

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**

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Commission on Human Medicines

British Pharmacopoeia Commission



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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

- 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

- 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 BMBCCh

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 Update¹’ 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

¹ [E-cigarette use or vaping: reporting suspected adverse reactions, including lung injury - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/news/e-cigarette-use-or-vaping-reporting-suspected-adverse-reactions-including-lung-injury)

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 to be taken forward through a public consultation². 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

² [Expanding access to naloxone - GOV.UK \(www.gov.uk\)](http://www.gov.uk)

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 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 Update³.

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.

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

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.
- 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](https://www.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/m² (obese), or ≥ 27 kg/m² to < 30 kg/m² (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 arrhythmia, 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 medicines 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 tonsillitis, 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 \leq 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 COVID-19 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 importance 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 newborn 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.

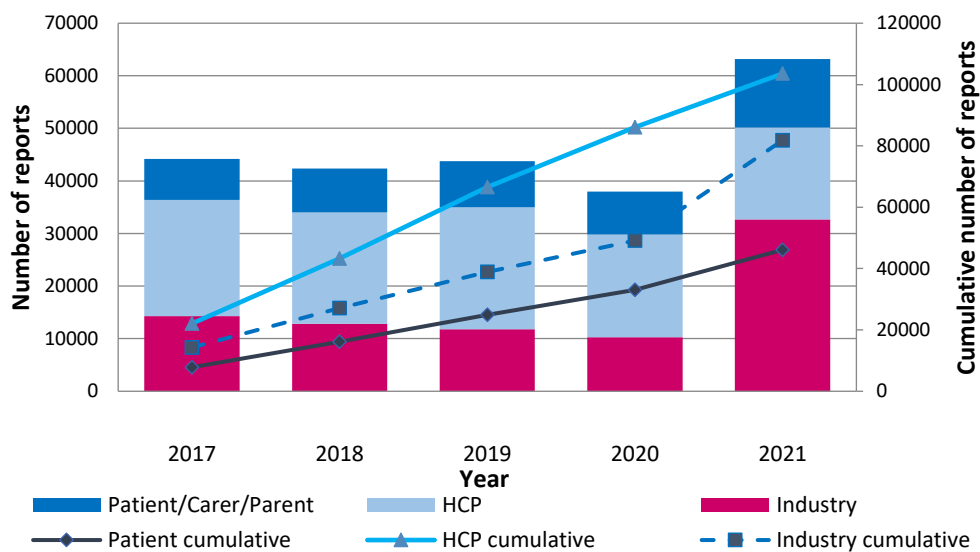
163. The total number of UK spontaneous suspected ADR reports received from all sources over the last five years shows a stable and robust system with an average of 46,296 reports as shown in Figure 1 below. As expected with social distancing measures introduced across the UK in March 2020 due to the 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

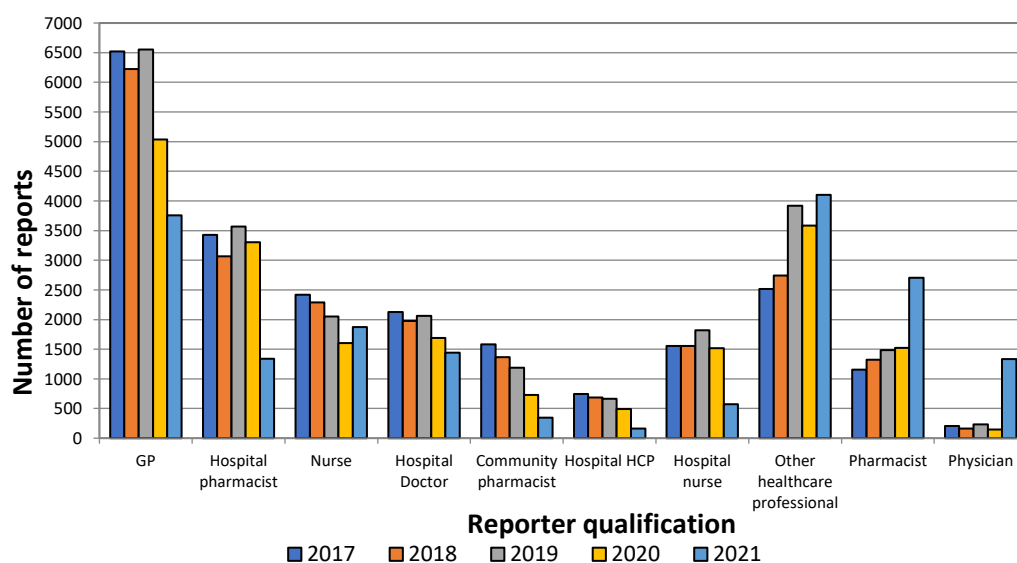
patients, carers and parents) were received by the Yellow Card Scheme to date with 13,027 suspected ADR reports received which represent 21% of all reports. Reports from members of the public increased by 66% (5,192 reports) over the last five years, since 2017. This is in part due to the MHRA's Yellow 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.

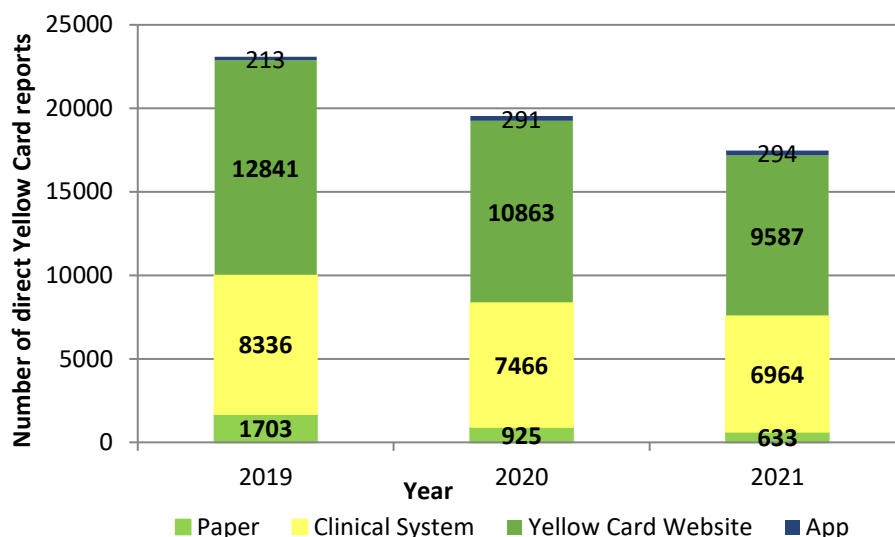
170. Figure 2 shows an increase in reporting from pharmacists and other healthcare professionals in 2021 compared to 2020, with increases of 78% and 15%, respectively. Similar increases were seen in these reporting groups when compared to 2019, of 82% and 5%, respectively.

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.

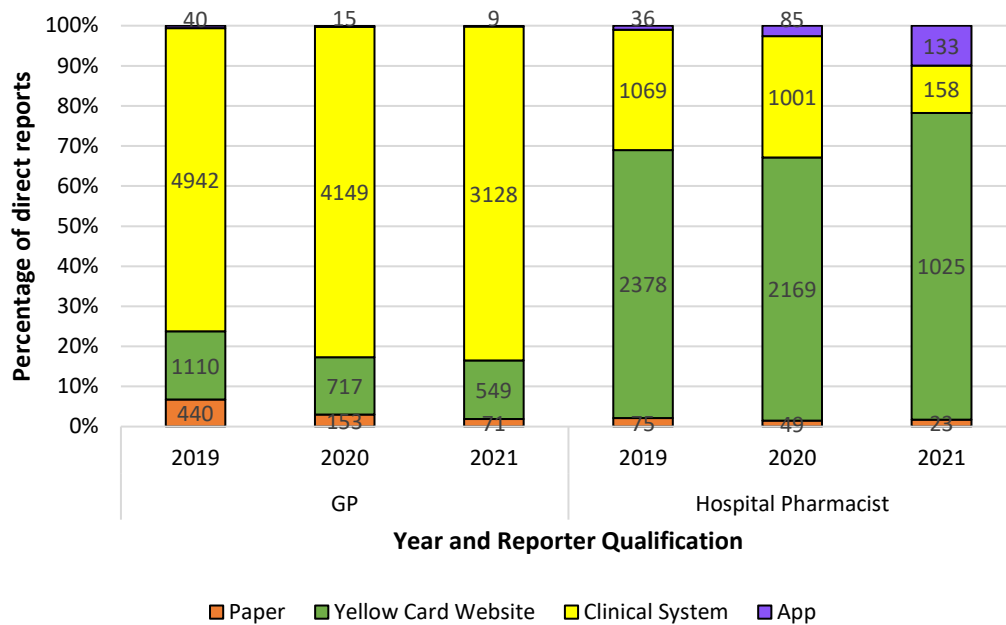
Figure 3 - Graph showing the breakdown of the main ways in which healthcare professionals reported suspected ADRs directly to the Yellow Card scheme over the last 3 years.



