by the University of Oxford' will start in 2022'. NovoNordisk provides drug for the trail, and salary support for colleagues in the University of Oxford Diabetes Trials Unit.
Amanda Drake	IEWG	Personal	NIL	N/A	N/A	
Amanda Drake	IEWG	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	Viiv Healthcare	Grant for registration to attend virtual Conference on Retroviruses & Opportunistic Infections (CROI)	Yes	

Andrew Freedman	IEAG	Non-Personal	NIL	N/A	N/A	
Andrew Grace	CDRRA EAG	Personal	NIL	N/A	N/A	
Andrew Grace	CDRRA EAG	Non-Personal	NIL	N/A	N/A	
Andrew Hattersley	RWD	Personal	NIL	N/A	N/A	
Andrew Hattersley	RWD	Non-Personal	NIL	N/A	N/A	
Andrew Pollard	CTBVEAG	Personal	NIL	N/A	Yes	
Andrew Pollard	CTBVEAG	Non-Personal	Astra Zeneca	Partnership between Oxford University and AZ for development of a Covid19 vaccine. (I have irrevocably waived any personal rights under this agreement)	~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	Sequirus, MSD	Grant to Oxford University	No	
Andrew Pollard	CTBVEAG	Additional				Chair of UK Dept. Health and Social Care's (DHSC) Joint Committee on Vaccination & Immunisation (JCVI), and member of the WHO's SAGE.

Andrew Pollard	CTBVEAG	Additional	Chair of the scientific advisory group on vaccines for the European Medicines Agency until March 2020 and a member of the World Health Organization’s SAGE until 31/12/21
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 pneumococcal vaccines in Nepal (2013-current).
Andrew Pollard	CTBVEAG	Additional	European Commission (EC): EC IMI grants (EBOVAC), on Ebola vaccine (Janssen; 2015-current); (PERISCOPE) on pertussis vaccines (2016-current); (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)

Andrew Pollard	CTBVEAG	Additional				Grants from Innovate UK to develop plague, zika, Q fever vaccines (2016-current).
Andrew Pollard	CTBVEAG	Additional				Grants from CEPI on COVID19 vaccines (2021-current)
Andrew Pollard	CTBVEAG	Additional				Grant from Meningitis Res Found'n on a booster of Bexsero in teens (2018-current), from BMA on RSV, and MRC on novel meningococcal vaccine; Grant from Bill & Melinda Gates Found'n on evaluating infant schedules (2019 – current)
Andrew Pollard	CTBVEAG	Additional				I have a patent pending on a meningococcal vaccine but will waive any personal rights if approved.
Andrew Rice	NPPEAG	Personal	Imperial College Consultants	Consultancy: ASCR undertakes consultancy and advisory board work for Imperial College Consultants- in the last 36 months this has included remunerated work for: Confo, Vertex, Pharmanovo, Lateral, Novartis, Mundipharma, Orion, Shanghai SIMR BiotechAsahi Kasei & Toray	No	
Andrew Rice	NPPEAG	Non-Personal	NIL	N/A	N/A	
Andrew Rice	NPPEAG	Additional				Owner of share options in Spinifex Pharmaceuticals

			from which personal benefit accrued upon the acquisition of Spinifex by Novartis in July 2015. The final payment was made to me in 2019. I continued to advise Novartis on subsequent clinical trials with EMA401. These trials were terminated early because of an emergent toxicity issue and no further development is anticipated by Novartis. Whilst I have not been paid in the relevant time period, I am still contributing to the writing up and publication of the two terminated clinical trials in an unpaid capacity.
Andrew Rice	NPPEAG	Additional	Named inventor on two patents from Imperial College (WO 2005/079771 & EP13702262.0/ WO2013 110945). Neither are being actively developed or commercialised.
Andrew Rice	NPPEAG	Additional	An elected Council Member of the International Association of the Study of Pain, which receives grants and other income from industry, including conference sponsorship and symposium/exhibition income from industry. Two of roles

						were as Chair of the 2021 World Congress of Pain Scientific Programme Committee and Chair of the Presidential Taskforce on cannabis and cannabinoid analgesia (concluded 2021).
Andrew Rice	NPPEAG	Additional				Chair of the Trial Steering Committee (TSC) of National Institute for Health Research (NIHR) for the OPTION-DM trial.
Andrew Rice	NPPEAG	Additional				Member of Joint Committee on Vaccine and Immunisation - varicella sub-committee
Andrew Rice	NPPEAG	Additional				Member of Analgesic Clinical Trial Translation: Innovations, Opportunities, and Networks (ACTTION) steering committee
Andrew Riordan	COVID-19 VBREWG	Personal	NIL	N/A	N/A	
Andrew Riordan	COVID-19 VBREWG	Non-Personal	Oxford University	Postgraduate External Examiner for Oxford University (Postgraduate Diploma in Paediatric Infectious Diseases)	N/A	
Andrew Riordan	COVID-19 VBREWG	Additional	Data Safety Monitoring Board		N/A	Member of Data Safety Monitoring Board for COV-BOOST trial.
Andrew Riordan	COVID-19 VBREWG	Additional	Oxford University		N/A	Participant in University of Oxford's ChAdOx1 nCoV-19 clinical trial

Angela Thomas	IEWG	Personal	Canna Capital plc Advisory Board	Preliminary discussions; not yet remunerated; single lunch meeting	No
Angela Thomas	IEWG	Personal	CTG Catapult	Non-Executive Director of the CTG Catapult (remunerated and travel and accommodation costs)	Yes
Angela Thomas	IEWG	Non-Personal	NIL	N/A	N/A
Anjan Dhar	GRIDEAG	Personal	Dr Falk Pharma UK	Speaker Fees and Honoraria for advisory work	No
Anjan Dhar	GRIDEAG	Personal	Janssen UK	Hospitality and support for attendance at meetings, donation for research	No
Anjan Dhar	GRIDEAG	Personal	Pfizer UK	Consultancy and Speaker Fees	No
Anjan Dhar	GRIDEAG	Personal	Pharmacosmos UK	Consultancy and Speaker Fees, hospitality and support for attending conferences	No
Anjan Dhar	GRIDEAG	Personal	Takeda Pharmaceuticals UK	Consultancy and Speaker Fees	No
Anjan Dhar	GRIDEAG	Personal	Tillotts UK	Consultancy and Speaker Fees, hospitality and support for attending conferences	No
Anjan Dhar	GRIDEAG	Non-Personal	NIL	N/A	N/A
Ann Daly	PEAG	Personal	NIL	N/A	N/A
Ann Daly	PEAG	Non-Personal	NIL	N/A	N/A
Anthony G Wilson	GRIDEAG	Personal			

Anthony G Wilson	GRIDEAG	Non-Personal				
Arianna Di Florio	IEWG	Personal	NIL	N/A	N/A	
Arianna Di Florio	IEWG	Non-Personal	NIL	N/A	N/A	
Arianne Matlin	Dental Caries Reclassification EWG	Personal	NIL	N/A	N/A	
Arianne Matlin	Dental Caries Reclassification EWG	Non-Personal	NIL	N/A	N/A	
Arianne Matlin	Dental Caries Reclassification EWG	Additional				Non-personal collaboration with Colgate UK since 2010. The British Dental Association has a longstanding agreement to support the annual Colgate Oral Health Month/Bright Smiles, Bright Futures campaign. This support is limited to general oral hygiene messages and does not involve endorsement or promotion of any products by the BDA. The BDA is also currently working with researchers at Heidelberg University on a project funded by Colgate. Again, there is no discussion of any products; the research focuses on population-level

						oral health status and inequalities.
Barbara Conway	CPSEAG	Personal	NIL	N/A	N/A	
Barbara Conway	CPSEAG	Non-Personal	NIL	N/A	N/A	
Ben Forbes	CPSEAG	Personal				
Ben Forbes	CPSEAG	Non-Personal				
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				The company Omeros has provided 11 weekly treatments of narsoplimab for compassionate use on a single patient. The first dose was given on the 24th November 2021
Catherine Stannard	NPPEAG	Personal	NIL	N/A	N/A	
Catherine Stannard	NPPEAG	Non-Personal	NIL	N/A	N/A	

