Human Medicines Regulations 2012 Advisory Bodies

Annual Report 2020

Commission on Human Medicines

British Pharmacopoeia Commission

Medicines and Healthcare products Regulatory Agency

HUMAN MEDICINES REGULATIONS 2012
ADVISORY BODIES ANNUAL REPORT 2020

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Commission on Human Medicines

British Pharmacopoeia Commission

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FOREWORD BY THE PARLIAMENTARY UNDER SECRETARY OF STATE FOR LIFE SCIENCES

It gives me great pleasure to present the annual reports for 2020 of the Human Medicines Regulations Advisory Bodies: the Commission on Human Medicines and the British Pharmacopoeia Commission. These reports include a record of members' interests in the pharmaceutical industry and code of practice.

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

Lord Bethell

COMMISSION ON HUMAN MEDICINES ANNUAL REPORT 2020

TERMS OF REFERENCE

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

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

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

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

MEMBERSHIP

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

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

    Expert Advisory Groups 2020

    Cardiovascular, Diabetes, Renal, Respiratory and Allergy (CDRRAEAG)
    Chaired by **Professor Amanda Adler** *(Interim for the first and second meeting);* **Professor Jamie Coleman**

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

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

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

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

Medicines for Women's Health (MWHEAG)
Chaired by **Dr Ailsa Gebbie** *(first meeting);* **Professor Philip Hannaford**

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

Oncology and Haematology (OHEAG)
Chaired by **Professor Angela E Thomas** *(for 6 meetings);* **Professor Poulam M Patel**

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

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

Working Groups 2020

Adrenaline Autoinjectors Working Group
Chaired by **Professor Kevin Taylor**

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

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

COVID-19 Vaccines Safety Surveillance Methodologies Expert Working Group
Chaired by **Dr Siraj Misbah**

Desogestrel Ad Hoc Stakeholder Group
Chaired by **Professor Kevin Taylor**

Isotretinoin Expert Working Group
Chaired by **Professor Sir Munir Pirmohamed**

Optimising data on medicines used in pregnancy Expert Working Group
Chaired by **Professor Jane Norman**

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

Ad Hoc Stakeholder Group to Consider a Product to Treat Vaginal Atrophy
Chaired by **Professor Kevin Taylor**

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

MEETINGS

6. The Commission held 22 meetings during 2020. Of these, 9 were two-day meetings. One-day meetings lasted an average of three hours. January and February's meetings were held at the Medicines and Healthcare products Regulatory Agency, 10 South Colonnade, London, E14 4PU, United Kingdom, whilst the remainder were held via videoconference.

SECRETARIAT

7. 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

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

FIRST CONSIDERATION BY THE COMMISSION

9. The Commission considered and advised on a total of 311 applications for marketing authorisations. The table below shows the outcome for National, Mutual Recognition, Decentralised and Centralised applications for new active substances and abridged applications at first consideration (i.e. before appeals).

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

	Grant advised	Grant not advised
New Active Substances	**5**	**67**
Abridged Applications	**5**	**148**

10. The Commission was extensively involved in applications made through the European Centralised Procedure. The Commission considered 88 new active substances, or new combinations of active substances, via the Centralised Procedure.

11. The Commission considered 20 papers under the Early Access to Medicines Scheme.

12. The Commission considered an average of 14 applications at each of its 22 meetings in 2020, in addition to clinical trial applications, appeals, reclassifications, pharmacovigilance issues and other matters.

APPEALS

13. The Commission considered three oral hearings, covering 6 National applications and advised against the grant of marketing authorisations for the 6 applications.

14. The Commission considered a total of 29 written representations covering 53 applications. Of these, the Commission advised that marketing authorisations could be granted for 22 and granted subject to the resolution of the outstanding concerns for 28. For the remaining 3, the Commission advised against the grant of marketing authorisations.

EXTERNAL EXPERTS AND STAKEHOLDERS

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

Dr Eileen M Baildam
Consultant Paediatric Rheumatologist and Honorary Senior Lecturer, Alder Hey Foundation NHS Trust and University of Liverpool
(October)

Professor David Baldwin
Professor of Psychiatry, Academic Lead for General Adult Psychiatry for Clinical Academic Training at University of Southampton
(November)

Professor Thomas R. E. Barnes
Emeritus Professor of Clinical Psychiatry, Imperial College London
(November)

Professor Mike Bennett MD FRCP FFPMRCA
St. Gemma's Professor of Palliative Medicine
Academic Unit of Palliative Care
(September)

Professor Kristien Boelaert MD, PhD, MRCP
Professor of Endocrinology and Honorary Consultant Endocrinologist
(December)

Dr Rebecca Bromley
Neuropsychologist at University of Manchester, Clinical Psychologist in NHS
(February)

Mr Kevin Brown
Public Health England (PHE)
(November)

Professor Wendy Burn
Professor of Psychiatry and President of the Royal College of Psychiatrists
(November)

Mr Andrew Evans
NHS Wales
(November)

Mr Christopher Garland
NHS Northern Ireland
(November)

Professor Philip Hannaford
Emeritus Professor of Primary Care, University of Aberdeen
(November)

Dr Gillian Hawksworth
Academic Community Pharmacist, Visiting Fellow at University of Huddersfield & Past President of the Royal Pharmaceutical Society of Great Britain (RPSGB)
(May, September, October, November)

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

Dr Sarah Jones
Consultant Perinatal Psychiatrist
GM Trust Lead for Perinatal Services
(November)

Professor Helen J Lachmann
Professor of Medicine & Honorary Consultant Nephrologist
Clinical Lead National Amyloidosis Centre, Clinical Service Lead Immunity & Rare Diseases Division, University College London & Royal Free Hospital London NHS Foundation Trust
(April)

Ms Emily Lawson
NHS England
(November)

Ms Claire Liew
Department of Health and Social Care (DHSC)
(February)

Mr Lois Lloyd
NHS Wales
(November)