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, SystemOne 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

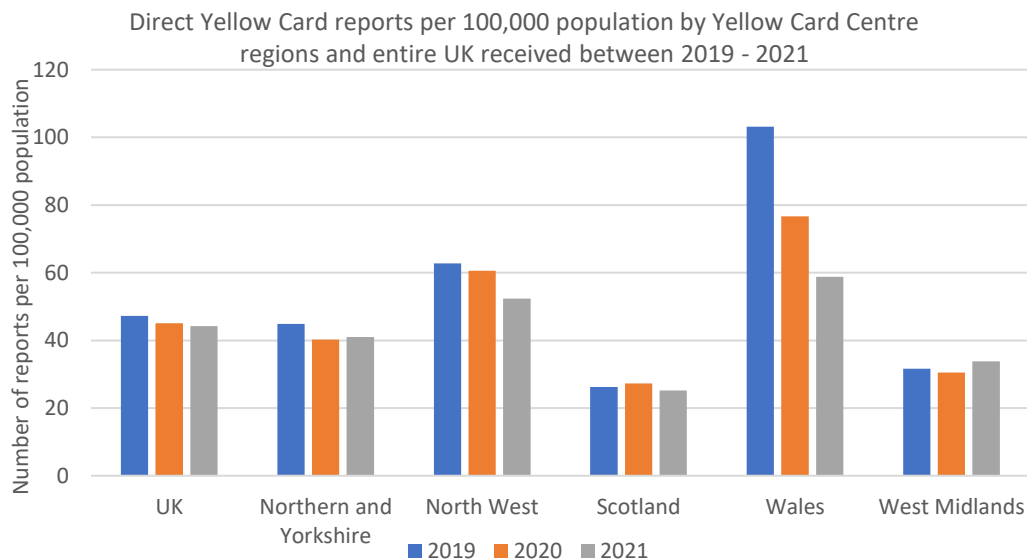
180. The MHRA works with five Yellow Card Centres (YCCs) based in the United Kingdom to increase awareness of the Yellow Card scheme and increase ADR reporting rates within their regions. The YCCs operate in Wales, Scotland, Northern & Yorkshire, North West and the West Midlands. The YCCs are involved 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 Ralston¹ MB ChB MD FRCP
FMedSci FRSE FFPM (Hon)

Professor of Rheumatology, University of
Edinburgh, Western General Hospital,
Edinburgh

Professor Sir Munir Pirmohamed² MB ChB
(Hons) PhD FRCP FRCP (Edin) FBPhS, FFPM
(Hon) FMedSci

David Weatherall Chair of Medicine, University
of Liverpool, NHS Chair of Pharmacogenetics,
Director of the Wolfson Centre for Personalised
Medicine, Director of the MRC Centre for Drug
Safety Science

Vice Chair

Professor Jonathan S Friedland³ MA PhD
FRCP FRCPE FRCPI FESCMID FMedSci

¹ End of appointment 11/02/2021

² Appointed 12/02/2021

³ Since 01/04/2021

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

Members

Professor Amanda Adler⁴

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 Cunningham⁵

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 MRCP

GP Partner, Southside Surgery, Inverness

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 Mann⁶ 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 Padmanabhan⁷

Professor of Cardiovascular Genomics and
Therapeutics, University of Glasgow

⁶ Stepped down 30/04/2021

⁷ Appointed 01/05/2021

Professor Poulam Patel MD, PhD, MBBS, FRCP

Professor of Clinical Oncology, Academic Unit of Clinical Oncology, University of Nottingham

Professor Yvonne Perrie⁸

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

⁸ Appointed 01/05/2021

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

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 BMBCCh
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 Adler⁹ MD PhD FRCP
Professor of Diabetic Medicine and Health
Policy, University of Oxford

Members

Dr John Firth¹⁰ BA BM ChB DM FRCP
Deputy Medical Director, Cambridge University
Hospitals FT, Consultant Physician and
Nephrologist, Addenbrooke's Hospital,
Cambridge

⁹ Appointed in 2021 and in line with CHM post
01/05/2021

¹⁰ End of Appointment 09/12/2021

Professor Andrew Grace¹¹ 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 McDonagh¹² 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

¹¹ End of Appointment 11/11/2021

¹² Reappointed 20/01/2021

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

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 Perrie¹³ 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 Taylor¹⁴ BPharm PhD
FRPharmS

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

¹³ Appointed in line with CHM post 01/06/2021

¹⁴ End of Appointment 31/05/2021

Members

Professor Hannah Batchelor¹⁵ 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 Conway¹⁶ BSc (Pharm)
PhD FRPharmS CMgr FCMI
Head of Pharmacy and Professor of
Pharmaceutics, University of Huddersfield,
Huddersfield

Professor Geoffrey W Hanlon¹⁷ BSc PhD
Emeritus Professor of Pharmaceutical
Microbiology, School of Pharmacy & Bio-
Molecular Sciences, University of Brighton

¹⁵ Appointed 30/08/2021

¹⁶ Appointed 30/08/2021

¹⁷ End of Appointment 16/09/2021

Mr V'lain G Fenton-May¹⁸ BPharm MIPharm
FRPharmS
Pharmaceutical Microbiologist

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

Dr Gillian M Hawksworth¹⁹ MBE PhD FFRPS
FRPharmS (Hon) DSc
Academic Community Pharmacist, Visiting
Fellow at University of Huddersfield & Past
President of the RPSGB

Mr Robert Lowe²⁰ 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

¹⁸ End of Appointment 11/11/2021

¹⁹ End of Appointment 10/11/2021

²⁰ End of Appointment 10/11/2021

Professor Afzal Mohammed²¹ BPharm, PhD
Professor of Pharmaceutics Aston Pharmacy
School, Aston University

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

Mrs Ruth Paulin²² BPharma MRPharmaS
Lay Member

Professor Kevin M G Taylor²³ BPharm PhD
FRPharmS
Chair of the British Pharmacopoeia
Commission and Professor of Clinical
Pharmaceutics, UCL School of Pharmacy,
London

Professor Michael D Threadgill²⁴ PGCE MA
PhD DSc FRSC CChem
Professor Emeritus in Medicinal Chemistry,
Department of Pharmacy and Pharmacology,
University of Bath, Visiting Professor IBERS,
Aberystwyth University

²¹ Appointed 30/08/2021

²² Appointed 01/11/2021

²³ Appointed 01/06/2021

²⁴ Reappointed 14/11/2021

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 Zaman²⁵ 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.