Catherine White	Dental Caries Reclassification EWG	Personal	NIL	N/A	N/A	
Catherine White	Dental Caries Reclassification EWG	Non-Personal	NIL	N/A	N/A	
Catherine White	Dental Caries Reclassification EWG	Additional				I do not believe I have any conflicts of interests. Roles held in the last year include Governing Body member to South Warks CCG (up to March 21); Chair of NICE Guideline 204; Trustee, information manager and rehab campaign lead for charity ICUsteps (voluntary role) Member of Monitoring Committee for UKRI intensive care trial and co-application to a NIHR sepsis research trial. PPI trainer for Swiss National Science Foundation (SNSF) in March 21. March-Oct 20 committee member for UKRI/DHSC/NIHR Rapid Response Covid research funding panel.
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
Chris Goldring	CTBVEAG	Personal	NIL	N/A	N/A
Chris Goldring	CTBVEAG	Non-Personal	Innovative Medicines Initiative project: Transbioline https://transbioline.com/project/ 7 Pharmaceutical Companies: Pfizer, MSD, Roche, Eli Lilly, Novartis, Janssen, Sanofi-Aventis	Grant	No
Chris Goldring	CTBVEAG	Non-Personal	Innovative Medicines Initiative project: TransQST http://transqst.org/ 9 Pharmaceutical Companies: Eli Lilly, Abbvie, Servier, Sanofi-Aventis, AZ, GSK, Janssen, Orion, B.I.	Grant	No
Chris Goldring	CTBVEAG	Non-Personal	KalVista Pharmaceuticals	Consultancy paid into University of Liverpool research account	No
Chris Goldring	CTBVEAG	Non-Personal	Merck	Grant	Yes
Chris Robertson	COVID-19 VBREWG	Personal	NIL	N/A	N/A

Chris Robertson	COVID-19 VBREWG	Non-Personal	NIL	N/A	N/A	
Christina Yap	CTBVEAG	Personal	Faron Pharmaceuticals	Independent Statistical Consultant	Yes	
Christina Yap	CTBVEAG	Non-Personal	Astra Zeneca	Trial grant (where I am a co-investigator)	Yes	
Christina Yap	CTBVEAG	Non-Personal	Plexxikon	Trial grant (where I am a co-investigator)	Yes	
Christina Yap	CTBVEAG	Non-Personal	Bloodwise/Celgene/Onyx	Trial grant (where I am a co-investigator)	No	
Christopher Marriott	CPSEAG	Personal	Halation Ltd	Company Secretary, Directorship, Fees, Shares.	No	
Christopher Marriott	CPSEAG	Personal	Vectura Ltd	Shares -These were sold on 18th October 2021	No	
Christopher Marriott	CPSEAG	Non-Personal	NIL	N/A	NIL	
Christopher Marriott	CPSEAG	Additional				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, RWD	Personal	NIL	N/A	N/A	
Christopher Weir	CHM, COVID-19 VBREWG, NPPEAG, RWD	Non-Personal	AB Science	DSMB membership for three trials (in ALS, mastocytosis and progressive MS), with income to my department	Yes	
Christopher Weir	CHM, COVID-19 VBREWG, NPPEAG, RWD	Non-Personal	Eli Lilly	Research grant to institution, on which I am co-applicant	Yes	

Clare Pain	PMEAG	Personal	NIL	N/A	N/A	
Clare Pain	PMEAG	Non-Personal	NIL	N/A	N/A	
Clive Grattan	IEWG	Personal	Celltrion	Consultancy	Yes	
Clive Grattan	IEWG	Personal	Sanofi Genzyme	Consultancy	Yes	
Clive Grattan	IEWG	Non-Personal	NIL	N/A	N/A	
Colin Forfar	RWD	Personal	UCB Pharma	Consultancy and presentation fee, travel/accommodation fee	Yes	
Colin Forfar	RWD	Non-Personal	NIL	N/A	N/A	
Colin Forfar	RWD	Additional				Romosuzumab; co-author of review on cardiovascular safety
Daniel Hawcutt	PEAG, PMEAG, RWD	Personal	NIL	N/A	N/A	
Daniel Hawcutt	PEAG, PMEAG, RWD	Non-Personal	Gilead	PI for research study they are carrying out on NIHR Alder Hey CRF	Yes	
Daniel Hawcutt	PEAG, PMEAG, RWD	Non-Personal	Medimmune Inc - Maryland	PI for research study they are carrying out on NIHR Alder Hey CRF	Yes	
Daniel Hawcutt	PEAG, PMEAG, RWD	Non-Personal	Zogenix, Inc.	PI for research study they are carrying out on NIHR Alder Hey CRF	Yes	
Daniel Hawcutt	PEAG, PMEAG, RWD	Additional				I chair the joint RCPCH/NPPG joint standing committee on Medicines - where the use,

						safety or other factors relating to individual medicines is routinely discussed.
Darragh Murnane	CPSEAG	Personal	Adare Pharmaceuticals Inc. (New Jersey, USA)	Consultancy - Specific	No	
Darragh Murnane	CPSEAG	Personal	Fluid Pharma Ltd. LS2 3AA	University Director, non-specific, no guaranteed personal benefit.	Yes	
Darragh Murnane	CPSEAG	Non-Personal	3M Ltd. (now called) Kindeva Drug Delivery Ltd	In-kind support for research project	Yes	
Darragh Murnane	CPSEAG	Non-Personal	AstraZeneca	In-kind support for research project	Yes	
Darragh Murnane	CPSEAG	Non-Personal	Bespak (now called Bespak Recipharm)	Funding for a collaborative Research Project, co-funded by Innovate UK.	Yes	
Darragh Murnane	CPSEAG	Non-Personal	Chiesi Ltd.	Sponsored PhD Studentship	Yes	
Darragh Murnane	CPSEAG	Non-Personal	Clement Clarke International	Contract research and in-kind support for research projects	Yes	
Darragh Murnane	CPSEAG	Non-Personal	Glatt	Collaborator of Fluid Pharma (company of which I hold a Directorship) to develop novel paediatric therapies	Yes	
Darragh Murnane	CPSEAG	Non-Personal	GlaxoSmithKline	In-kind support for research project, and sponsored PhD studentships	Yes	
Darragh Murnane	CPSEAG	Non-Personal	Merxin Ltd	Funded PhD studentship	Yes	
Darragh Murnane	CPSEAG	Non-Personal	Philips Respironics	Sponsored PhD Studentship and loaned equipment	Yes	

Darragh Murnane	CPSEAG	Non-Personal	Reviral	Research Collaboration between Fluid Pharma (company of which I hold a Directorship) to develop novel paediatric therapies	Yes
Darragh Murnane	CPSEAG	Non-Personal	UnitAid	Funding a research project by Fluid Pharma (company of which I hold a Directorship) to develop novel paediatric therapies	Yes
Darren Ashcroft	PEAG, IEWG	Personal	NIL	N/A	N/A
Darren Ashcroft	PEAG, IEWG	Non-Personal	Abbvie, Amgen (was Celgene), Janssen	Research grant to support the development of the Global Psoriasis Atlas	Yes
Darren Ashcroft	PEAG, IEWG	Non-Personal	AbbVie, Becton Dickinson, Celgene (Bristol Myer Squibb/Amgen)	MRC Stratified Medicine Research Grant: Psoriasis Stratification to Optimise Relevant Therapy (PSORT)	No
Darren Ashcroft	PEAG, IEWG	Non-Personal	Eli Lilly,Janssen, LEO Pharma,	MRC Stratified Medicine Research Grant: Psoriasis Stratification to Optimise Relevant Therapy (PSORT)	No
Darren Ashcroft	PEAG, IEWG	Non-Personal	LEO Foundation, Eli Lilly, Novartis (Sandoz),Almirall, UCB	Research grant to support the development of the Global Psoriasis Atlas	Yes
Darren Ashcroft	PEAG, IEWG	Non-Personal	Medimmune (Astra Zeneca), Novartis (Sandoz), Pfizer, Qiagen, Stiefel-GSK	MRC Stratified Medicine Research Grant: Psoriasis Stratification to Optimise Relevant Therapy (PSORT)	No
Darren Ashcroft	PEAG, IEWG	Non-Personal	Mundipharma	Research grant	No
David Bowen	OHEAG	Personal	Abbvie	Consultancy	No