Mr Jamie Lopez
Public Health England (PHE)
(November)

Ms Sarah McAleer
Department of Health and Social Care (DHSC)
(February)

Professor Hamish McAllister-Williams
Professor of Affective Disorders at Newcastle University
(November)

Dr Rupert McShane
Associate Professor, Consultant Psychiatrist
(September, November, December)

Ms Kate Mitchell
Department of Health and Social Care (DHSC)
(February)

Dr Ipshita Mukherjee
Consultant Perinatal Psychiatrist Greater Manchester Mental Health NHS Trust
(November)

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

Professor David G C Owens
Professor of Clinical Psychiatry, Edinburgh University
(September, November, December)

Professor Poulam M Patel
Professor of Clinical Oncology, Academic Unit of Clinical Oncology, University of Nottingham
(September)

Mr Steve Powis
NHS England
(November)

Mr Keith Ridge
NHS England
(November)

Mr Richard Roberts
NHS Wales
(November)

Professor Peter Sandercock
Chairman RECOVERY DMC
(June)

Ms Justine Scanlan
NHS England
(November)

Dr Catherine F Stannard
Consultant in Complex Pain/Pain Transformation Programme Clinical Lead, NHS Gloucestershire
(July)

Ms Alison Strath
NHS Scotland
(November)

Ms Josephine Tapper
Patient Representative
(November)

Professor David Taylor
Chief Pharmacist, South London and Maudsley NHS Foundation Trust and Professor of Psychopharmacology, King's College, London
(November)

Professor Kevin M G Taylor
Chair of the British Pharmacopoeia Commission and Professor of Clinical Pharmaceutics, UCL School of Pharmacy, London
(January, February, March, April, May, June, July, September, October, November, December)

Professor Angela E Thomas
Consultant Paediatric Haematologist, Royal Hospital for Sick Children, Edinburgh
(April, May, July, September)

Mr Gareth Paul Thomas
Public Health England (PHE)
(November)

Professor Marc Turner
Professor of Cellular Therapy; Medical Director Scottish National Blood Transfusion Service (SNBTS)
(September)

Ms Frederique Marie Uy
Toxicological Risk Assessor, Food Standards Agency
(March)

Mrs Helen M Ward
Nurse Practitioner, PGCEA, PG Cert NMP, Queens Nurse Advanced Nurse Practitioner
(April, May, June, July, September, October, November, December)

Mr Simon Wigglesworth
Deputy Chief Executive, Epilepsy Action
(February)

Professor Christopher Weir
Personal Chair in Medical Statistics and Clinical Trials, Usher Institute, University of Edinburgh
(June, September)

Mr Alex Williams
NHS England
(November)

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

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

Dr Morris Zwi
Consultant Child & Adolescent Psychiatrist & Clinical Lead, Child & Adolescent Mental Health Services, Whittington Health, Child & Adolescent Mental Health Services
(December)

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

Mr Ian Bateman
Director of Quality, NHS Blood and Transplant
(October)

Ms Jenna Dilkes
National Institute for Health and Care Excellence (NICE)
(January, April, May, June, July, October, November, December)

Ms Kay Ellis
NHS Blood and Transplant Sponsor
(October)

Dr Aiden Fowler
NHS England
(November)

Mr Christopher Garland
Principal Pharmaceutical Officer, Northern Ireland
(November)

Professor Peter Groves
Chair of the MHRA Devices Expert Advisory Committee, Chair of the NICE Medical Technologies Advisory Committee
(February)

Ms Laura Hontoria Del Hoyo
Assistant Director Strategic Business Transformation, NHS Blood and Transplant
(October)

Dr Sonia Macleod
Independent Medicines and Medical Devices Safety Review
(May)

Mr Eric Power
Programme Director, National Institute for Health and Social Care Excellence (NICE)
(November)

Ms Jenniffer Prescott
National Institute for Health and Social Care Excellence (NICE)
(February, May)

Dr Keith Ridge
Chief Pharmaceutical Officer, NHS
(November)

Ms Ellie Rose
Head of Flu Policy
(October)

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

Ms Alison Strath
Interim Chief Pharmaceutical Officer, Scotland
(November)

Mrs Madeleine Wang
Lay Member
(November)

CONSIDERATION OF OTHER MATTERS

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

SAFETY OF MARKETED MEDICINES

Valproate and implementation of the pregnancy prevention programme (PPP)

18. The Commission on Human Medicines (CHM) considered updates on progress with implementation of the Pregnancy Prevention Plan (PPP) on three occasions in 2020 (February, March and May). The CHM supported MHRA's current work with healthcare sector organisations. Following reviews of the available prescribing and dispensing data, and noting that a patient survey conducted by UK epilepsy charities showed only half of patients taking valproate reported signing the Annual Risk Acknowledgement Form, the CHM advised that further action was required to prevent harm from valproate. After consideration of the full

range of regulatory options, the CHM in May considered the latest information on the implementation of the valproate PPP and proposals for next steps to reduce harm from valproate exposure during pregnancy. CHM noted the continued decrease in prescribing of valproate to women and the decline in the number of exposed pregnancies by 50% between 2018 and 2019 and advised that although good progress was being made, further work was required. At their May meeting the CHM considered regulatory options to further reduce harm from valproate use in pregnancy. CHM concluded that further work should be done to re-assess the place of valproate in the treatment of bipolar disorder in women of childbearing potential. CHM advised exploring options to reduce off-label use of valproate for migraine in women of childbearing age and once a UK wide registry is in place, how this could be used to support compliance with the PPP. In April, the CHM also considered and advised on the assessment of paediatric safety data with the use of valproate for the treatment of epilepsy.