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
FRCPPath

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

Members

Professor Farzin Farzaneh DPhil FRCPPath
FRSB

Professor of Molecular Medicine, King's College
London

Honorary Consultant in Specialist Medicine,
King's College Hospital NHS Trust

Professor Chris Goldring²⁶ BSc, PhD,
PGCert, FBPhS

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

Professor Helen J Lachmann²⁷ MD FRCP
FRCPath (Vice Chair)

Reader and Honorary Consultant in
Amyloidosis and Renal Medicine, University
College London

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 Thorpe²⁸ PhD FRCPath

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

²⁶ Appointed 06/08/2021

²⁷ End of Appointment 11/11/2021

²⁸ Reappointed 13/04/2021

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

Mrs Madeleine Wang²⁹ BA (Hons)
Lay Representative. Patient Advocate

Professor Christina Yap³⁰ 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

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 Aziz³¹ 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 Dhar³² 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 Din³³ BMSc, MBChB, PhD, FRCP
(Edin)
Consultant Gastroenterologist & NRS Clinician,
NHS Lothian
Honorary Senior Clinical Lecturer, University of
Edinburgh

³¹ Stepped down 19/02/2021

³² Appointed 01/07/2021

³³ Appointed 01/11/2021

Professor Kevin Moore³⁴ 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

Professor Stuart Ralston³⁵ MB ChB MD
FRCP FMedSci FRSE FFPM (Hon)
Professor of Rheumatology, University of
Edinburgh

Dr Ravishankar Sargur³⁶ MD, FRCPPath,
FRCP, MBA
Consultant Clinical Immunologist and Clinical
Lead for Laboratory Immunology, Northern
General Hospital, Sheffield

³⁴ End of Appointment 13/10/2021

³⁵ Appointed 18/02/2021

³⁶ Appointed 18/02/2021

Professor Nidhi Sofat³⁷ PhD MBBS FRCP
PGCert FHEA
Professor of Rheumatology, St Georges
University London

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 Brown³⁸ 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

³⁸ Appointed 01/11/2021

Professor Geraint Rhys Davies³⁹ 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 Grandjean⁴⁰ MBBS BSc MSc PhD
MRCPCH Associate Professor Paediatric
Infectious Diseases Great Ormond Street
Hospital and University College London

³⁹ Appointed 01/08/2021

⁴⁰ Appointed 01/08/2021

Dr Richard Hobson⁴¹ 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

Dr Lim S Jones⁴² 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 Moore⁴³ BSc MB BS PhD
FRCP
Professor of Hepatology, Royal Free Hospital, London

⁴¹ End of Appointment 17/04/2021

⁴² Appointed 01/11/2021

⁴³ Stepped down 29/10/2021

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

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-Llobell⁴⁴

GP at Higherland Surgery

⁴⁴ Appointed 11/03/2021

GPwSI in Women's Health
Speciality Dr in GUM

Professor Lucy Chappell⁴⁵ PhD FRCOG
FMedSci
NIHR Research Professor in Obstetrics, King's
College London

Dr Caitlin Dean⁴⁶ RGN, MSc, PhD
Lay member. Chair Trustee, Pregnancy
Sickness Support

Dr Kenneth Hodson⁴⁷ 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

⁴⁵ Appointed 11/03/2021; Resigned
30/07/2021

⁴⁶ Appointed 11/03/2021

⁴⁷ Appointed 11/03/2021

Professor Stuart Ralston⁴⁸ MB ChB MD
FRCP FMedSci FRSE FFPM (Hon)
Professor of Rheumatology, University of
Edinburgh, Western General Hospital,
Edinburgh

Mr Ertan Saridogan⁴⁹ PhD MRCOG
Consultant in Gynaecology, Reproductive
Medicine and Minimal Access Surgery,
University College London Hospitals (UCLH)
Elizabeth Garrett Anderson Wing

Professor Jonathan H Tobias⁵⁰ BA (Cantab)
MBBS (London) MD (London) PhD (London)
FRCP (London)
Professor of Rheumatology, University of
Bristol; Honorary Consultant Rheumatologist,
North Bristol Trust

Dr Laurie Tomlinson⁵¹ MBBS MSc PhD
Department of Non-communicable Disease
Epidemiology
Faculty of Epidemiology and Population Health
London School of Hygiene & Tropical Medicine

⁴⁸ Appointed 11/03/2021

⁴⁹ Appointed 11/03/2021

⁵⁰ End of Appointment 12/03/2021

⁵¹ Appointed 11/03/2021

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

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 Brownell⁵² 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

⁵² Appointed 11/03/2021

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 Miller⁵³ 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 Owens⁵⁴ 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

⁵³ Appointed 09/12/2021

⁵⁴ Appointed 11/03/2021

Professor Andrew Rice⁵⁵ MB BS, MD, FRCP, FRCA, FFPMRCA

Professor of Pain Research, Imperial College London, United Kingdom Honorary Consultant in Pain Medicine, Chelsea and Westminster Hospital, London, England

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

Dr Aditya Sharma⁵⁶ 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 Stannard⁵⁷ MB ChB FRCA FFPMRCA

Consultant in Complex Pain/Pain Transformation Programme Clinical Lead, NHS Gloucestershire CCG

⁵⁵ Appointed 11/03/2021

⁵⁶ Reappointed 14/07/2021

⁵⁷ End of Appointment 08/12/2021

Dr Hoo Kee Tsang⁵⁸ 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

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 Bowen⁵⁹ MA MB BChir MD MRCP FRCPPath
Consultant Haematologist, Leeds Teaching Hospitals and Honorary Professor of Myeloid Leukaemia Studies, University of Leeds

Professor Janet E Brown⁶⁰ FRCP, MD, MSc, BMedSci, MBBS

⁵⁹ Reappointed 16/06/2021

⁶⁰ Appointed 18/02/2021

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 Kristeleit⁶¹ BSc MBChB PhD
FRCP FRSB
Consultant Medical Oncologist, Guy's and St
Thomas' NHS Foundation Trust.

Professor Siow Ming Lee⁶² PhD FRCP
Professor of Medical Oncology, Consultant
Medical Oncologist

Dr Robert Marcus⁶³
Consultant Haematologist at Kings College
Hospital London, UK

⁶¹ Appointed 18/02/2021

⁶² Appointed 11/03/2021

⁶³ Resigned 04/05/2021

Professor James Spicer⁶⁴ FRCP, PhD
Professor of Experimental Cancer Medicine,
King's College London; Consultant in Medical
Oncology, Guy's & St Thomas' NHS Foundation
trust

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 Cunningham⁶⁵ 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 Mann⁶⁶ BMBS FRCPCH Consultant Paediatrician, Taunton and Somerset NHS Foundation Trust

⁶⁵ Appointed in line with CHM post 01/05/2021

⁶⁶ End of Appointment 30/04/2021

Members

Mrs Catrin Barker

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

Dr Jayesh Mahendra Bhatt⁶⁷ MBBS, MD, DCH, FRCPCH

Consultant Respiratory Paediatrician, Nottingham Childrens Hospital

Miss Elinor Burrows⁶⁸ 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

⁶⁷ Appointed 18/02/2021

⁶⁸ Appointed 18/02/2021

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

Professor Meriel Jenney⁶⁹ 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 Johnson⁷⁰ MBChB FRCPCH
Consultant Neonatologist, Leeds Teaching Hospitals NHS Trust and Honorary Senior Lecturer, Leeds University

Dr Caroline Jones⁷¹ MB ChB FRCPCH MD
Consultant Paediatric Nephrologist, Alder Hey Children's NHS Foundation Trust

Professor Nigel Klein BSc MBBS MRCP PhD FRCPCH

⁶⁹ Reappointed 16/01/2021

⁷⁰ Appointed 18/02/2021

⁷¹ Reappointed 17/02/2021

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 Pain⁷² 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 Pieleles PhD MD (**Vice Chair**)

Consultant Congenital Cardiologist, Congenital Heart Unit, Bristol Heart Institute

Professor Heather M Wallace PhD FRCPATH
FRSC FRSB FBTS FBPhS European
Registered Toxicologist ERT Professor of
Biochemical Pharmacology and Toxicology,

⁷² Appointed 18/02/2021

School of Medicine, Medical Sciences and Nutrition, Institute of Medical Sciences, University of Aberdeen

Dr William John Watkins⁷³ 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

⁷³ Appointed 18/02/2021

MEMBERSHIP OF THE PHARMACOVIGILANCE OF THE ADVISORY GROUP EXPERT

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 Coleman⁷⁴ MD MA (Med Ed)
FRCP FBPhS

⁷⁴ Appointed in line with CHM post in 2021

Professor in Medical Education / Consultant
Clinical Pharmacologist, University of
Birmingham

Members

Mrs Alana Adams⁷⁵ BPharm (Hons) MSc
MRPharmS IP
Principal Pharmacist, Welsh Medicine
Information Service and Advice, University
Hospital of Wales, Cardiff