David Bowen	OHEAG	Personal	Janssen	Consultancy	No	
David Bowen	OHEAG	Non-Personal	NIL	N/A	N/A	
David Bowen	OHEAG	Additional				Patent for Siglec-9 binding agents: WO 2007/049044 A1
David Chandler	GRIDEAG	Personal	NIL	N/A	N/A	
David Chandler	GRIDEAG	Non-Personal	NIL	N/A	N/A	
David Chandler	GRIDEAG	Additional	N/A	N/A		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	COVID-19 Therapeutics EWG	Personal	VIIV	Consultancy, Lecture Fees	No	
David Dockrell	COVID-19 Therapeutics EWG	Non-Personal	VIIV	Consultancy paid to department	No	
David Goldblatt	COVID-19 VBREWG	Personal	NIL	N/A	N/A	
David Goldblatt	COVID-19 VBREWG	Non-Personal	NIL	N/A	N/A	
David Goldblatt	COVID-19 VBREWG	Additional				I chair the scientific advisory board of a small start-up company, GlycoEra Ag based in Schlieren, Switzerland. The company is involved in pre-clinical research linked to glycan mediated therapies. The company is not involved in any research related to COVID.
David Gunnell	IEWG	Personal	NIL	N/A	N/A	
David Gunnell	IEWG	Non-Personal	NIL	N/A	N/A	
David Gunnell	IEWG	Additional				I was co-author on a research paper, published in 2014, that examined all medicines

						associated with yellow card adverse drug reaction reporting of depression and suicidal behaviour (see Thomas K, Martin RM, Potokar J, Pirmohamed M, Gunnell D. Reporting of drug induced depression and fatal and non-fatal suicidal behaviour in the UK from 1998 to 2011. BMC Pharmacology and Toxicology 2014; 15: 54. DOI: 10.1186/2050-6511-15-54).
David Hunt	NPPEAG	Personal	NIL	N/A	N/A	
David Hunt	NPPEAG	Non-Personal	NIL	N/A	N/A	
David Owens	NPPEAG	Personal	NIL	N/A	N/A	
David Owens	NPPEAG	Non-Personal	NIL	N/A	N/A	
Deborah Ashby	RWD	Personal	NIL	N/A	N/A	
Deborah Ashby	RWD	Non-Personal	NIL	N/A	N/A	
Deenan Pillay	COVID-19 Therapeutics EWG	Personal	NIL	N/A	N/A	
Deenan Pillay	COVID-19 Therapeutics EWG	Non-Personal	NIL	N/A	N/A	

Diana Wellesley	MWHEAG	Personal	Glaxo-Smith-Kline through OXON Epidemiology Limited study	Assessment on this study. Pension Share Holding	
Diana Wellesley	MWHEAG	Non-Personal	NIL	N/A	N/A
Elinor Burrows	PMEAG	Personal	NIL	N/A	N/A
Elinor Burrows	PMEAG	Non-Personal	NIL	N/A	N/A
Ertan Saridogan	MWHEAG	Personal	Hologic	Fee for contributing to educational activities at ESGE Congress	No
Ertan Saridogan	MWHEAG	Personal	Intuitive	Fee for contributing to educational activities at ESGE Congress	No
Ertan Saridogan	MWHEAG	Personal	Viatris	Fee for giving a presentation in a webinar	No
Ertan Saridogan	MWHEAG	Non-Personal	N/A	N/A	N/A
Farzin Farzaneh	CTBVEAG	Personal	Cellectis, France	Contract manufacture and R & D collaborations	Yes
Farzin Farzaneh	CTBVEAG	Personal	Autolus Therapautics	Shares, consultancy payments, contract manufacture and R & D collaborations	Yes
Farzin Farzaneh	CTBVEAG	Personal	Apterna	Consultancy	Yes
Farzin Farzaneh	CTBVEAG	Personal	Servier	Contract manufacture	Yes
Farzin Farzaneh	CTBVEAG	Personal	Orchard Therapeutics	Contract manufacture	Yes

Farzin Farzaneh	CTBVEAG	Personal	GlaxoSmithKline	Consultancy – member of Cell and Gene Therapy Scientific Advisory Board	Yes	
Farzin Farzaneh	CTBVEAG	Personal	Centre Hospitalier Universitaire Vaudois	Consultancy	Yes	
Farzin Farzaneh	CTBVEAG	Personal	Dawn Therapeutics Ltd	Shares and consultancy	Yes	
Farzin Farzaneh	CTBVEAG	Personal	ViroCell Biologics Ltd	Chief Scientific Officer, Co-Founder and shareholder	Yes	
Farzin Farzaneh	CTBVEAG	Non-Personal	King's College London	Professor of molecular medicine	Yes	
Farzin Farzaneh	CTBVEAG	Non-Personal	University College London	Honorary Professor of molecular medicine	Yes	
Farzin Farzaneh	CTBVEAG	Non-Personal	Great Ormond Street Hospital	Honorary contract – Pharmacy, Qualified Person	Yes	
Fergus Rugg-Gunn	NPPEAG	Personal	NIL	N/A	N/A	
Fergus Rugg-Gunn	NPPEAG	Non-Personal	NIL	N/A	N/A	
Geoffrey Hanlon	CPSEAG	Personal	NIL	N/A	N/A	
Geoffrey Hanlon	CPSEAG	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	
Geraint Davies	IEAG	Additional				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 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.
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.
Geraint Davies	IEAG	Additional	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 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.
Geraint Davies	IEAG	Additional	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)

Gian Giacomo Ollandini	IEWG	Personal	Flynn Pharma	Lecture fee for a webinar	No
Gian Giacomo Ollandini	IEWG	Non-Personal	N/A	N/A	N/A
Gillian Hawksworth	CPSEAG	Personal			
Gillian Hawksworth	CPSEAG	Non-Personal			
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
Gudrun Moore	IEWG	Personal	NIL	N/A	N/A
Gudrun Moore	IEWG	Non-Personal	NIL	N/A	N/A
Guido Pieles	PMEAG, OHEAG	Personal	Canon Medical Systems Ltd.	Consultancy (lecturing, strategy of sports cardiology imaging)	Yes
Guido Pieles	PMEAG, OHEAG	Personal	Cardiac Health & Performance Ltd.	Director (clinical sports cardiology and sports medicine consulting)	Yes
Guido Pieles	PMEAG, OHEAG	Non-Personal	NIL	N/A	N/A
Hannah Batchelor	CPSEAG	Personal	NIL	N/A	N/A
Hannah Batchelor	CPSEAG	Non-Personal	NIL	N/A	N/A
Heather Wallace	PMEAG, HMAC	Personal	CellProTx	Director	Yes

Heather Wallace	PMEAG, HMAC	Personal	NovaBiotics	Shares less than 0.01% of company	Yes	
Heather Wallace	PMEAG, HMAC	Non-Personal	NIL	N/A	N/A	
Heather Wallace	PMEAG, HMAC	Additional				As immediate past president of EUROTOX I am still on the Executive Committee and the Society raises money to support educational conferences. I am now Chair of Medical Research Scotland a registered charity.
Helen Burdett	PMEAG, OHEAG	Personal				
Helen Burdett	PMEAG, OHEAG	Non-Personal				
Helen J Cross	PEAG	Personal	NIL	N/A	N/A	
Helen J Cross	PEAG	Non-Personal	Zogenix (now UCB)	Investigator clinical trial, advisory board, speaker on educational symposia, all remuneration to department	No	
Helen J Cross	PEAG	Non-Personal	GW/Jazz Pharmaceuticals	Investigator clinical trial, advisory board, speaker educational symposium, all remuneration to department	No	
Helen J Cross	PEAG	Non-Personal	Marinius	Investigator clinical trial, remuneration to department	No	
Helen J Cross	PEAG	Non-Personal	Stoke Therapeutics	Investigator clinical trial, all remuneration to department	No	
Helen J Cross	PEAG	Non-Personal	Biocodex	Speaker educational symposium, remuneration to department	No	