Valproate in women of childbearing potential with bipolar disorder

19. The CHM in November considered whether the risks of valproate in the treatment of women of childbearing potential with bipolar disorder could be considered to outweigh the benefits. CHM noted that the teratogenic risk is the same regardless of indication, that alternative treatments with less teratogenic risk are available and there is some evidence to suggest that women with bipolar disorder have fluctuating capacity and therefore may be less able to engage fully with the PPP. When unwell, women diagnosed with bipolar disorder may also be more at risk of unplanned pregnancy. The Commission heard that an ongoing clinical audit suggests there is inconsistent implementation of the PPP in mental health services and discussed the place of valproate in bipolar disorder with experts in psychiatry. Based on all the evidence presented the Commission advised that a small proportion of women may need access to valproate as add on therapy in difficult to control bipolar disorder although lamotrigine could be considered in some. CHM advised further efforts to increase compliance with the existing regulatory requirements should be considered through further communications and increased engagement with mental health charities and patient groups.

Anti-epileptic drugs (AEDs) in pregnancy

20. On two occasions in 2020 the CHM considered and discussed an assessment of the available safety data relating to the use of antiepileptic drugs (AEDs) during pregnancy. The review, which was initiated in the context of the known harms of valproate, considered the available data relating to the safety of use of antiepileptic drugs during pregnancy including data on the risk of physical birth abnormalities, harmful effects on the growth of the unborn baby and adverse effects on the child's learning and thinking abilities. At its February meeting the CHM considered a preliminary assessment, which as previously agreed, focussed on a prioritised set of products based on clinical usage and available safety data. The CHM broadly supported the conclusions of the

preliminary assessment including that lamotrigine is safer to use during pregnancy than the other prioritised AEDs. The CHM also noted that a recent Europe-wide review had concluded that levetiracetam can be used during pregnancy after careful assessment if clinically needed. The CHM advised that further work was needed to ensure that, where appropriate and supported by the available data, the information for patients and prescribers is as clear and informative as possible across the antiepileptic drugs, and also to develop communications to make public the conclusions of the review.

21. In December the CHM considered the final assessment and conclusions of a review of the available data for all authorised antiepileptic drugs except those only authorised for status epilepticus, acute convulsions or refractory convulsive disorders. The CHM fully supported the conclusions of this review, which included that lamotrigine and levetiracetam are safer to use during pregnancy than other epilepsy medicines and that some other reviewed antiepileptic drugs may also be associated with harms to the child, although not to such a severe extent as valproate. The CHM also endorsed the plans for public communication on the conclusions of the review through the MHRA's Drug Safety Update bulletin, and a public assessment report providing more information on the data that has been reviewed and how the conclusions of the review were reached. These will be accompanied by a Patient Safety Information Leaflet to support discussions between women and healthcare professionals. The CHM noted that the communication materials had been developed with input from relevant stakeholders, including representatives from epilepsy charities and patient groups.

Prescribed medicines dependency

22. In September 2019 Public Health England (PHE) published a report of the evidence for dependence on, and withdrawal from, prescribed medicines. In January 2020, the CHM considered proposals for an Expert Working Group on dependence and withdrawal to take forward some of the recommendations of the report. The CHM advised on suitable expertise for the Group and agreed it would be appropriate to focus on the therapeutic areas reviewed by PHE including benzodiazepines, z-drugs, gabapentin and pregabalin, along with antidepressants and antipsychotics. The CHM endorsed the draft terms of reference for the Group: to consider the current data on the utilisation in the UK of (non-opioid) medicines which may be associated with dependence and/or withdrawal; to make recommendations for regulatory action to ensure the risks of dependence or withdrawal are clearly labelled; to make recommendations for communications; and to advise on how risks of dependence on, and withdrawal effects from, medicines might be further assessed as part of the product lifecycle.

Opioid medicines and morphine equivalent dose (MED)

23. In February 2020 a paper on morphine equivalence was presented to the CHM which considered improvements in the information for prescribers

on the safest possible effective dose of morphine or its equivalent for other opioids in the treatment of non-cancer related pain in adults and children. Advice had been previously sought from the Opioids Expert Working Group (EWG) and the Paediatric Medicines Expert Advisory Group (PMEAG) on improving information for healthcare professionals. The Opioid EWG and the PMEAG agreed on the need to provide consistent information to opioid prescribers on how to administer the safest possible effective dose of morphine or Total MED (whether from one opioid or a combination of opioids). Therefore, based on the outcome of the discussion, amendment of section 4.2 of the SmPC was proposed and will be implemented once finalised.

Outcomes in atrial fibrillation patients treated with Direct Oral Anticoagulants (DOACs) or warfarin within the NHS

24. In December, the CHM was presented with information on the prescribing and use of DOACs and outcomes in patients taking these medicines, derived from NHS data and recently published studies. DOACs are used to treat or prevent blood clots, which can affect many areas of the body, including the brain (leading to ischaemic stroke), legs (deep vein thrombosis), and lungs (pulmonary embolism). This class of medicines includes apixaban. dabigatran, edoxaban and rivaroxaban. The CHM noted that use of DOAC medicines had increased during the COVID-19 pandemic and use of warfarin had fallen. The CHM discussed the data and its limitations and recommended asking for further information about the NHS data to better understand it and help inform the need for any further risk minimisation measures. On the basis of the data currently available, no regulatory action or direct communication to healthcare professional or patients was considered warranted. However, the CHM recognised that use of DOACs may not be optimal and advised on potential additions to clinical guidance for DOACs. These include potential strategies to support correct DOAC dosing, treatment adherence, and to minimise the risk of drug interactions with these medicines. The CHM's recommendations will be taken forward at a national level.

Levothyroxine and assessment of evidence for adverse events on product-switching

25. In December, the CHM considered evidence from the Yellow Card scheme and scientific literature relating to the reporting of adverse events in patients switched between different levothyroxine tablet products and whether this has any impact on current UK advice for generic prescribing. The CHM advised on the need for updates to product information and communication with patients and healthcare professionals to address the concerns raised in these reports.

Medicines available without prescription applications

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

27. Firstly, in relation to two applications to reclassify from Prescription Only Medicine (POM) to P desogestrel, a medicine for use as an oral contraception, the CHM advised that the applications were approvable.