Professor Darren Ashcroft⁷⁶ BPharm, MSc,
PhD, FRPharmS
Professor of Pharmacoepidemiology, University
of Manchester

Professor Ann Daly⁷⁷ 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

⁷⁵ Appointed 22/01/2021

⁷⁶ Reappointed 11/12/2021

⁷⁷ Reappointed 11/12/2021

Dr Richard Fitzgerald⁷⁸ 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

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 Hawcutt⁷⁹ 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 Hunneyball⁸⁰ BSc (Hons) Lay
Member

⁷⁸ Appointed 22/01/2021

⁷⁹ Reappointed 11/12/2021

⁸⁰ Reappointed 11/12/2021

Dr Patricia McGettigan⁸¹ 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 Payne⁸² 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 Wang⁸³ BA (Hons)

Lay Representative and Patient Advocate

⁸¹ Appointed 22/01/2021

⁸² Reappointed 14/07/2021

⁸³ Appointed 22/01/2021

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

Chair

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Director of the Wolfson Centre for Personalised
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FmedSci

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Professor Gordon Dougan FRS

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FRPharmS

Pharmaceutical Microbiologist

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Consultant in Paediatric Immunology, NIHR
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Ms Susan Hunneyball BSc(Hons)
Lay Member, Member of the
Pharmacovigilance Expert Advisory Group
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Professor of Epidemiology and Honorary
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Sir Michael Jacobs MA PhD MB BS FRCP
FRCP Edin DTM&H

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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
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Wellcome Trust Principal Research Fellow

Honorary Consultant Infectious Diseases,
Cambridge Institute of Therapeutic Immunology
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Practising Hospital Pharmacist, Specialist
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FRCPPath

Consultant Clinical Immunologist, Lead for
Clinical Immunology, Oxford University
Hospitals & Member of the Commission on
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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)

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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

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Chair, Neurological Science, Director, NIHR
Health Protection Research Unit in Emerging
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Chancellor for Infrastructure and Environment,
Faculty of Health and Life Sciences, University
of Liverpool & Honorary Consultant Neurologist,
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Chair of the British Pharmacopoeia
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Pharmaceutics, UCL School of Pharmacy,
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Retired, Head, Division of Biotherapeutics,
National Institute for Biological Standards and
Control (NIBSC) & Member of the Clinical Trials,
Biologicals & Vaccines Expert Advisory Group
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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,
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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 MRCP
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 Olandini 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
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Members

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Lay Representative, Member of the
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Reader in Cancer Informatics and Health
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Professor Andrew Hattersley CBE FRCP
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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
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Invited Expert of the Commission on Human
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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
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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.

APPENDIX I

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 Cook¹ BPharm PhD MRPharmS
Senior Director, Process Knowledge/Quality by
Design, Pfizer

Professor Alastair G Davidson¹ 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

¹ Retired 31/12/2021

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

Professor John Miller¹ MSc PhD MRSC
CChem
Visiting Professor, Strathclyde Institute of
Pharmacy and Biomedical Sciences; former
Head of the EDQM Laboratory

Ms Sharon Palsler 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 Torano¹ BSc PhD MRSC CChem
Pharmacopoeial Intelligence and Advisory
Specialist; GlaxoSmithKline

Dr Paul Varley¹ 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 Prounce*, 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 Bale¹, 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
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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 Ruddy (*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 (<i>Specialist</i>), 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 (<i>Specialist</i>)
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 chairman or member is in any doubt.

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

Support by the pharmaceutical industry or any other relevant industry: any payment, other support or sponsorship by the pharmaceutical or other industry that does not convey any pecuniary or material

benefit to the individual personally but that benefits his/her position or department;

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

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

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

Other relevant interests

- 4.7 It is not only financial interests in the pharmaceutical industry that are relevant. A wide range of other matters may also be considered to be relevant, depending on the circumstances and matters under consideration by a committee on which an individual serves, and could include non-financial interests. There are no hard and fast rules concerning “other” interests that need to be declared. In considering whether

an interest is relevant and therefore should be declared, the guiding principle must be whether the matter might reasonably be perceived as affecting a member's impartiality. Some examples of matters that might fall under this heading are set out below. These are not exhaustive and individuals should always seek advice from the MHRA Secretariat if they are in any doubt about whether or not a matter is relevant:

- An individual, or his department, has done research work relating to a particular product, or class of products. Although the research has not been funded by any particular pharmaceutical company, the research has taken a particular line e.g. in relation to the safety of the products, or their efficacy;
- An individual has made public statements (either favourable or unfavourable) about a particular company, or product, or class of products or about a competitor's product or class of product;
- The relevant committee is considering whether a product should be reclassified e.g. from prescription only, to a pharmacy medicine, and the individual has a particular interest in the

reclassification being made e.g. because he is a retail pharmacist and he will benefit financially;

- An individual participates in, or is connected with, a charity or pressure group that would have an interest in the outcome of the advice being given;
- An individual has a family member who suffers from an illness who would benefit from treatment if a product under discussion were to be authorised;
- An individual has a family member who has suffered a severe reaction or other problem as a result of treatment with a product under discussion;
- Matters relating to persons who are not immediately family members, but are closely connected with the committee expert e.g. adult child no longer living in the same household, or non-family member whose work or other interests are closely associated with the pharmaceutical industry and which could reasonably be perceived as affecting the individual's impartiality. An example might be where a committee is giving advice in relation to a product and a close family member or friend has had a major development responsibility for that product;

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

Attendance at conferences, scientific meetings and similar

4.8 Government recognises that it is usual for conferences, scientific meetings and other events associated with healthcare, medicines or related matters to receive some form of sponsorship either directly, or indirectly via a special fund, from the pharmaceutical industry. Government also recognises the importance of being able to receive advice from leading experts who are able to keep themselves up to date with developments at the cutting edge of science, and that this is mainly done through attendance at educational and scientific events and meetings. It is therefore essential to set out rules for attendance at these and similar events as questions may be legitimately raised as to whether participation in the event, or even mere attendance, will compromise their impartiality in any way. This is particularly important in respect of 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 Moham med	CPSEAG	Personal	Aston Particle Technologies	shares, consultanc y	Yes
Afzal Moham med	CPSEAG	Non- Personal	Catalent Pharma	Research Grant	Yes
Afzal Moham med	CPSEAG	Non- Personal	Colorcon Ltd	Research Grant	Yes
Afzal Moham med	CPSEAG	Non- Personal	MaxBiotech Ltd	Research Grant	Yes
Afzal Moham med	CPSEAG	Non- Personal	Proveca Ltd	Research Grant	Yes
Afzal Moham med	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	Yes

Allan
Young

IEWG

Personal

COMPASS

and
advisory
boards for
the
company
with drugs
used in
affective
and
related
disorders

Paid
lectures
and
advisory
boards for
the
company
with drugs

Yes

Allan Young	IEWG	Personal	Janssen	used in affective and related disorders 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

Yes

Allan
Young

IEWG

Personal

Novartis

company
with drugs
used in
affective
and
related
disorders

Paid
lectures
and
advisory
boards for
the
company
with drugs
used in
affective
and

Yes

Allan Young	IEWG	Personal	Sumitomo Dainippon Pharma	related disorders 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	Yes

Allan Young	IEWG	Non-Personal	Janssen Cilag NV	boards for the company with drugs used in affective and related disorders A Double-Blind, Placebo-Controlled, Multi-Center Study Investigating the Efficacy,	Yes
-------------	------	--------------	------------------	---	-----

Safety, and
Tolerability
of JNJ-
61393215
as
Adjunctive
Treatment
in Adults
with Major
Depressive
Disorder
with
Anxious
Distress
with
Suboptimal
Response
to Standard
Antidepress

Allan Young	IEWG	Non-Personal	Janssen Pharmaceutica N.V.	ants. Young, A. An Open-label Long-term Extension Safety Study of Intranasal Esketamine in Treatment-resistant Depression Safety and Sustainance of Esketamin	No
-------------	------	--------------	----------------------------	---	----

Allan Young	IEWG	Non-Personal	LivaNova plc	e Treatment Response With Repeated Doses at Intervals Determine d by Symptom Severity (SUSTAIN -3) Young, A.	Yes
				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

Allan Young	IEWG	Non-Personal	N/A	depression Young, 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	Yes

Allan Young	IEWG	Non-Personal	N/A	Clinical Trials Portfolio 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	Yes	The ISAP collaborative trail sponsored by

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.