Helen J Cross	PEAG	Non-Personal	UCB	Speaker educational symposium, remuneration to department	No
Helen Lachmann	CTBVEAG, COVID-19 VBREWG	Personal	Novartis	Speakers fees/consultancy	Yes
Helen Lachmann	CTBVEAG, COVID-19 VBREWG	Personal	SOBI	Speakers fees/consultancy	Yes
Helen Lachmann	CTBVEAG, COVID-19 VBREWG	Non-Personal	SOBI	Support for research nurse salary, unrestricted grant to support UKSAID national meetings	Yes
Helen Ward	CHM	Personal	NIL	N/A	N/A
Helen Ward	CHM	Non-Personal	NIL	N/A	N/A
Hilary Shenton	IEAG	Personal	NIL	N/A	N/A
Hilary Shenton	IEAG	Non-Personal	NIL	N/A	N/A
Hugo Ford	OHEAG	Personal			
Hugo Ford	OHEAG	Non-Personal			
Ian Douglas	PEAG	Personal	GlaxoSmithKline	Shares	Yes
Ian Douglas	PEAG	Non-Personal	GlaxoSmithKline	Research Grant	Yes
James Spicer	OHEAG	Personal	Epsilogen	Co-founder and shareholder	Yes

James Spicer	OHEAG	Non-Personal	Various	Compensation to department for expenses related to recruitment and treatment of patients in clinical trials	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	Personal	NIL	N/A	N/A
Jamie Fraser	CHM	Non-Personal	NIL	N/A	N/A
Jancy Pope	Dental Caries Reclassification EWG	Personal	NIL	N/A	N/A
Jancy Pope	Dental Caries Reclassification EWG	Non-Personal	NIL	N/A	N/A
Janet Brown	OHEAG	Personal			
Janet Brown	OHEAG	Non-Personal			
Janet Darbyshire	RWD	Personal	NIL	N/A	N/A
Janet Darbyshire	RWD	Non-Personal	NIL	N/A	N/A
Jayesh Bhatt	PMEAG	Personal	NIL	N/A	N/A
Jayesh Bhatt	PMEAG	Non-Personal	Astra Zeneca	Principle Investigator	Yes

Jayesh Bhatt	PMEAG	Non-Personal	Astra Zeneca	Chief Investigator	Yes
Jayesh Bhatt	PMEAG	Non-Personal	Enanta Pharmaceuticals, Inc.	Principle Investigator	Yes
John Firth	CDRRA EAG	Personal	NIL	N/A	N/A
John Firth	CDRRA EAG	Non-Personal	AMGEN	Occasional support of renal unit educational meetings	No
John Firth	CDRRA EAG	Non-Personal	ASTELLAS	Occasional support of renal unit educational meetings	No
John Firth	CDRRA EAG	Non-Personal	GENZYME	Occasional support of renal unit educational meetings	No
John Firth	CDRRA EAG	Non-Personal	NOVARTIS	Occasional support of renal unit educational meetings	No
John Firth	CDRRA EAG	Non-Personal	ROCHE	Occasional support of renal unit educational meetings	No
John Firth	CDRRA EAG	Non-Personal	SHIRE	Occasional support of renal unit educational meetings	No
John Firth	CDRRA EAG	Non-Personal	WYETH	Occasional support of renal unit educational meetings	No
Jonathan H Tobias	MWHEAG	Personal	NIL	NIL	N/A
Jonathan H Tobias	MWHEAG	Non-Personal	NIL	NIL	N/A
Jonathan S Friedland	CHM, COVID-19 Therapeutics EWG, COVID-19 VSSMEAG, IEAG	Personal	NIL	N/A	N/A
Jonathan S Friedland	CHM, COVID-19 Therapeutics	Non-Personal	Astra Zeneca	The commercial company is a sponsor / funder of research at	

	EWG, COVID-19 VSSMEAG, IEAG			St. George's, University of London which does not involve me (and of which I am generally unaware of the topic)
Jonathan S Friedland	CHM, COVID-19 Therapeutics EWG, COVID-19 VSSMEAG, IEAG	Non-Personal	Beckman Coulter Genomics Inc.	As above
Jonathan S Friedland	CHM, COVID-19 Therapeutics EWG, COVID-19 VSSMEAG, IEAG	Non-Personal	Boston Scientific Limited	As above
Jonathan S Friedland	CHM, COVID-19 Therapeutics EWG, COVID-19 VSSMEAG, IEAG	Non-Personal	Chiesi Limited	As above
Jonathan S Friedland	CHM, COVID-19 Therapeutics EWG, COVID-19 VSSMEAG, IEAG	Non-Personal	Fondazione PENTA ONLUS	As Above
Jonathan S Friedland	CHM, COVID-19 Therapeutics EWG, COVID-19 VSSMEAG, IEAG	Non-Personal	Gilead Sciences Ltd.	As above
Jonathan S Friedland	CHM, COVID-19 Therapeutics EWG, COVID-19	Non-Personal	GlaxoSmithKline	As above

	VSSMEAG, IEAG			
Jonathan S Friedland	CHM, COVID-19 Therapeutics EWG, COVID-19 VSSMEAG, IEAG	Non-Personal	Jay Pharma Inc.	As above
Jonathan S Friedland	CHM, COVID-19 Therapeutics EWG, COVID-19 VSSMEAG, IEAG	Non-Personal	LDN Pharma	As above
Jonathan S Friedland	CHM, COVID-19 Therapeutics EWG, COVID-19 VSSMEAG, IEAG	Non-Personal	McColl's Retail Group	As Above
Jonathan S Friedland	CHM, COVID-19 Therapeutics EWG, COVID-19 VSSMEAG, IEAG	Non-Personal	Merck Serono Ltd	As above
Jonathan S Friedland	CHM, COVID-19 Therapeutics EWG, COVID-19 VSSMEAG, IEAG	Non-Personal	Merck Sharpe & Dohme Ltd	As above
Jonathan S Friedland	CHM, COVID-19 Therapeutics EWG, COVID-19 VSSMEAG, IEAG	Non-Personal	Pfizer UK / Global / USA	As above

Jonathan S Friedland	CHM, COVID-19 Therapeutics EWG, COVID-19 VSSMEAG, IEAG	Non-Personal	Shockwave Medical Incorporated	As above	
Jonathan S Friedland	CHM, COVID-19 Therapeutics EWG, COVID-19 VSSMEAG, IEAG	Non-Personal	SPD Development Co Ltd	As above	
Jonathan S Friedland	CHM, COVID-19 Therapeutics EWG, COVID-19 VSSMEAG, IEAG	Non-Personal	St Jude Medical, AFD Inc.	As above	
Jonathan S Friedland	CHM, COVID-19 Therapeutics EWG, COVID-19 VSSMEAG, IEAG	Non-Personal	Takeda UK Ltd	As above	
Judith Breuer	COVID-19 VBREWG	Personal	NIL	N/A	N/A
Judith Breuer	COVID-19 VBREWG	Non-Personal	NIL	N/A	N/A
Juliette Reeves	Dental Caries Reclassification EWG	Personal	NIL	N/A	N/A
Juliette Reeves	Dental Caries Reclassification EWG	Non-Personal	NIL	N/A	N/A
Kamini Shah	Dental Caries Reclassification EWG	Personal	NIL	N/A	N/A

Kamini Shah	Dental Caries Reclassification EWG	Non-Personal	NIL	N/A	N/A
Karen Miller	IEWG, PEAG	Personal	NIL	N/A	N/A
Karen Miller	IEWG, PEAG	Non-Personal	NIL	N/A	N/A
Kathryn Johnson	PMEAG	Personal	Cheisi	Attended 2 day conference facilitated by Cheisi. They had no input in the programme/speakers or content.	No
Kathryn Johnson	PMEAG	Non-Personal	NIL	N/A	N/A
Kenneth Baillie	COVID-19 Therapeutics EWG	Personal	BBSRC	Funder	
Kenneth Baillie	COVID-19 Therapeutics EWG	Personal	FEAT	Funder	Yes
Kenneth Baillie	COVID-19 Therapeutics EWG	Personal	NIHR	Funder	Yes
Kenneth Baillie	COVID-19 Therapeutics EWG	Personal	Tropical Animal Genetics (UK) Ltd	Funder	Yes
Kenneth Baillie	COVID-19 Therapeutics EWG	Personal	UKRI	Funder	Yes
Kenneth Baillie	COVID-19 Therapeutics EWG	Personal	Wellcome Trust	Salary	Yes