28. Secondly, the CHM gave preliminary advice against an application to reclassify from POM to P a product for the cutaneous treatment of mild to moderate acne.

29. Lastly, the CHM advised that an application to reclassify from POM to P a medicine for the treatment of vaginal atrophy in postmenopausal women was approvable.

30. One application was for General Sales List (GSL) availability.

31. The CHM advised that an application to reclassify from POM to GSL a medicine for the relief of symptoms associated with seasonal allergic rhinitis was approvable.

Ad Hoc Reclassification Stakeholder Groups

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

33. In 2020 two ad hoc stakeholder groups were established and met to consider POM to P reclassification applications. One group met to consider two applications to reclassify desogestrel. The other met to consider an application to reclassify a medicine for the treatment of vaginal atrophy.

THE COMMISSION'S EXPERT ADVISORY GROUPS (EAGs)

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

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

Adrenaline Auto-injector Expert Working Group

36. The Adrenaline Auto-injector Expert Working Group (EWG) was formed to examine ways to ensure the effective and safe use of adrenaline auto-injectors (AAIs) for the emergency treatment of anaphylaxis. The Commission on Human Medicines (CHM) endorsed the formation of the EWG in March 2020.

37. CHM noted that coroners' inquests into fatalities from anaphylaxis had highlighted a range of issues in relation to the prescribing and use of AAIs. Coroners' concerns had been conveyed in prevention of future death (PFD) notices, addressed to a range of stakeholders, including the Chief Executive of the MHRA. Matters of concern raised by coroners included a) device-related factors that may influence the effectiveness of AAIs; b) clinical practice in relation to the prescribing and use of AAIs; c) the availability of AAIs for emergency use in the wider community; and d) the communication of vital messages to patients and other stakeholders concerning the management of anaphylaxis.

38. CHM also noted that new insight had been gained into factors that may affect the uptake of adrenaline into the bloodstream following AAI administration. This arose from adrenaline blood level data acquired in clinical studies conducted following a safety review of AAIs. The AAI EWG was asked to consider this new knowledge, to inform its advice on prescribing and use of AAIs.

39. The AAI EWG met on four occasions in April, May, June and July 2020. The AAI EWG membership was drawn from a wide cross-section of stakeholders including Patient Support Groups and representatives of the patient experience; leading allergy and immunology specialists in primary and secondary care, and critical care medicine; leaders from NHS England/NHS Improvement, the Royal Pharmaceutical Society, community pharmacists, and the British Paramedic Association. The EWG was chaired by Professor Kevin Taylor, Chair of the CHM's Chemistry, Pharmacy and Standards Expert Advisory Group.

40. In July 2020 CHM considered and endorsed the final report of the AAI EWG that laid out its conclusions and recommendations, to which CHM added some of its own recommendations. CHM also endorsed that a public-facing report should be released in a timely manner, bearing in mind the need to avoid dilution of the core, vital messages by communications related to the Covid-19 pandemic.

41. The AAI EWG recommendations include a number in relation to the prescribing and use of AAIs, such as the need for early administration of adrenaline at the first signs of anaphylaxis; the need to carry two AAIs at all times; the need for patients experiencing anaphylaxis to remain lying

down; and the need for patients to know how to use their particular AAI device. The AAI EWG also recommended that reassurance should be conveyed to prescribers and patients, from the new insight acquired from blood level data, that brands of AAI available in a maximum strength of 300 mcg (Epipen and Jext) are suitable alternatives to the Emerade brand in a 500 mcg strength.

42. The AAI EWG further recommended, in principle, that AAIs should be made available in public locations for use to treat anaphylaxis in exceptional circumstances, provided suitable safeguards can be implemented to ensure safe and effective use of the AAIs. The AAI EWG recognised the need for legislative amendment to enable such a change in policy, as well as the need for this to embody a requirement for training to ensure responsible acquisition and deployment of AAIs in a range of settings. Consultation with relevant stakeholders would also be necessary to inform a hierarchy of need and feasibility so that roll-out could proceed in order of priority. The need for the supply of AAIs to meet any additional demand was also acknowledged.

43. The AAI EWG recommended improvements in adverse event reporting so that potential device malfunction can be more clearly distinguished from a patient's failure to respond to adrenaline delivered as intended. A need for more robust data on device usage (deployment to treat anaphylaxis) was also recognised, given that the majority of AAIs carried by patients are not used and never put to the test. Adverse event rate expressed as a proportion of devices sold can be misleadingly low, as a result. Recommendations therefore included the need for systematic, prospective collection of data on AAI deployment in anaphylaxis, to accompany improved spontaneous reporting.

44. A key AAI EWG recommendation, endorsed by CHM, was that an effective communications strategy would be needed to underpin the delivery, and understanding, of key messages to patients, carers and healthcare professionals, as well as to the wider public. This would be triggered by release of the AAI EWG public report and would be sustained in the form of an ongoing campaign to ensure timely, accurate delivery of key messages to support the progressive implementation of the AAI EWG recommendations.

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

45. In 2020, the CDRRAEAG convened four times and provided advice by written correspondence on twelve occasions.

46. In January, the EAG provided written comments on:
    - a paper discussing the proposed harmonisation of the product information of bendroflumethiazide, a medicine indicated for the treatment of high blood pressure and for the treatment of oedema (build-up of fluid in the body, which causes swelling).

- a medicine indicated for the treatment of asthma.

47. In February, the EAG provided written comments on:
    - a paper providing an update on cases of e-cigarette or vaping associated lung injury in the UK.

48. In March, the EAG discussed and made recommendations on:
    - a new lipid lowering medicine proposed for the treatment of patients with high triglycerides who are at high risk for future cardiac events.
    - the necessity of controlled distribution of a generic version of tolvaptan, a medicine indicated for the treatment of certain endocrine and kidney disorders.