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 &	Yes

				Opportunistic Infections (CROI)	
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	~Yes

Andrew Pollard	CTBVEAG	Non-Personal	Johnson and Johnson	agreement) 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

Andrew Pollard CTBVEAG Additional

and Social Care's (DHSC) Joint Committee on Vaccination & Immunisation (JCVI), and member of the WHO's SAGE.

Chair of the scientific advisory group on vaccines for the European Medicines Agency until March 2020

Andrew Pollard CTBVEAG Additional

and a member of the World Health Organization's SAGE until 31/12/21
Non-commercial: Grants from Wellcome and Bill & Melinda Gates Found'n on typhoid vaccines (Tybar-CV, Bharat Biotech,

Andrew Pollard CTBVEAG Additional

2013-current);
from MRC on
paratyphoid
vaccine (U.
Maryland;
from 2018-));
Grant from
the Gavi on
pneumococca
l vaccines in
Nepal (2013-
current).
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/D
IAMONDS)
on fever in
children and

Andrew Pollard CTBVEAG Additional

pneumonia
(2016-
current); EC
grant
(Innovac4) to
develop a
CDiff
challenge
model (2021-
current)
Grants from
Innovate UK
to develop
plague, zika,
Q fever
vaccines
(2016-
current).

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

Andrew Pollard	CTBVEAG	Additional				Gates Found'n on evaluating infant schedules (2019 – current) 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 undertake	No	

s
consultanc
y and
advisory
board
work for
Imperial
College
Consultant
s- in the
last 36
months
this has
included
remunerat
ed work
for:
Confo,
Vertex,

Pharmano
vo,
Lateral,
Novartis,
Mundiphar
ma, Orion,
Shanghai
SIMR
BiotechAs
ahi Kasei
& Toray

Andrew
Rice

NPPEAG

Non-
Personal

NIL

N/A

N/A

Andrew
Rice

NPPEAG

Additional

Owner of
share options
in Spinifex
Pharmaceutic
als 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

Andrew Rice NPPEAG Additional

the two terminated clinical trials in an unpaid capacity.

Named inventor on two patents from Imperial College (WO 2005/079771 & EP13702262.0/ WO2013 110945).

Neither are being actively developed or

Andrew
Rice

NPPEAG

Additional

commercialis
ed.
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

Andrew Rice	NPPEAG	Additional	(concluded 2021). 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

Andrew Rice	NPPEAG	Additional				sub-committee Member of Analgesic Clinical Trial Translation: Innovations, Opportunities, and Networks (ACTION) 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	N/A

				University (Postgraduate Diploma in Paediatric Infectious Diseases)		
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	No

Anjan Dhar	GRIDEAG	Personal	Pharmacosmos UK	Speaker Fees 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	No

				Fees, hospitality and support for attending conferenc es	
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 Reclassifi cation EWG	Personal	NIL	N/A	N/A
Arianne Matlin	Dental Caries Reclassifi cation EWG	Non- Personal	NIL	N/A	N/A

Arianne
Matlin

Dental
Caries
Reclassifi
cation
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 compassionat

e 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	Non-Personal	NIL	N/A	N/A

Catherine White	Reclassification EWG 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/	Grant	No
			7 Pharmaceutical Companies:		

Pfizer, MSD,
Roche, Eli
Lilly,
Novartis,
Janssen,
Sanofi-
Aventis

Chris
Goldring

CTBVEAG

Non-
Personal

Innovative
Medicines
Initiative
project:
TransQST
[http://transqs
t.org/](http://transqs
t.org/)
9
Pharmaceuti
cal
Companies:
Eli Lilly,

Grant

No

Abbvie,
Servier,
Sanofi-
Aventis, AZ,
GSK,
Janssen,
Orion, B.I.

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 Roberts on	COVID-19 VBREWG	Personal	NIL	N/A	N/A
Chris Roberts on	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,	Non-Personal	AB Science		DSMB membership for three	Yes

NPPEAG,
RWD

trials (in
ALS,
mastocytosis and
progressive MS),
with
income to
my
department

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	Consultan cy	Yes
Clive Grattan	IEWG	Personal	Sanofi Genzyme	Consultan cy	Yes
Clive Grattan	IEWG	Non- Personal	NIL	N/A	N/A
Colin Forfar	RWD	Personal	UCB Pharma	Consultan cy and presentati on fee, travel/acco mmodatio n 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.	Consultancy - Specific	No		

(New Jersey,
USA)

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	Yes

Darragh Murnane	CPSEAG	Non-Personal	Glatt	research projects Collaborator of Fluid Pharma (company of which I hold a Directorship) to develop novel paediatric therapies	Yes
Darragh Murnane	CPSEAG	Non-Personal	GlaxoSmith Kline	In-kind support for research project, and	Yes

Darragh Murnane	CPSEAG	Non-Personal	Merxin Ltd	sponsored PhD studentships 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	Yes

Darragh Murnane	CPSEAG	Non-Personal	UnitAid	Pharma (company of which I hold a Directorship) to develop novel paediatric therapies	Funding a research project by Fluid Pharma (company of which I hold a Directorship)	Yes
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				p) to develop novel paediatric therapies	
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,	MRC Stratified Medicine	No

Celgene
(Bristol Myer
Squibb/Amger
)
Research
Grant:
Psoriasis
Stratificati
on to
Optimise
Relevant
Therapy
(PSORT)

Darren
Ashcroft

PEAG,
IEWG

Non-
Personal

Eli
Lilly,Janssen
, LEO
Pharma,

MRC
Stratified
Medicine
Research
Grant:
Psoriasis
Stratificati
on to
Optimise
Relevant

No

Darren Ashcroft	PEAG, IEWG	Non-Personal	LEO Foundation, Eli Lilly, Novartis (Sandoz), Almirall, UCB	Therapy (PSORT) 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	No

				Optimise Relevant Therapy (PSORT)	
Darren Ashcroft	PEAG, IEWG	Non- Personal	Mundipharma	Research grant	No
David Bowen	OHEAG	Personal	Abbvie	Consultan cy	No
David Bowen	OHEAG	Personal	Janssen	Consultan cy	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

al 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
accommodati
on. 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
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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 Wellesey	MWHEAG	Personal	Glaxo-Smith-Kline through OXON Epidemiology Limited study	Assessment on this study. Pension Share Holding	
Diana Wellesey	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	No

Ertan Saridogan	MWHEAG	Personal	Intuitive	at ESGE Congress Fee for contributing to educational activities at ESGE Congress	No
Ertan Saridogan	MWHEAG	Personal	Viatrix	Fee for giving a presentation in a webinar	No
Ertan Saridogan	MWHEAG	Non-Personal	N/A	N/A	N/A

Farzin Farzaneh	CTBVEAG	Personal	Collectis, France	Contract manufacture and R & D collaborations	Yes
Farzin Farzaneh	CTBVEAG	Personal	Autolus Therapeutics	Shares, consultancy payments, contract manufacture and R & D collaborations	Yes
Farzin Farzaneh	CTBVEAG	Personal	Apterna	Consultancy	Yes

Farzin Farzaneh	CTBVEAG	Personal	Servier	Contract manufactu re	Yes
Farzin Farzaneh	CTBVEAG	Personal	Orchard Therapeutics	Contract manufactu re	Yes
Farzin Farzaneh	CTBVEAG	Personal	GlaxoSmithK line	Consultan cy – member of Cell and Gene Therapy Scientific Advisory Board	Yes
Farzin Farzaneh	CTBVEAG	Personal	Centre Hospitalier Universitaire Vaudois	Consultan cy	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	Yes

Farzin Farzaneh	CTBVEAG	Non-Personal	Great Ormond Street Hospital	molecular medicine 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
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Geraint Davies	IEAG	Non-Personal	NIL	N/A	N/A
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Geraint Davies	IEAG	Additional				From 2011-2017 I was the academic co-ordinator of the PreDiCT-TB consortium, a public-private partnership
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funded by the
EU Innovative
Medicines
Initiative and
the European
Federation of
Pharmaceutic
al 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

Geraint
Davies

IEAG

Additional

industrial
partners.
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
pharmaceutic
al 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

Geraint
Davies

IEAG

Additional

the University
of Malawi
College of
Medicine
receive any
funding from
pharmaceutic
al
collaborators
as part of
these
activities.