Kenneth Baillie	COVID-19 Therapeutics EWG	Non-Personal	N/A	Involved in the following studies: GenOMICC, ISARIC4C, RECOVERY	
Kenneth Hodson	MWHEAG	Personal	NIL	N/A	N/A
Kenneth Hodson	MWHEAG	Non-Personal	Pfizer	I am the local primary investigator for a study investigating the efficacy and safety of Pfizer-BioNTech vaccine in pregnancy.	Yes
Kevin Moore	GRIDEAG, IEAG	Personal	Mallinckrodt	Consultancy	Yes
Kevin Moore	GRIDEAG, IEAG	Personal	Salutare Group Ltd	Director	Yes
Kevin Moore	GRIDEAG, IEAG	Personal	Servier	Consultancy	No
Kevin Moore	GRIDEAG, IEAG	Non-Personal	NIL	N/A	N/A
Kevin Taylor	CHM, COVID-19 Therapeutics EWG, COVID-19 VBREWG, CPSEAG, Dental Caries Reclassification EWG	Personal	NIL	N/A	N/A
Kevin Taylor	CHM, COVID-19 Therapeutics EWG, COVID-19 VBREWG, CPSEAG, Dental Caries	Non-Personal	NIL	N/A	N/A

	Reclassification EWG				
Kimme Hyrich	COVID-19 VBREWG	Personal	Abbvie	I delivered an educational lecture on management of difficult to treat rheum. The honorarium on this one occasion was paid to me directly	No
Kimme Hyrich	COVID-19 VBREWG	Non-Personal	Abbvie	I delivered an educational lecture on difficult to treat Rheumatoid Arthritis. Speakers Honorarium paid to my institution	No
Kimme Hyrich	COVID-19 VBREWG	Non-Personal	BMS	I am a named Co-I on a research grant aid to University of Manchester on management of Rheumatoid Arthritis and role of autoantibodies	Yes
Kimme Hyrich	COVID-19 VBREWG	Non-Personal	Pfizer	I am a named Co-I on a research grant aid to University of Manchester on management of Rheumatoid Arthritis (role of drug adherence)	Yes
Laurie Tomlinson	MWHEAG	Personal	NIL	N/A	N/A
Laurie Tomlinson	MWHEAG	Non-Personal	Bayer	Departmental consultancy for a real world study of CKD in type II diabetes	Yes
Laurie Tomlinson	MWHEAG	Non-Personal	GSK	I participate in a departmental collaboration which funds PhD students and a post-doctoral fellow to undertake methods research	Yes
Linda Pepper	MWHEAG, IEWG	Personal	NIL	N/A	N/A

Linda Pepper	MWHEAG, IEWG	Non-Personal	NIL	N/A	N/A	
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 / Advisory Boards	No	
Louis Grandjean	IEAG	Non-Personal	NIL	N/A	N/A	
Lucy Chappell	MWHEAG	Personal	NIL	N/A	N/A	
Lucy Chappell	MWHEAG	Non-Personal	NIL	N/A	N/A	
Madeleine Wang	CTBVEAG, COVID-19 VBREWG, IEWG, Opioids EWG, PEAG, Sodium Valproate EWG	Personal	NIL	N/A	N/A	
Madeleine Wang	CTBVEAG, COVID-19 VBREWG, IEWG, Opioids EWG, PEAG, Sodium Valproate EWG	Non-Personal	NIL	N/A	N/A	
Madeleine Wang	CTBVEAG, COVID-19 VBREWG, IEWG, Opioids	Additional				Immediate family members with autoimmune diseases and other long term chronic health conditions

	EWG, PEAG, Sodium Valproate EWG					
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	
Malcolm Macleod	CHM, NPPEAG	Additional	N/A	N/A		I am academic coordinator of the EQIPD IMI consortium (funded period Oct 2017 to Sept 2020, now in no cost extension. Consortium partners include: AbbVie Inc. (ABBVIE) Arlenda SA (Arlenda) Boehringer Ingelheim International GmbH (BI) concentris research management GmbH (concentris) Eberhard Karls Universität Tübingen (EKUT)

						F. Hoffmann-La Roche AG (ROCHE) Institut de Recherches Servier (SERVIER) Janssen Pharmaceutica NV (JANSSEN) Noldus Information Technology BV (NOLDUS) Novartis Pharma AG (NOV) Orion Corporation (ORION) PAASP GmbH (PAASP) Pfizer Ltd. (Pfizer)Porsolt SAS (Porsolt) PsychoGenics Inc. (PGI) Sanofi-Aventis Recherche & Développement (SARD) Science Exchange Inc. (SE) Stichting Buro ECNP (ECNP) Synaptologics BV (SYLICS) UCB Biopharma SPRL (UCB)
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 Glover	PEAG	Personal	NIL	N/A	N/A	
Mark Glover	PEAG	Non-Personal	NIL	N/A	N/A	
Martin Duerden	Dental Caries Reclassification EWG	Personal	NIL	N/A	N/A	

Martin Duerden	Dental Caries Reclassification EWG	Non-Personal	NIL	N/A	N/A
Martin Wilson	CHM	Personal	NIL	N/A	N/A
Martin Wilson	CHM	Non-Personal	NIL	N/A	N/A
Matthias Schmid	IEAG	Personal			
Matthias Schmid	IEAG	Non-Personal			
Meriel Jenney	PMEAG	Personal	NIL	N/A	N/A
Meriel Jenney	PMEAG	Non-Personal	Bayer	The drug is being investigated as part of study for which I am Chief Investigator. The drug and supporting costs are provided by the company through agreement with the Trials Unit.	Yes
Michael Ardern-Jones	GRIDEAG	Personal	Sanofi-Genzyme	Conference attendance, Speaker fees	No
Michael Ardern-Jones	GRIDEAG	Personal	Leo Pharma	Consultancy, Advisory board fees	Yes
Michael Ardern-Jones	GRIDEAG	Personal	AbbVie	Consultancy, Advisory board fees	Yes
Michael Ardern-Jones	GRIDEAG	Personal	Pfizer	Consultancy, Advisory board fees	Yes
Michael Ardern-Jones	GRIDEAG	Personal	Lilly	Consultancy, Advisory board fees	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	Non-Personal	Heptares	UoS collaboration research	Yes	
Michael Ardern-Jones	GRIDEAG	Non-Personal	Ducentis	UoS collaboration research	Yes	
Michael Ardern-Jones	GRIDEAG	Additional				Biotechnology and Biological Sciences Research Council iCASE industrial studentships have been funded at my institution with Unilever. I supervised PhDs. Unilever is a consumer goods manufacturer, with an interest in skin science.
Michael Jacobs	COVID-19 Therapeutics EWG, COVID-19 VBREWG	Personal	NIL	N/A	N/A	
Michael Jacobs	COVID-19 Therapeutics EWG, COVID-19 VBREWG	Non-Personal	NIL	N/A	N/A	
Michael Jacobs	COVID-19 Therapeutics EWG, COVID-19 VBREWG	Additional				A member of the Study Management Team (SMT) and antiviral drug prioritisation group for the AGILE proof of concept (phase I/II) platform study. The SMT also submits new antiviral compounds against SARS-CoV2 for

						consideration by MHRA for testing on this platform. No commercial or financial interest in the trial, any of the compounds, or any pharmaceutical or biotechnology company.
Michael Threadgill	CPSEAG	Personal	NIL	N/A	N/A	
Michael Threadgill	CPSEAG	Non-Personal	NIL	N/A	N/A	
Mick Armstrong	Dental Caries Reclassification EWG	Personal	NIL	N/A	N/A	
Mick Armstrong	Dental Caries Reclassification EWG	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 Therapeutics EWG, COVID-19 VBREWG, COVID-19 VSSMEAG, IEWG, RWD	Personal	NIL	N/A	N/A	
Munir Pirmohamed	CHM, COVID-19 Therapeutics EWG, COVID-19 VBREWG,	Non-Personal	Astra Zeneca	Research grant to UoL to support PhD in drug-drug interactions co-funded by the EPSRC		