49. Also in March, the EAG provided written comments on:
    - a new medicine proposed for the treatment of a metabolic condition (metabolic acidosis) caused by kidney disease in adults and children.
    - a paper discussing issues about the reliability of a blood test measuring the activity of andexanet-alpha, a medicine used to reverse the action of certain medicines used to prevent blood clotting.

50. In April, the EAG provided written comments on:
    - a new generic medicine indicated for the treatment of heart failure and oedema (build-up of fluid in the body, which causes swelling).
    - a proposed extension of the indications of a medicine used to prevent blood clotting, to include treatment of patients with certain types of stroke.

51. In May, the EAG discussed and made recommendations on:
    - a new lipid lowering medicine proposed for the treatment of patients with high cholesterol.
    - a new generic medicine proposed for the treatment of patients with life-threatening cardiac arrhythmias (abnormal heart rhythm).
    - a paper discussing the monitoring of patients with COVID-19 infection taking warfarin, a medicine used to prevent blood clotting.

52. In June, the EAG provided written comments on:
    - a paper discussing educational materials, for patients and healthcare professionals, for a generic version of treprostinil, a medicine indicated for the treatment of pulmonary arterial hypertension (a condition where high blood pressure occurs in the arteries of the lungs).

53. In July, the EAG provided written comments on:
    - a new medicine proposed for the prevention of recurrent attacks of hereditary angioedema (a rare genetic disorder that results in

recurrent episodes of severe swelling affecting different parts of the body) in patients aged 12 years and older.

54. In September, the EAG discussed and made recommendations on:
    - an extension of the indications of a medicine used to prevent blood clotting to include use in patients with certain types of stroke.
    - a paper discussing concerns raised in the UK press, and by patients and healthcare professionals regarding limited awareness of the known risk of neuropsychiatric reactions (including suicidal thinking and behaviour) in association with the asthma drug montelukast, especially in children and adolescents.

55. In September also, the EAG provided written comments on:
    - a new medicine proposed for the treatment of symptomatic chronic heart failure in adult patients.

56. In November, the EAG discussed and made recommendations on:
    - a paper discussing salbutamol (a medicine used for the treatment of asthma) and measures to improve the consistency of the dosing advice and the safety warnings available to health care professionals.

57. In November also, the EAG provided written comments on:
    - a new medicine proposed for the treatment of patients with heart failure.
    - a paper discussing outcomes in patients with atrial fibrillation (which causes an irregular and often abnormally fast heart rate) treated within the NHS with medicines which prevent blood clotting.

Chemistry, Pharmacy and Standards Expert Advisory Group (CPSEAG)

58. In 2020, the CPSEAG convened 11 times and provided advice by written correspondence on four occasions.

59. In January, the EAG discussed and made recommendations on medicines indicated for the treatment of:
    - chronic hepatitis delta virus (HDV) infection, which causes inflammation of the liver in adult patients.
    - and prevention of bladder infections, kidney and other parts of the urinary tract.
    - spasm of the stomach, gut, and for the symptomatic relief of Irritable Bowel Syndrome.
    - and the prevention of vitamin D deficiency in adults, adolescents and children with an identified risk.
    - stomach ulcers, due to excess acid in the stomach both in children and adults.
    - asthma and Chronic Obstructive Pulmonary Disease (COPD).

- temporary relief of mild to moderate pain associated with migraine, headache, backache, period pain, dental pain, cold and flu symptoms, sore throat and fever.
- Cardiac arrest as a result of abnormally elevated level of potassium in the blood.
- Bipolar Depression Disorder.

Also on a medicine used to detect bronchial airway hyperreactivity, to assist in the diagnosis of asthma.

60. Also in January the EAG were updated
    - and advised on EpiPen containing trace levels of Pralidoxime Chloride.
    - on ongoing developments in the investigation of Nitrosamine contamination of medicinal products.
    - on the potential of a nitrosamine impurity in rifampicin-containing medicinal products.

61. Also in January, the EAG provided written comments on:
    - a medicine indicated for the treatment or prevention of a gout attack.

62. In February, the EAG discussed and made recommendations on medicines indicated for the treatment of:
    - blood clots and to prevent blood clots from reoccurring.
    - patients with locally advanced or metastastic non-small cell lung cancer.
    - an itchy or lumpy rash.
    - fungal infections in adults.
    - severe abdominal and gynaecological infections where sensitive bacteria are suspected to be the cause.
    - adrenal insufficiency in children and adolescents.
    - fungal skin infection and which reduces the associated swelling and itching.
    - interrupted breathing in premature babies.
    - sleeping disorders.
    - primary and secondary levocarnitine deficiency in children less than 12 years of age, infants and newborns.
    - patients with human immunodeficiency virus (HIV-1) infection (two medicines).
    - breast cancer, certain forms of lung cancer (non-small cell lung cancer), prostate cancer, gastric cancer or head and neck cancer.
    - nausea and vomiting.
    - active pulmonary and extra-pulmonary tuberculosis and for the treatment of acute urinary tract infections.
    - all forms of leprosy.

Also on the following:

- a medicine indicated for the short-term relief of occasional constipation.
- a medicine indicated for use during ‘assisted reproductive techniques’ to encourage pregnancy.
- a medicine indicated for relieving the craving and withdrawal symptoms associated with stopping smoking.
- a delivery system for contraception in adult women of fertile age.

63. Also in February, the EAG was updated on
    - and advised on the pharmacokinetic data of Emerade versus other marketed adrenaline auto-injectors.
    - and advised on the developments in the investigation into the activation failures associated with Emerade adrenaline auto injectors.