Since 2020 I
have been an
academic
partner to the
UNITE4TB
consortium, a
new public-

private
partnership
funded by the
EU Innovative
Medicines
Initiative and
the European
Federation of
Pharmaceutic
al 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

Geraint
Davies

IEAG

Additional

EFPIA or from
the individual
industrial
partners.

I have
attended
expert
advisory
meetings
relating to TB
drug
development
convened by
GSK and
Janssen for
which I
received no
payment or
benefit

(honorarium,
expenses,
hospitality)

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 Hawksw orth	CPSEAG	Personal			
Gillian Hawksw orth	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	Consultan cy	Yes
Graham Buckton	CPSEAG	Personal	ALVOGEN	Consultan cy	Yes
Graham Buckton	CPSEAG	Personal	MYLAN	Consultan cy	Yes
Graham Buckton	CPSEAG	Personal	AZURITY	Consultan cy	Yes
Graham Buckton	CPSEAG	Personal	LUPIN	Consultan cy	Yes
Graham Buckton	CPSEAG	Personal	SUN	Consultan cy	Yes
Graham Buckton	CPSEAG	Personal	APOTEX	Consultan cy	Yes
Graham Buckton	CPSEAG	Personal	TEVA	Consultan cy	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 Pieleles	PMEAG, OHEAG	Personal	Canon Medical Systems Ltd.	Consultancy (lecturing, strategy of sports cardiology imaging)	Yes
Guido Pieleles	PMEAG, OHEAG	Personal	Cardiac Health & Performance Ltd.	Director (clinical sports cardiology and sports medicine consulting)	Yes
Guido Pieleles	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 No clinical trial, advisory board, speaker on educational symposia, all remuneration to department	No
Helen J Cross	PEAG	Non-Personal	GW/Jazz Pharmaceuticals	Investigator No clinical trial, advisory board, speaker educational symposium, all	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	No

Helen J Cross	PEAG	Non-Personal	UCB	<p>I symposiu m, remunerati on to departmen t</p> <p>Speaker educationa l symposiu m, remunerati on to departmen t</p>	No
Helen Lachman	CTBVEAG, COVID-19 VBREWG	Personal	Novartis	Speakers fees/consu ltancy	Yes

Helen Lachman	CTBVEAG, COVID-19 VBREWG	Personal	SOBI	Speakers fees/consultancy	Yes
Helen Lachman	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	No

John Firth	CDRRA EAG	Non- Personal	ROCHE	educationa l meetings Occasional support of renal unit educationa l meetings	No
John Firth	CDRRA EAG	Non- Personal	SHIRE	Occasional support of renal unit educationa l meetings	No
John Firth	CDRRA EAG	Non- Personal	WYETH	Occasional support of renal unit educationa l meetings	No

Jonathan H Tobias	MWHEAG	Personal	NIL	NIL	N/A
Jonathan H Tobias	MWHEAG	Non-Personal	NIL	NIL	N/A
Jonathan Friedland	CHM, COVID-19 Therapeutics EWG, COVID-19 VSSMEAG, IEAG	Personal	NIL	N/A	N/A
Jonathan Friedland	CHM, COVID-19 Therapeutics EWG, COVID-19 VSSMEAG, IEAG	Non-Personal	Astra Zeneca	The commercial company is a sponsor / funder of research at St.	

George's,
University
of London
which
does not
involve me
(and of
which I am
generally
unaware
of the
topic)

As above

Jonathan Friedland	CHM, COVID-19 Therapeuti cs EWG, COVID-19 VSSMEAG , IEAG	Non- Personal	Beckman Coulter Genomics Inc.
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Jonathan Friedland	CHM, COVID-19 Therapeutics EWG, COVID-19 VSSMEAG, IEAG	Non-Personal	Boston Scientific Limited	As above
Jonathan Friedland	CHM, COVID-19 Therapeutics EWG, COVID-19 VSSMEAG, IEAG	Non-Personal	Chiesi Limited	As above
Jonathan Friedland	CHM, COVID-19 Therapeutics EWG, COVID-19	Non-Personal	Fondazione PENTA ONLUS	As Above

VSSMEAG
, IEAG

Jonathan Friedland	CHM, COVID-19 Therapeut ics EWG, COVID-19 VSSMEA G, IEAG	Non- Personal	Gilead Sciences Ltd.	As above
Jonathan Friedland	CHM, COVID-19 Therapeut ics EWG, COVID-19 VSSMEA G, IEAG	Non- Personal	GlaxoSmithK line	As above
Jonathan Friedland	CHM, COVID-19 Therapeuti	Non- Personal	Jay Pharma Inc.	As above

cs EWG,
COVID-19
VSSMEAG
, IEAG

Jonathan Friedland CHM, COVID-19 Therapeutics
Non-Personal LDN Pharma As above

cs EWG,
COVID-19
VSSMEAG
, IEAG

Jonathan Friedland CHM, COVID-19 Therapeutics
Non-Personal McColl's Retail Group As Above

cs EWG,
COVID-19
VSSMEAG
, IEAG

Jonathan Friedland	CHM, COVID-19 Therapeutics EWG, COVID-19 VSSMEAG, IEAG	Non-Personal	Merck Serono Ltd	As above
Jonathan Friedland	CHM, COVID-19 Therapeutics EWG, COVID-19 VSSMEAG, IEAG	Non-Personal	Merck Sharpe & Dohme Ltd	As above
Jonathan Friedland	CHM, COVID-19 Therapeutics EWG, COVID-19	Non-Personal	Pfizer UK / Global / USA	As above

	VSSMEAG , IEAG			
Jonathan Friedland	CHM, COVID-19 Therapeuti cs EWG, COVID-19 VSSMEAG , IEAG	Non- Personal	Shockwave Medical Incorporated	As above
Jonathan Friedland	CHM, COVID-19 Therapeuti cs EWG, COVID-19 VSSMEAG , IEAG	Non- Personal	SPD Development Co Ltd	As above
Jonathan Friedland	CHM, COVID-19 Therapeuti	Non- Personal	St Jude Medical, AFD Inc.	As above

	cs EWG, COVID-19 VSSMEAG , IEAG				
Jonathan Friedland	CHM, COVID-19 Therapeuti cs 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 Reclassifi	Personal	NIL	N/A	N/A

	cation EWG				
Juliette Reeves	Dental Caries Reclassifi cation EWG	Non- Personal	NIL	N/A	N/A
Kamini Shah	Dental Caries Reclassifi cation EWG	Personal	NIL	N/A	N/A
Kamini Shah	Dental Caries Reclassifi cation 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: GenOMIC C, 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	Yes

				study investigati ng the efficacy and safety of Pfizer- BioNTech vaccine in pregnancy.	
Kevin Moore	GRIDEAG , IEAG	Personal	Mallinckrodt	Consultan cy	Yes
Kevin Moore	GRIDEAG , IEAG	Personal	Salutare Group Ltd	Director	Yes
Kevin Moore	GRIDEAG , IEAG	Personal	Servier	Consultan cy	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,	Non-Personal	NIL	N/A	N/A

Dental
Caries
Reclassifi
cation
EWG

Kimme
Hyrich

COVID-19
VBREWG

Personal

Abbvie

I delivered No
an
educational
lecture on
manageme
nt of
difficult to
treat
rheum. The
honorarium
on this one
occasion
was paid to
me directly

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	Yes

Kimme Hyrich	COVID-19 VBREWG	Non-Personal	Pfizer	University of Manchester on management of Rheumatoid Arthritis and role of autoantibodies	Yes
				I am a named Co-I on a research grant aid to University of	

				Manchester on managem ent of Rheumatoi d Arthritis (role of drug adherence)	
Laurie Tomlins on	MWHEAG	Personal	NIL	N/A	N/A
Laurie Tomlins on	MWHEAG	Non- Personal	Bayer	Departme ntal consultanc y for a real world study of	Yes