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

	VBREWG, COVID-19 VSSMEAG, IEWG, RWD					
Munir Pirmohamed	CHM, COVID-19 Therapeutics EWG, COVID-19 VBREWG, COVID-19 VSSMEAG, IEWG, RWD	Non-Personal	Vistagen Therapeutics	Work on L-amino acid transporter type 1.	Yes	
Munir Pirmohamed	CHM, COVID-19 Therapeutics EWG, COVID-19 VBREWG, COVID-19 VSSMEAG, IEWG, RWD	Additional				In November 2020, I became a member of Innovative Medicines Initiative-funded consortium called Accelerating research & development for advanced therapies (ARDAT: www.ardat.org). As part of this the UoL will receive research funding directly from the EU Commission. Like all IMI consortia, this is a public-private partnership, and academic and clinical members of the consortium will work in collaboration with industry partners (Pfizer, Bayer, Janssen, Lonza, Novartis, Novo Nordisk, Sanofi-Aventis, Spark Therapeutics, Takeda, Viscofan and Astella Pharma), but will not receive

						direct funding from the industry partners.
Naomi Fineberg	NPPEAG	Personal	NIL	N/A	N/A	
Naomi Fineberg	NPPEAG	Non-Personal	Biohaven	Biohaven is a corporate member of the International College of OC Spectrum Disorders (ICOCS) (a charity, of which I am the Secretary)	Yes	
Naomi Fineberg	NPPEAG	Additional				I WORK AS A MEDICAL LEAD OF AN NHS ENGLAND SERVICE PROVIDING PHARMACOLOGICALTREATMENT FOR OBSESSIVE COMPULSIVE DISORDERS. I ACT AS AN UNPAID MEDICALADVISER AND TRUSTEE TO NATIONAL CONSUMER CHARITIES FOR OCD AND RELATED DISORDERS. I CHAIR THE WORLD PSYCHIATRIC ASSOCIATION SCIENTIFIC SECTION ON ANXIETY, OCD AND RELATED DISORDERS. I HAVE CONTRIBUTED TO THE BRITISH ASSOCIATION FOR PSYCHOPHARMACOLOGY (BAP) TREATMENT GUIDELINES FOR ANXIETY DISORDERS (2014) AND THE NICE TREATMENT GUIDELINES INCLUDING

						THE MOST RECENT UPDATE (2013). 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. 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 AN HONORARIUM FOR EDUCATIONAL LECTURES ON DIAGNOSIS FROM THE GLOBAL MENTAL HEALTH ACADEMY.
Neil French	COVID-19 VBREWG	Personal	NIL	N/A	N/A	
Neil French	COVID-19 VBREWG	Non-Personal	Glaxo-Smith-Kline	Research grant to department supporting staff salaries.	Yes	
Nicol Ferrier	IEWG	Personal	NIL	N/A	N/A	

Nicol Ferrier	IEWG	Non-Personal	NIL	N/A	N/A
Nidhi Sofat	GRIDEAG	Personal	Bristol Myers Squibb	Grant	No
Nidhi Sofat	GRIDEAG	Non-Personal	NIL	N/A	N/A
Nigel Klein	COVID-19 Therapeutics EWG, PMEAG	Personal	NIL	N/A	N/A
Nigel Klein	COVID-19 Therapeutics EWG, PMEAG	Non-Personal	NIL	N/A	N/A
Pallav Shah	CDRRA EAG	Personal	Creo medical	consultancy	No
Pallav Shah	CDRRA EAG	Personal	Pulmonx	consultancy/lecture	No
Pallav Shah	CDRRA EAG	Non-Personal	CSA	RCT with RejuvenAir Chelsea & Westminster 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
Patient 1	Dental Caries Reclassification EWG	Personal	NIL	N/A	N/A
Patient 1	Dental Caries Reclassification EWG	Non-Personal	NIL	N/A	N/A

Patricia McGettigan	PEAG	Personal	NIL	N/A	N/A
Patricia McGettigan	PEAG	Non-Personal	NIL	N/A	N/A
Patrick Mark	CDRRA EAG	Personal	Astellas	Consultancy	No
Patrick Mark	CDRRA EAG	Personal	Astra Zeneca	Consultancy, Lecture fee	No
Patrick Mark	CDRRA EAG	Personal	Pharmacosmos	Lecture Fee	No
Patrick Mark	CDRRA EAG	Non-Personal	Astra Zeneca	Lecture and Consultancy Fees	No
Paul Lehner	COVID-19 VBREWG	Personal	NIL	N/A	N/A
Paul Lehner	COVID-19 VBREWG	Non-Personal	Glaxo-Smith-Kline	I have collaborated on a non-SARS CoV-2 project with GSK and received funding from them. This project terminated in Jan 2020 and is not ongoing.	No
Peter Hall	RWD	Personal	NIL		
Peter Hall	RWD	Non-Personal	Lilly, Roche, Eisai, Sanofi, Gilliad, SeaGen, Novartis, Pfizer	Institutional research funding	Yes
Peter Hindmarsh	IEWG	Personal	NIL	N/A	N/A
Peter Hindmarsh	IEWG	Non-Personal	NIL	N/A	N/A
Philip Hannaford	MWHEAG, IEWG	Personal	NIL	N/A	N/A

Philip Hannaford	MWHEAG, IEWG	Non-Personal	NIL	N/A	N/A
Poulam M Patel	CHM, OHEAG	Personal	NIL	N/A	N/A
Poulam M 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 M Patel	CHM, OHEAG	Non-Personal	Scancell	Co- supervisor for translational research project into hepatotoxicity. Project part funded by grant from Scancell	Yes
Poulam M Patel	CHM, OHEAG	Non-Personal	BMS	Local PI for multicentre company sponsored trial	No
Poulam M Patel	CHM, OHEAG	Non-Personal	Scancell	Chief Investigator for company sponsored clinical trial	Yes
Poulam M Patel	CHM, OHEAG	Non-Personal	Pfizer	Local PI for multicentre company sponsored trial	Yes
Poulam M Patel	CHM, OHEAG	Non-Personal	Merck	Local PI for multicentre company sponsored trial	No
Poulam M 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
Qasim Aziz	GRIDEAG	Personal			
Qasim Aziz	GRIDEAG	Non-Personal			

Raymond Anderson	Dental Caries Reclassification EWG	Personal	NIL	N/A	N/A
Raymond Anderson	Dental Caries Reclassification EWG	Non-Personal	NIL	N/A	N/A
Ravishankar Sargur	GRIDEAG	Personal	NIL	N/A	N/A
Ravishankar Sargur	GRIDEAG	Non-Personal	Abbott	Expert consultant to Abbott Laboratories, Inc. and its related group companies (together, "Abbott") in connection with the inquest and MHRA investigation of an adverse reaction to a transcatheter cardiac procedure	No
Rebecca Kristeleit	OHEAG	Personal			
Rebecca Kristeleit	OHEAG	Non-Personal			
Rebecca Mann	CHM, PMEAG	Personal	NIL	N/A	N/A
Rebecca Mann	CHM, PMEAG	Non-Personal	Sanofi	PI for MET 52 clinical trial only	No
Rebecca Shepherd	Dental Caries Reclassification EWG	Personal	NIL	N/A	N/A
Rebecca Shepherd	Dental Caries Reclassification EWG	Non-Personal	NIL	N/A	N/A
Regina Ahmed	Dental Caries Reclassification EWG	Personal	NIL	N/A	N/A

Regina Ahmed	Dental Caries Reclassification EWG	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 Fitzgerald	PEAG	Additional				I am the director of NIHR Royal Liverpool and Broadgreen Clinical research facility based within Liverpool University Hospitals NHS Foundation Trust which conducts academic and commercially funded research
Richard Gilson	CHM, COVID-19 Therapeutics EWG, IEAG	Personal	NIL	N/A	N/A	
Richard Gilson	CHM, COVID-19 Therapeutics 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)	No	
Richard Gilson	CHM, COVID-19 Therapeutics 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 Therapeutics 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 Therapeutics 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 Therapeutics EWG, IEAG	Non-Personal	Mylan	My department was a collaborating site in a clinical trial using a product supplied by Mylan, funded by NHS England. Research funds to the department (Central and North West London NHS Foundation Trust were received from Public Health England)	No
Richard Gilson	CHM, COVID-19 Therapeutics 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 Therapeutics EWG, IEAG	Non-Personal	ViiV	My department is a collaborating site in clinical trials sponsored by ViiV, who have provided research funds to the department	No