64. In March, the EAG discussed and made recommendations on medicines indicated for the treatment of:
    - cystic fibrosis in patients aged 12 years and older who have at least one change in the cystic fibrosis gene.
    - influenza and post exposure of influenza in individuals aged from 12 years and at least 40kg body weight.
    - severe bacterial infections such as typhoid and meningitis (inflammation of the lining that covers the brain and spinal cord). It is also used where oral administration is not possible or where higher than usual blood concentrations are required.
    - 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).
    - jet lag in adults, sleep disorders in children and adolescents aged 6-17 years with Attention deficit hyperactivity disorder (ADHD).
    - Human Immunodeficiency Virus (HIV) infection in adults, adolescents and children weighing at least 25 kg.
    - endometriosis (painful symptoms due to displaced tissue of the lining of the womb).
    - muscular spasms and pain including low back pain (lumbalgia) and torticollis (twisted neck due to muscle spasm) in adults.
    - and short-term management of moderate to severe psychomotor agitation (restlessness) in adults and in the elderly for agitation and restlessness.
    - epilepsy (fits).
    - and prevention of anaemia in adults and children, in pregnancy, due to side effects from other medicines, and in those with damaged red blood cells or on kidney dialysis. Also used during pregnancy to prevent spina bifida (an abnormality of the spine) in babies (two medicines).
    - overactive thyroid gland (hyperthyroidism) and to restore normal function of the thyroid before (partial) removal by surgery.

Also on a medicine to reduce cardiovascular risk relating to or affecting the heart and blood vessels in adult patients.

65. Also in March, the EAG was updated on:
    - how the Agency will determine the action to be taken when nitrosamine contamination is suspected or reported in medicinal products.

66. In April, the EAG discussed and made recommendations on medicines indicated for the treatment of:
    - relapsed leukaemia, a cancer that affects the blood and bone marrow to develop the white blood cells which helps the body to fight infection.
    - adults with bile duct cancer.
    - kidney disorder to remove the acids from the blood into the urine in patients aged 6 months and older.
    - chronic lung disease to breath more easily.
    - swelling in one particular part of the body as a result of fluid retention.
    - venous thromboembolism (VTE) and prevention of VTE recurrence, to help prevent blood clots that starts in deep veins, most commonly in the leg, groin or arm in infants and toddlers, children, and adolescents aged less than 18 years.
    - Epilepsy. Adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults and children aged 6 years and above.

    Also on a medicine indicated to help the body get rid of extra fluid which can cause heart failure, hepatic cirrhosis with ascites and oedema, malignant ascites, nephrotic syndrome and diagnosis and treatment of primary hyperaldosteronism.

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

68. In May, the EAG discussed and made recommendations on medicines indicated for the treatment of:
    - adult patients with an enlarged spleen or with symptoms related to myelofibrosis, a rare form of blood cancer.
    - adults who have breast cancer which is positive for human epidermal growth factor receptor 2, or has spread beyond the original tumour or to other organs, and for cancers that have been treated with other treatments.
    - procedural sedation.
    - adults with HIV-1 infections, used in combination with other antiretrovirals.
    - certain types of cancer such as multiple myeloma and cancer of the ovaries.

- heavy menstrual bleeding, where it may be particularly useful in women with heavy menstrual bleeding requiring (reversible) contraception.
- severe insomnia, which is interfering with normal daily life and where other therapies have failed.
- ventricular arrhythmias which are considered as life threatening by the physician.
- urge incontinence and/or increased primary frequency and urgency as may occur in patients with overactive bladder syndrome (two medicines).
- cancer in combination with other cancer medicines.
- tuberculosis, leprosy, brucellosis, Legionnaires disease and serious staphylococcal infections.
- tuberculosis and for prophylaxis in cases of inactive tuberculosis or large tuberculin positive reaction (two medicines).
- of an illness called 'Primary Hyperoxaluria Type 1' (PH1). PH1 is a rare illness that makes the liver make too much of something called 'oxalate which is removed by the kidneys and through urine.

Also on the following:

- a medicine for hormone replacement therapy.
- a medicine used to lower cholesterol in addition to a cholesterol lowering diet.

69. In June, the EAG discussed and made recommendations on medicines indicated for the treatment of:
    - asthma where use of a combination product is appropriate.
    - allergic rhinitis, inflammation of the inside of the nose caused by an allergen in adults and adolescents aged 12 years and older and in children aged 4 to 12 years to improve symptoms.
    - glaucoma or pressure inside the eye who are insufficiently responsive to other medicines.
    - bacterial infections in adults.
    - overactive bladder symptoms when other treatments have not worked.
    - and therapy of fungal pneumonia to build up the body's immune system to fight microorganisms and sickness.
    - depression in adults, migraine and tension headaches and bed wetting in children aged 6 and above.
    - and prevention of post-exposure prevention of influenza during a pandemic influenza outbreak.
    - overactive bladder symptoms when other treatments have not worked.
    - human immunodeficiency virus type 1 (HIV-1) infection.
    - of a wide range of conditions, such as inflammation with asthma, arthritis and allergies and suppression of the immune system.
    - high blood pressure, heart failure and to help protect the kidneys from damage due to diabetes.

- an underactive thyroid gland.
- a toothpaste containing high dose of fluoride indicated for the prevention and treatment of tooth decay.
- a genetic disease called spinal muscular atrophy that causes muscle weakness and wasting.
- gout (inflammation of the joints). It is also is also sometimes used in to treat the rare condition of Familial Mediterranean Fever (FMF) is a genetic disorder that causes recurrent episodes of fever that are typically accompanied by pain in the abdomen, chest, or joints.

Also on the following:

- a medicine indicated in adults in addition to primary therapy to treat patients with Parkinson's disease (PD), to help relieve symptoms of the disease.
- a medicine used as an oral contraceptive.