Laurie Tomlison	MWHEAG	Non-Personal	GSK	CKD in type II diabetes I participate in a departmental collaboration which funds PhD students and a post-doctoral fellow to undertake methods research	Yes
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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	Non-Personal	NIL	N/A	N/A

	EWG, PEAG, Sodium Valproate EWG					
Madeleine Wang	CTBVEAG, COVID-19 VBREWG, IEWG, Opioids EWG, PEAG, Sodium Valproate EWG	Additional				Immediate family members with autoimmune diseases and other long term chronic health conditions
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
Pharmaceutic
a NV
(JANSSEN)
Noldus
Information
Technology
BV
(NOLDUS)
Novartis

Pharma AG
(NOV) Orion
Corporation
(ORION)
PAASP
GmbH
(PAASP)
Pfizer Ltd.
(Pfizer)Porsolt
SAS (Porsolt)
PsychoGenic
s Inc. (PGI)
Sanofi-
Aventis
Recherche &
Développement
nt (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 Reclassifi cation EWG	Personal	NIL	N/A	N/A
Martin Duerden	Dental Caries Reclassifi cation 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	Yes

				through agreement with the Trials Unit.	
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
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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
pharmaceutic
al or

biotechnology
company.

Michael Threadgi II CPSEAG Personal NIL N/A N/A

Michael Threadgi II 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 Pirmoha med	CHM, COVID-19 Therapeut ics EWG, COVID-19 VBREWG, COVID-19 VSSMEA G, IEWG, RWD	Personal	NIL	N/A	N/A
Munir Pirmoha med	CHM, COVID-19 Therapeut ics EWG, COVID-19	Non- Personal	Astra Zeneca	Research grant to UoL to support PhD in	

VBREWG,
COVID-19
VSSMEA
G, IEWG,
RWD

drug-drug
interaction
s co-
funded by
the
EPSRC

Munir
Pirmoha
med

CHM,
COVID-19
Therapeut
ics EWG,
COVID-19
VBREWG,
COVID-19
VSSMEA
G, IEWG,
RWD

Non-
Personal

BMS (Bristol
Myers
Squibb)

Unrestrictec
educational
grant to Uol
to support
UK
Pharmacog
enetics and
Stratified
Medicine
network
open
meeting

Munir Pirmoha med	CHM, COVID-19 Therapeut ics EWG, COVID-19 VBREWG, COVID-19 VSSMEA G, 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 Pirmoha med	CHM, COVID-19 Therapeut	Non- Personal	Novartis	Research grant to UoL to

	ics EWG, COVID-19 VBREWG, COVID-19 VSSMEA G, IEWG, RWD			support clinical training fellowships jointly with MRC
Munir Pirmoha med	CHM, COVID-19 Therapeut ics EWG, COVID-19 VBREWG, COVID-19 VSSMEA G, 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 VBREWG, COVID-19 VSSMEAG, IEWG, RWD	Non-Personal	UCB Pharma	Research grant to UoL to support clinical training fellowships jointly with MRC	
Munir Pirmohamed	CHM, COVID-19 Therapeutics EWG, COVID-19 VBREWG, COVID-19 VSSMEA	Non-Personal	Vistagen Therapeutics	Work on L-amino acid transporter type 1.	Yes

	G, IEWG, RWD		
Munir Pirmoha med	CHM, COVID-19 Therapeut ics EWG, COVID-19 VBREWG, COVID-19 VSSMEA G, 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.or

g). 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 NPPEAG Additional
Fineberg

I WORK AS A
MEDICAL
LEAD OF AN
NHS
ENGLAND
SERVICE
PROVIDING
PHARMACOL
OGICAL TREA
TMENT FOR
OBSESSIVE
COMPULSIVE
DISORDERS.
I ACT AS AN
UNPAID
MEDICAL ADV
ISER AND
TRUSTEE TO
NATIONAL

CONSUMER
CHARITIES
FOR OCD
AND
RELATED
DISORDERS.
I CHAIR THE
WORLD
PSYCHIATRIC
ASSOCIATIO
N SCIENTIFIC
SECTION ON
ANXIETY,
OCD AND
RELATED
DISORDERS.
I HAVE
CONTRIBUTE
D 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
NEUROPSYCHOPHARMAC
OLOGY
(ECNP). I AM
SECRETARY
OF THE
INTERNATIO
NAL
COLLEGE OF
OBSESSIVE-
COMPULSIVE
SPECTRUM

DISORDERS.
I HAVE
RECEIVED
RESEACH
GRANTS
FROM THE
NIHR AND
HORIZON
2020 (COST).
I RECEIVE AN
HONORARIU
M FROM
ELSEVIER
FOR
EDITORIAL
DUTIES FOR
THE
JOURNAL
COMPREHEN

SIVE
PSYCHIATRY.
I HAVE
RECEIVED
AN
HONORARIU
M FOR
EDUCATIONA
L 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 Reclassifi	Personal	NIL	N/A	N/A

	cation EWG				
Patient 1	Dental Caries Reclassifi cation EWG	Non- Personal	NIL	N/A	N/A
Patricia McGetti gan	PEAG	Personal	NIL	N/A	N/A
Patricia McGetti gan	PEAG	Non- Personal	NIL	N/A	N/A
Patrick Mark	CDRRA EAG	Personal	Astellas	Consultan cy	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	No

and received funding from them. This project terminated in Jan 2020 and is not ongoing.

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	Yes

for
translation
al research
project into
hepatotoxi
city.

Project
part
funded by
educationa
l grant
from Pfizer

Poulam
M Patel

CHM,
OHEAG

Non-
Personal

Scancell

Co-
supervisor
for
translation
al
research
project into

Yes

				hepatotoxi city. Project part funded by grant from Scancell	
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 Investigato r 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	Collaborati on on research project and prospectiv e phase 1	Yes

trial where
AZ are
providing
drug to be
added
during
preparatio
n of
dendritic
cell
vaccine

Qasim GRIDEAG Personal
Aziz

Qasim GRIDEAG Non-
Aziz Personal

Raymond Dental Personal NIL N/A N/A
Anderson Caries
Reclassifi

	Reclassification EWG				
Raymond Anderson	Dental Caries Reclassification EWG	Non- Personal	NIL	N/A	N/A
Ravisha nkar Sargur	GRIDEAG	Personal	NIL	N/A	N/A
Ravisha nkar Sargur	GRIDEAG	Non- Personal	Abbott	Expert consultant to Abbott Laboratori es, Inc. and its related group companies	No

(together,
"Abbott")
in
connection
with the
inquest
and MHRA
investigati
on of an
adverse
reaction to
a
transcathe
ter cardiac
procedure

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 Reclassifi	Personal	NIL	N/A	N/A

	Regina Ahmed	Reclassification EWG 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

Richard
Gilson

CHM,
COVID-19
Therapeut

Personal

NIL

N/A

N/A

Clinical
research
facility based
within
Liverpool
University
Hospitals
NHS
Foundation
Trust which
conducts
academic and
commercially
funded
research

	ics EWG, IEAG				
Richard Gilson	CHM, COVID-19 Therapeut ics EWG, IEAG	Non- Personal	Gilead Sciences	My department is a collaboratin g site in clinical trials sponsored by Gilead Sciences, who have provided research funds to the department (Central and North	No

Richard Gilson	CHM, COVID-19 Therapeut ics EWG, IEAG	Non- Personal	GSK	West London NHS Foundation Trust)	No
				My department is a collaboratin g 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 investigator for trials sponsored GSK.