				(received by UCL and by Central and North London NHS Foundation Trust)		
Richard Gilson	CHM, COVID-19 Therapeutics EWG, IEAG	Additional				Members of the UCL Institute for Global Health are investigators or sub-investigators 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. From 1 August 2021, I have been the interim director of the Institute for Global Health and therefore have overall responsibility for the research undertaken in the Institute.
Richard Hobson	IEAG	Personal				
Richard Hobson	IEAG	Non-Personal				
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	
Robert Marcus	OHEAG	Personal				

Robert Marcus	OHEAG	Non-Personal				
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	
Rod Mitchell	IEWG	Personal	NIL	N/A	N/A	
Rod Mitchell	IEWG	Non-Personal	NIL	N/A	N/A	
Ruben Thanacoody	PEAG	Personal	NIL	N/A	N/A	
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	
Rupert Payne	PEAG	Personal	NIL	N/A	N/A	
Rupert Payne	PEAG	Non-Personal	Pfizer	Grant to University of Bristol to fund health service evaluation	Yes	
Rupert Payne	PEAG	Additional				I am consultant editor (remunerated position) for the journal Prescriber (John Wiley & Sons publishers) which carries pharmaceutical industry advertising. I am not involved in decisions around

						advertisements for the journal. I receive funding from the National Institute for Health Research (NIHR) to undertake research on polypharmacy, medicines optimisation and pharmacoepidemiology, and from MRC.
Sandosh Padmanabhan	CHM	Personal	NIL	N/A	N/A	
Sandosh Padmanabhan	CHM	Non-Personal	NIL	N/A	N/A	
Sandosh Padmanabhan	CHM	Additional				I am the Founder and CEO of a digital health start-up company (Kvatchii Ltd). I hold founder shares. The company is not trading currently. I have just been appointed Chief Medical Officer of a digital health start-up company (MedKalHealth Ltd). I will be allocated shares in due course. The company is not trading currently.
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				Family member is a high court judge in intellectual property cases in the Chancery division of the high court

						concerning medicates and medical devices
Sara Pruneddu	IEWG	Personal	NIL	N/A	N/A	
Sara Pruneddu	IEWG	Non-Personal	NIL	N/A	N/A	
Sarah Meredith	CHM, RWD	Personal				
Sarah Meredith	CHM, RWD	Non-Personal				
Sarah Wild	CDRRA EAG	Personal	Gilead	Honorarium paid to research account for attending advisory board discussing epidemiological data		
Sarah Wild	CDRRA EAG	Personal	Novo Nordisk	Accommodation, subsistence and contribution to registration fees provided as part of unrestricted educational grant during attendance at biannual meetings of the Scottish Study Group for Care of Diabetes in the Young in role as member of Steering Group	Yes	
Sarah Wild	CDRRA EAG	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	Non-Personal	AstraZeneca	This NPNS interest relates to donations provided by AstraZeneca to the British		

	EWG, COVID-19 VBREWG			Toxicology Society (BTS) to support their Annual Congress and Education and Training of which I am currently President of the Society (2020-2022)		
Shirley Price	CHM, COVID-19 Therapeutics EWG, COVID-19 VBREWG	Non-Personal	GSK	This NPNS interest relates to donations provided by GSK to the British Toxicology Society (BTS) to support their Annual Congress and Education and Training of which I am currently President of the Society (2020-2022)		
Siow Ming Lee	OHEAG	Personal				
Siow Ming Lee	OHEAG	Non-Personal				
Siraj Misbah	CHM, COVID-19 Therapeutics EWG, COVID-19 VBREWG, CTBVEAG	Personal	NIL	N/A	N/A	
Siraj Misbah	CHM, COVID-19 Therapeutics EWG, COVID-19 VBREWG, CTBVEAG	Non-Personal	NIL	N/A	N/A	
Siraj Misbah	CHM, COVID-19 Therapeutics EWG, COVID-19 VBREWG, CTBVEAG	Additional				I have taken part in non-remunerated discussions with Astra Zeneca on possible therapeutic approaches to Vaccine-induced immune

						thrombocytopenia and thrombosis (VITT).
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	Janssen	IDMC Chair with fees paid to the University of Edinburgh	No	
Steven Cunningham	CHM, PMEAG	Non-Personal	MedImmune and AstraZeneca	Local PI for MELODY study (Study D5290C00004).	No	
Steven Cunningham	CHM, PMEAG	Non-Personal	Pfizer BioNTech	Local sub PI for maternal vaccine study (early termination of study)	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	Valneva	Local PI for adolescent study (withdrawal prior to recruitment)	No	
Steven Cunningham	CHM, PMEAG	Non-Personal	Vertex	Local PI for ARRIVAL study (VX15-770-124)	No	

Steven Cunningham	CHM, PMEAG	Additional				Jan-Dec 2021: I am a member of an EU IMI research consortium (RESCEU) which has Oxford University and Imperial College as academic partners. 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 H Ralston	CHM, GRIDEAG, MWHEAG	Personal	NIL	N/A	N/A	
Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non-Personal	Abbvie	Sponsorship of clinical meeting	No	
Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non-Personal	Alexion	Sponsorship of clinical meeting	No	
Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non-Personal	Amgen	Sponsorship of clinical meeting	No	
Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non-Personal	Astra Zeneca	Support for recruiting patients into a clinical registry study	No	

Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non-Personal	Bristol Myers-Squibb	Sponsorship of clinical meeting	No
Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non-Personal	Celgene	Sponsorship of clinical meeting	No
Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non-Personal	Consilient Health	Sponsorship of clinical meeting	No
Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non-Personal	Eli Lilly	Donation of Teriparatide for clinical trial	No
Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non-Personal	Eli-Lilly	Sponsorship of clinical meeting	No
Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non-Personal	Janssen	Sponsorship of clinical meeting	No
Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non-Personal	Kyowa Kirin	Support for recruiting patients into a clinical trial	No
Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non-Personal	Kyowa Kirin	Support for recruiting patients into a clinical registry study	No
Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non-Personal	Kyowa Kirin Ipsen Kyowa Kirin	Consultancy Fees	No
Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non-Personal	Novartis	Sponsorship of clinical meeting	No

Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non-Personal	Pfizer	Sponsorship of clinical meeting	No	
Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non-Personal	Roche	Sponsorship of clinical meeting	No	
Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non-Personal	Sandoz	Sponsorship of clinical meeting	No	
Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non-Personal	Sanofi-Genzyme	Sponsorship of clinical meeting	No	
Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non-Personal	Thornton &Ross	Sponsorship of clinical meeting	No	
Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non-Personal	UCB	Sponsorship of clinical meeting	No	
Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non-Personal	UCB	Invited speaker at clinical symposia	No	
Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Additional				External examiner for Oxford University Clinical trials MSc course, Mar - Dec 2021
Susan Bradford	CHM, COVID-19 Therapeutics EWG, RWD	Personal	NIL	N/A	N/A	
Susan Bradford	CHM, COVID-19 Therapeutics EWG, RWD	Non-Personal	Roche	Speaker at sponsored event.	No	
Susan Hopkins	IEAG	Personal				

Susan Hopkins	IEAG	Non-Personal				
Susan Hunneyball	ABRHP, PEAG, COVID-19 VBREWG	Personal	NIL	N/A	N/A	
Susan Hunneyball	ABRHP, PEAG, COVID-19 VBREWG	Non-Personal	NIL	N/A	N/A	
Susan Hunneyball	ABRHP, 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 Baron	IEWG	Personal	Pfizer	I am working with Pfizer to support educational meetings presenting material on the mechanism and studies to date of biologic medication. I have previously given educational lectures on behalf of Pfizer and have been given lecture fees for this		
Susannah Baron	IEWG	Personal	Sanofi	I am being supported by Sanofi to go to the British Association of Dermatologists annual educational meeting in July 2022 in Glasgow	Yes	