70. In July, the EAG discussed and made recommendations on medicines indicated for the treatment of:

- primary hyperoxaluria type1(PH1) a rare illness.
- hormone dependent metastatic prostate cancer in adult men and for the treatment of high-risk non-metastatic hormone dependent prostate cancer in combination with radiotherapy.
- moderate to severe symptoms of uterine fibroids (commonly known as myomas), which are non-cancerous tumours of the uterus (womb).
- topical (on the skin) treatment of actinic keratosis in adults. Actinic keratoses are rough areas of skin found in people who have been exposed to too much sunshine over the course of their lifetime.
- Hutchinson-Gilford Progeria Syndrome' and some types of 'Progeroid Laminopathies' in children 12 months of age and older.
- angioedema attacks in patients with HAE (a condition that causes swelling and pain).
- multiple myeloma (a type of cancer affecting white blood cells).
- overactive bladder symptoms when other treatments have not worked.
- vitamin D deficiency Vitamin D3.
- a condition known as primary hypercholesterolaemia (when cholesterol in the blood is elevated) in adults.
- enlarged thyroid (without abnormal thyroid function).
- some forms of epilepsy.
- upper and lower respiratory tract infections such as bronchitis, pneumonia, sinusitis and pharyngitis and also for skin and soft tissue infections (two medicines).
- and to reduce the size of tumours that grow along nerves, called plexiform neurofibromas in children aged 3 and above.

- and to be used in combination with other antiepileptic medicines to treat a type of epilepsy that has focal-onset seizures with or without secondary generalisation. For use in adults only.
- and to help the body get rid of extra fluid which can cause heart failure, hepatic cirrhosis with ascites and oedema, malignant ascites, nephrotic syndrome and diagnosis and treatment of primary hyperaldosteronism.
- angioedema attacks in patients with HAE (a condition that causes swelling and pain).

71. Also in July the EAG was updated on:
    - recent developments on nitrosamine impurities in human medicinal products.
    - and advised on the reissue of end of life of medicines.

72. Also in July, the EAG provided written comments on:
    - a medicine indicated for the treatment of mild to moderate acne on the skin.

73. In August the EAG provided written comments on:
    - a paper on the use of an infusion bag as a reconstitution fluid.

74. In September, the EAG discussed and made recommendations on medicines indicated for the treatment of:
    - adult patients with relapsing forms of multiple sclerosis with active disease defined by clinical or imaging features.
    - adult patients with schizophrenia where psychotic symptoms are moderate to severe and where patients previously are stabilised with antipsychotics.
    - chronic hepatitis C infection (liver disease) in children 3 to 12 years of age.
    - a rare, progressive disorder characterized by high blood pressure (hypertension) in the arteries of the lungs.
    - adult patients with rearranged during transfection (RET)-positive locally advanced or metastatic non-small cell lung cancer (NSCLC) previously treated with platinum-based chemotherapy.
    - iron deficiency in adult patients with chronic kidney disease.
    - advanced lung cancer.
    - premature puberty and to reduce the levels of testosterone and oestrogen.
    - adult patients with type 2 diabetes mellitus.
    - an underactive, an enlarged thyroid and thyroid cancer.
    - enlarged bladder symptoms.
    - high blood pressure (hypertension) or certain types of chest pain called angina.
    - acute moderate pain, such as dental pain or headache on a short term symptomatic basis.
    - cancer such as lung or pancreas cancer.
    - itching or as a sedative for children between 2 and 7 years.

- fungal infections of the blood or other internal organs.
- bacterial infections of the eye.

Also on the following:

- a medicine indicated as maintenance therapy in adult patients with acute myeloid leukaemia who achieved complete remission or complete remission with incomplete blood count recovery following induction therapy with or without consolidation treatment and who are not candidates for, including those who choose not to proceed to, hematopoietic stem cell transplantation.
- a medicine used to reduce the clotting ability of the blood, and to prevent blood clots forming in the legs, lungs, brain and heart.

75. In October, the EAG discussed and made recommendations on medicines indicated for the treatment of:

- symptomatic long term (chronic) heart failure in adult patients who had a previous worsening heart failure event. Heart failure is a condition where the heart does not work as well as it should.
- patients 2 years of age and older with inflammation of multiple moving joints (active polyarticular course juvenile idiopathic arthritis).
- adult patients with a rare genetic condition that is associated with the growth of dozens to hundreds of polyps (abnormal growths or tumours) in the gastrointestinal (GI) tract (familial adenomatous polyposis). The medicine is used in addition to standard of care, and is only for use in patients with an intact colon, rectum, or ileo-anal pouch.
- adult patients with a type of blood cancer (Waldenström's macroglobulinaemia) who have received at least one prior therapy, or as a first line treatment for patients unsuitable for chemo-immunotherapy.
- various infections caused by bacteria in adults and children; including new-born babies.
- high blood pressure (hypertension).
- high blood pressure (hypertension), that is also used to prevent or treat heart failure, when the heart is unable to pump blood around the body properly.
- infections such as pneumonia, lung and bronchial infections, urinary tract infections, infections in the abdomen, infections caught during or after child delivery, skin and soft tissue infections and bacterial infections of the brain (meningitis).
- treatment and prevention of infections, such as infections of the bladder, kidney and other parts of the urinary tract (genitourinary infections).
- illnesses involving inflammation in adults and children.

Also on the following:

- a medicine used in the prevention of and treatment of infections of the bladder, kidney and other parts of the urinary tract (two medicines).

- a medicine used to help clear a blocked nose and sinuses caused by colds and allergies such as hay fever.
- a medicine indicated for routine prevention of recurrent attacks of hereditary angioedema (HAE) in patients aged 12 years and older.

76. In November, the EAG discussed and made recommendations on medicines indicated for the treatment of:
    - various types of cancer such as lung cancer and thyroid cancer.
    - osteoporosis (a disease that causes bones to become thin and fragile) in adults.
    - hereditary angioedema (HAE) in adults, a condition that could lead to swelling and bruising in adolescents and children aged 2 and above (five medicines).
    - fungal infections caused by fungal or yeast cells called Candida.
    - severe acute pain, cancer pain and breakthrough cancer pain.
    - adults and adolescents 12 years of age and older with severe atopic dermatitis, also known as atopic eczema.

    Also a medicine used to relieve pain and reduce inflammation and swelling in painful conditions affecting the joints and muscles.