Richard Gilson

CHM, COVID-19 Therapeutics EWG, IEAG

Non-Personal

Janssen

My department is a collaborating site in clinical

No

trials
sponsored
by
Janssen,
who have
provided
research
funds to the
department
(Central
and North
West
London
NHS
Foundation
Trust)

Richard
Gilson

CHM,
COVID-19
Therapeut

Non-
Personal

Merck

My
department
is a

No

ics EWG,
IEAG

collaboratin
g site in
clinical
trials
sponsored
by Merck,
who have
provided
research
funds to the
department
(Central
and North
West
London
NHS
Foundation
Trust)

Richard
Gilson

CHM,
COVID-19
Therapeut
ics EWG,
IEAG

Non-
Personal

Mylan

My
department
was a
collaboratin
g site in a
clinical trial
using a
product
supplied by
Mylan,
funded by
NHS
England.
Research
funds to the
department
(Central
and North
West

No

Richard Gilson	CHM, COVID-19 Therapeut ics EWG, IEAG	Non- Personal	Pfizer	London NHS Foundation Trust were received from Public Health England)	No
				My departmen t is a collaborati ng site in clinical trials sponsored by Pfizer, who have provided	

research
funds to
the
departmen
t (received
by UCL
and by
Central
and North
West
London
NHS
Foundatio
n Trust)

Richard
Gilson

CHM,
COVID-19
Therapeut
ics EWG,
IEAG

Non-
Personal

ViiV

My
department
is a
collaboratin
g site in

No

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

Richard
Gilson

CHM,
COVID-19

Additional

Members of
the UCL

Therapeutics
EWG,
IEAG

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 Thanaco ody	PEAG	Personal	NIL	N/A	N/A
Ruben Thanaco ody	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
pharmaceutic
al industry
advertising. I
am not
involved in
decisions
around
advertisement
s for the
journal. I
receive
funding from
the National
Institute for
Health
Research
(NIHR) to
undertake

						research on polypharmacy , medicines optimisation and pharmacoepid emiology, and from MRC.
Sandosh Padman abhan	CHM	Personal	NIL		N/A	N/A
Sandosh Padman abhan	CHM	Non-Personal	NIL		N/A	N/A
Sandosh Padman abhan	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

Sarah Wild	CDRRA EAG	Personal	Novo Nordisk	attending advisory board discussing epidemiological data Accommodation, subsistence and contribution to registration fees provided as part of unrestricted educational	Yes
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I grant
during
attendanc
e at
biannual
meetings
of the
Scottish
Study
Group for
Care of
Diabetes
in the
Young in
role as
member of
Steering
Group

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 EWG, COVID-19 VBREWG	Non-Personal	AstraZeneca	This NPNS interest relates to donations provided by AstraZeneca 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)

Shirley
Price

CHM,
COVID-19

Non-
Personal

GSK

This
NPNS

Therapeutics
EWG,
COVID-19
VBREWG

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
Therapeuti
cs 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	No

				for trial steering committee.	
				Local PI for clinical study.	
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	No

Steven
Cunning
ham

CHM,
PMEAG

Non-
Personal

Valneva

Monitoring
Committee
allocated
AbbVie
study with
fees paid
by US
CFF to
Edinburgh
University.

Local PI for No
adolescent
study
(withdrawal
prior to
recruitment
)

Steven
Cunning
ham

CHM,
PMEAG

Non-
Personal

Vertex

Local PI
for
ARRIVAL
study
(VX15-
770-124)

No

Steven
Cunning
ham

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	Sponsorsh ip of clinical meeting	No
Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non- Personal	Alexion	Sponsorsh ip of clinical meeting	No
Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non- Personal	Amgen	Sponsorsh ip 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	Sponsorsh ip of clinical meeting	No
Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non- Personal	Celgene	Sponsorsh ip of clinical meeting	No
Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non- Personal	Consilient Health	Sponsorsh ip of	No

Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non-Personal	Eli Lilly	clinical meeting 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	No

Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non-Personal	Kyowa Kirin	patients into a clinical trial 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	Sponsorsh ip of clinical meeting	No
Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non- Personal	Roche	Sponsorsh ip of clinical meeting	No
Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non- Personal	Sandoz	Sponsorsh ip of clinical meeting	No
Stuart H Ralston	CHM, GRIDEAG, MWHEAG	Non- Personal	Sanofi- Genzyme	Sponsorsh ip 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.

Susanna IEWG
h Baron

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

Susanna h Baron	IEWG	Personal	Sanofi	given lecture fees for this I am being supported by Sanofi to go to the British Association of Dermatolog ists annual educational meeting in July 2022 in Glasgow	Yes
Susanna h Baron	IEWG	Non- Personal	NIL	N/A	N/A

Susanna h Walsh	COVID-19 VBREWG, CPSEAG	Personal	Better Vision Solutions	Consultanc y and licence agreement for technology. Named on patents.	Yes
Susanna h Walsh	COVID-19 VBREWG, CPSEAG	Personal	Chemical Biological Center of Combat Capabilities Development	Research collaborati on and MTA. Named on DMU Patents associated with work.	Yes

Susanna h Walsh	COVID-19 VBREWG, CPSEAG	Personal	DSTL	Research grant. Named on DMU patents associated with grant.	No
Susanna h Walsh	COVID-19 VBREWG, CPSEAG	Personal	PAL International	Research collaborati on and MTA. Named on DMU patents associated with work.	Yes
Susanna h Walsh	COVID-19 VBREWG, CPSEAG	Personal	Safer Disinfectant Network	Working group member	Yes

Susanna h Walsh	COVID-19 VBREWG, CPSEAG	Non- Personal	Better Vision Solutions	Consultan cy and licence agreement for patented technology with De Montfort University	Yes
Susanna h Walsh	COVID-19 VBREWG, CPSEAG	Non- Personal	Chemical Biological Center of Combat Capabilities Development	Research collaborati on and MTA. Named on DMU Patents associated with work.	Yes

Susanna h Walsh	COVID-19 VBREWG, CPSEAG	Non- Personal	DSTL	Research grant. Named on DMU patents associated with work.	No
Susanna h Walsh	COVID-19 VBREWG, CPSEAG	Non- Personal	PAL	Research collaborati on and MTA. Named on DMU patents associated with work.	Yes
Susanna h 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
(Preparednes
s 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 Reclassifi cation EWG	Personal	NIL	N/A	N/A
Vijay Sudra	Dental Caries Reclassifi cation 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	No

				and joint PhD funding.	
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	Non-Personal	Everna	Knowledge exchange	No

	VBREWG, CPSEAG			research contracts from company to University of Strathclyde.	
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	Non- Personal	Haver Pharmaceuticals	Knowledge exchange research	No

	VBREWG, CPSEAG			contracts from company to University of Strathclyde.	
Yvonne Perrie	CHM, COVID-19 VBREWG, CPSEAG	Non- Personal	Janssen Pharmaceuti cals	PhD funded studentshi p 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	Non- Personal	Microfluidics	Equipment loan to University	No

VBREWG,
CPSEAG

of
Strathclyde
and in-kind
research
support
(consumables).

Yvonne
Perrie

CHM,
COVID-19
VBREWG,
CPSEAG

Non-
Personal

Mologic

Knowledge No
exchange
research
contracts
from
company to
University
of
Strathclyde.

Yvonne
Perrie

CHM,
COVID-19

Non-
Personal

Pfizer Inc,

Grant No
which
includes

	VBREWG, CPSEAG			contribution s to University of Strathclyde.	
Yvonne Perrie	CHM, COVID-19 VBREWG, CPSEAG	Non- Personal	Astra Zeneca	Grant which includes contribution s to University of Strathclyde	No
Yvonne Perrie	CHM, COVID-19 VBREWG, CPSEAG	Non- Personal	Precision Nanosystems	Grant which includes contribution s to University	No

Yvonne Perrie	CHM, COVID-19 VBREWG, CPSEAG	Non-Personal	Centre for process Innovation Ltd	of Strathclyde 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. SmartScotl and 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	No

of
Strathclyde.

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

Additional

Controlled
Release
Society,

VBREWG,
CPSEAG

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:**

Member	Personal Interest		Non-Personal Interest		Current	Additional Information
	Company Name	Nature of Interest	Company Name	Nature of Interest		
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
	Viatrix	Shares				

Prof A G Davidsor (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 Reckitt Benckiser Individior	Salary, Shares Shares Shares	None		N/A	None
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	Chair (unpaid)	Yes

Research
Association

Hong Kong Department of Health, Pharmacop oeia Internationa l Advisory Committee	Member (unpaid)	Yes
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Proctor & Gamble Responsible Beauty Advisory Council	Member (unpaid)	Yes
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			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 Sanofi	Salary, Shares, Shares	None		N/A	None

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