Susannah Baron	IEWG	Non-Personal	NIL	N/A	N/A
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	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 International	Research collaboration and MTA. Named on DMU patents associated with work.	Yes
Susannah Walsh	COVID-19 VBREWG, CPSEAG	Personal	Safer Disinfectant Network	Working group member	Yes
Susannah Walsh	COVID-19 VBREWG, CPSEAG	Non-Personal	Better Vision Solutions	Consultancy and licence agreement for patented technology with De Montfort University	Yes
Susannah Walsh	COVID-19 VBREWG, CPSEAG	Non-Personal	Chemical Biological Center of Combat Capabilities Development	Research collaboration and MTA. Named on DMU Patents associated with work.	Yes
Susannah Walsh	COVID-19 VBREWG, CPSEAG	Non-Personal	DSTL	Research grant. Named on DMU patents associated with work.	No
Susannah Walsh	COVID-19 VBREWG, CPSEAG	Non-Personal	PAL	Research collaboration and MTA. Named on DMU patents associated with work.	Yes

Susannah Walsh	COVID-19 VBREWG, CPSEAG	Non-Personal	Safer Disinfectant Network	Working group member	Yes	
Theresa McDonagh	CDRRA EAG	Personal	Boehringer Ingilheim	Advisory Board Fees	Yes	
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	
Tom Solomon	COVID-19 VBREWG	Additional				Employed by the University of Liverpool. A panel member of the Research Excellence Framework (REF) 2021, the Medical Research Council (MRC) Infection and Immunity Board. Supported by the National Institute for Health Research (NIHR) Health Protection Research Unit in Emerging and Zoonotic Infections (Grant Nos. IS-HPU-1112-10117 and NIHR200907), NIHR Programme Grant for Applied Research (No. RP-PG-0108-10,048), NIHR Global Health Research Group on Brain Infections (No. 17/63/110), and the European Union's Horizon 2020 research and innovation program ZikaPLAN (Preparedness Latin America

						Network), grant agreement No. 734584. President of the Encephalitis Society, and on the council of the Royal College of Physicians.
Tony Benford	Dental Caries Reclassification EWG	Personal	NIL	N/A	N/A	
Tony Benford	Dental Caries Reclassification EWG	Non-Personal	NIL	N/A	N/A	
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	
Vijay Sudra	Dental Caries Reclassification EWG	Personal	NIL	N/A	N/A	
Vijay Sudra	Dental Caries Reclassification EWG	Non-Personal	NIL	N/A	N/A	
Waqar Rashid	NPPEAG	Personal				
Waqar Rashid	NPPEAG	Non-Personal				
William John Watkins	PMEAG	Personal	NIL	N/A	N/A	
William John Watkins	PMEAG	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	AMRI/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	Avanti polar lipids/CRODA	In-kind support with lipids and joint publications	No
Yvonne Perrie	CHM, COVID-19 VBREWG, CPSEAG	Non-Personal	Carocell	Knowledge exchange research contracts from company to University of Strathclyde.	Yes
Yvonne Perrie	CHM, COVID-19 VBREWG, CPSEAG	Non-Personal	Everna	Knowledge exchange research contracts from company to University of Strathclyde.	No
Yvonne Perrie	CHM, COVID-19 VBREWG, CPSEAG	Non-Personal	GSK	EU Grant to University of Strathclyde (completed June 2021). Publications still being written.	No
Yvonne Perrie	CHM, COVID-19 VBREWG, CPSEAG	Non-Personal	Haver Pharmaceuticals	Knowledge exchange research contracts from company to University of Strathclyde.	No
Yvonne Perrie	CHM, COVID-19 VBREWG, CPSEAG	Non-Personal	Janssen Pharmaceuticals	PhD funded studentship with Janssen	No
Yvonne Perrie	CHM, COVID-19 VBREWG, CPSEAG	Non-Personal	Lamellar Biomedical	KTP Grant to University of Strathclyde.	No
Yvonne Perrie	CHM, COVID-19 VBREWG, CPSEAG	Non-Personal	Microfluidics	Equipment loan to University of Strathclyde and in-kind research support (consumables).	No

Yvonne Perrie	CHM, COVID-19 VBREWG, CPSEAG	Non-Personal	Mologic	Knowledge exchange research contracts from company to University of Strathclyde.	No	
Yvonne Perrie	CHM, COVID-19 VBREWG, CPSEAG	Non-Personal	Pfizer Inc,	Grant which includes contributions to University of Strathclyde.	No	
Yvonne Perrie	CHM, COVID-19 VBREWG, CPSEAG	Non-Personal	Astra Zeneca	Grant which includes contributions to University of Strathclyde	No	
Yvonne Perrie	CHM, COVID-19 VBREWG, CPSEAG	Non-Personal	Precision Nanosystems	Grant which includes contributions to University of Strathclyde	No	
Yvonne Perrie	CHM, COVID-19 VBREWG, CPSEAG	Non-Personal	Centre for process Innovation Ltd	Grant which includes contributions to University of Strathclyde	No	
Yvonne Perrie	CHM, COVID-19 VBREWG, CPSEAG	Non-Personal	Malvern Instruments, Croda	Grant which includes contributions 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	StablePharma	Knowledge exchange research contracts from company to University of Strathclyde.	No	
Yvonne Perrie	CHM, COVID-19 VBREWG, CPSEAG	Additional	Institute of Pharmacy and Biomedical Sciences			Head of Institute of Pharmacy and Biomedical Sciences, where a number of industrial collaborations and grants are held by members of the Institute.

Yvonne Perrie	CHM, COVID-19 VBREWG, CPSEAG	Additional	Controlled Release Society, President-elect Jan 2020 – June 2020 President June 2020 – Aug 2021. Immediate Past President. Aug 2021 - June 2022. This is a non-salaried volunteer position for a scientific society

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

	Personal Interest		Non-Personal Interest			Additional Information
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	
Prof K Taylor	None		None		N/A	None
Dr E Amirak	Orphazyme A/S	Salary, Shares	None		N/A	None
	Vionelix Pharmaceuticals	Salary, Shares				
Dr A Barnes	A R Barnes Ltd	Consultancy	None		N/A	None
Dr J Beaman	Pfizer	Salary, Shares	None		N/A	None
Dr A-M Brady	AstraZeneca	Shares (immediate family member)	Biologicals (journal)	Section Editor (unpaid)	Yes	None
	GlaxoSmithKline	Shares (immediate family member)	VAC2VAC Regulatory Advisory Working Party	Member (unpaid)	Yes	
	Vernalis	Shares (immediate family member)				
Dr G D Cook	Pfizer	Salary	None		N/A	None
	Viatris	Shares				
Prof A G Davidson (Vice-Chair)	None		None		N/A	None

Dr A Gleadle	Tesco PLC	Shares	None		N/A	None
	AstraZeneca (Medimmune)	Salary (other person)				
Dr V Jaitely	Ares Trading (Merck KGaA)	Salary	None		N/A	None
Mr R Lowe	None		None		N/A	None
Dr P Marshall	Jazz Pharmaceuticals	Salary, Shares	None		N/A	None
	Reckitt Benckiser	Shares				
	Individior	Shares				
	Sims Marshall Consultancy	Consultancy (range of products)				
Prof J Miller	None		None		N/A	None
Ms S Palser	None		None		N/A	None
Prof M Simmonds	None		Polypharmakos Ltd	Director (unpaid)	Yes	None
			College of Medicine	Member (unpaid)	Yes	
			DEFRA Darwin Initiative Advisory Committee	Member (unpaid)	Yes	
			DEFRA Group Evidence Science and Analysis Committee	Member (unpaid)	Yes	

			Good Practice Traditional Chinese Medicine Research Association	Chair (unpaid)	Yes	
			Hong Kong Department of Health, Pharmacopoeia International Advisory Committee	Member (unpaid)	Yes	
			Proctor & Gamble Responsible Beauty Advisory Council	Member (unpaid)	Yes	
			Royal Holloway University of London Department of Health Advisory Board	Member (unpaid)	Yes	
Dr R Torano	GlaxoSmithKline	Salary, Shares	None		N/A	None
Dr P Varley	Alchemab Therapeutics	Salary, Shares	None		N/A	None
	Sanofi	Shares				

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

Published by the Medicine and Healthcare products Regulatory Agency

ISBN 978-1-8384147-1-9