77. Also in November the EAG was updated on:
    - proposals outlining that levels of nitroso dimethylamine (NDMA) in metformin products meet predetermined standards equivalent to an intake of no more than 96.0ng/day. These proposals are in line with those agreed by the Co-ordination group for Mutual recognition and Decentralised procedures – human (CMDh) at its October meeting. It is not anticipated that supplies to patients will be affected. Batches not meeting the standard may only be released if agreed with the MHRA. Implementation is planned from 1st December 2020. The proposals were endorsed.
    - and advised on a medicine used to treat certain yeast and fungal infections.

78. In December, the EAG discussed and made recommendations on medicines indicated for the treatment of:
    - a type of blood cancer.
    - moderate or severe pain.
    - Myelodysplastic syndrome (MDS) which is an illness that causes anemia and β-thalassemia which is a blood disorder.
    - anxiety and depression.
    - an underactive thyroid gland.
    - adults with bile duct cancer (also known as cholangiocarcinoma).
    - two medicines indicated to relieve pain, and reduce inflammation in arthritis; and to treat pain associated with menstrual bleeding.

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

79. In 2020 the CTBVEAG convened on seven occasions and provided advice by written correspondence on 115 occasions.

80. In January, the EAG provided written comments on:
    - a medicine indicated for the treatment of ‘neuromyelitis optica spectrum disorders’ (NMOSD).

81. In February, the EAG provided written comments on:
    - a clinical trial application for the treatment of COVID-19.
    - a vaccine indicated help protect against influenza (flu).

82. In March, the EAG discussed and made recommendations on:
    - a medicine indicated for the treatment of Metachromatic Leukodystrophy (MLD) in children and adolescents from birth up to 17 years old, and in older patients who developed MLD before they were 17 years old. People with MLD have a fault in the gene to make an enzyme called arylsulphatase A (ARSA). This leads to a build-up of substances called sulfatides in the brain and nervous system, causing the progressive loss of physical and, later, mental skills.
    - a clinical trial application for a medicine indicated for the treatment of clinically significant Bronchopleural Fistula (BPF). A bronchopleural fistula is an abnormal passageway that develops between the large airways in the lungs and the space between the membranes that line the lungs.
    - a clinical trial application for a medicine indicated for the treatment of Relapsed or Refractory Multiple Myeloma, a cancer of mature plasma cells in the bone marrow that has returned or does not respond to therapy.

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

84. In April, the EAG discussed and made recommendations on:
    - a medicine indicated for the treatment of adult patients with relapsed or refractory hairy cell leukaemia (HCL) after receiving at least two prior systemic therapies, including treatment with a purine nucleoside analogue (PNA).
    - a medicine indicated for the treatment of adult patients with severe haemophilia, a rare condition that affects the blood's ability to clot.
    - a medicine indicated for the prevention of herpes zoster (HZ) and post-herpetic neuralgia in adults 18 years of age or older at increased risk of HZ.

85. Also in April, the EAG discussed a paper considering the use of UK-sourced plasma as a starting material for COVID-19 hyperimmune immunoglobulins.

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

87. In May, the EAG discussed and made recommendations on:
    - a medicine indicated for the treatment of patients with a certain type of cancer called multiple myeloma that has not responded to three prior treatments.
    - a monoclonal antibody for the treatment of relapsing forms of multiple sclerosis (RMS) in adults.
    - a gene therapy medicine for the treatment of mantle cell lymphoma (a cancer of the lymph tissue within the immune system) in adults, where other treatments have stopped working.

88. Also in May, the EAG considered and advised on a vaccine to help prevent hepatitis A infection in children aged from 12 months to 15 years.

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

90. In June, the EAG provided written comments on:
    - 17 clinical trial applications for the treatment of COVID-19.

91. In July, the EAG discussed and made recommendations on:
    - a medicine indicated for the treatment of moderate to severe chronic pain associated with osteoarthritis (OA) in adult patients for whom treatment with non-steroidal anti-inflammatory drugs (NSAIDs) and/or an opioid is ineffective, not tolerated or inappropriate.

92. Also in July, the EAG provided written comments on:
    - seven clinical trial applications for the treatment of COVID-19.

93. In August, the EAG provided written comments on:
    - five clinical trial applications for the treatment of COVID-19.

94. In September, the EAG discussed and made recommendations on:
    - a medicine indicated for the treatment of moderate-to-severe atopic dermatitis in adult patients who are candidates for systemic therapy.
    - a therapeutic monoclonal antibody directed against B cells to be used in combination with lenalidomide followed by tafasitamab monotherapy for adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), including DLBCL arising from low grade lymphoma, who are not eligible for or refuse autologous stem cell transplant.

- a medicine indicated for the treatment of severe house dust mite-induced allergic rhinitis or rhinoconjunctivitis in adolescents (12-17 years) and adults.
- a clinical trial application to evaluate the efficacy and safety of a new personalised cancer vaccine in patients with unresectable advanced (Stage III/IV skin cancer) malignant melanoma and non-small cell lung carcinoma. (Stage IV lung cancer).
- an application for a line extension for an enzyme replacement therapy for patients with Fabry disease (α-galactosidase A deficiency).

95. Also in September, the EAG provided written comments on:
    - nine clinical trial applications for the treatment of COVID-19.

96. In October, the EAG discussed and made recommendations on:
    - a medicine indicated for the treatment of patients with multiple myeloma (a type of blood cancer).
    - a medicine indicated for the treatment of patients with breast cancer that has spread to other parts of the body or cannot be removed by surgery.
    - a clinical trial application to evaluate the efficacy and safety of a new drug substance for use in patients with a condition of the eye wherein the optic nerve, which connects the eye to the brain, becomes damaged (glaucoma).
    - a clinical trial application to evaluate the efficacy and safety of a new drug substance for use in patients with a disease that causes nerve damage through the build-up of a protein called amyloid.

97. In October, the EAG also considered and discussed an application for an influenza vaccine.

98. In October, the EAG also discussed a paper on the ban on UK-sourced plasma for fractionation which was introduced in 1999 due to vCJD transmission concerns.

99. Also in October, the EAG provided written comments on:
    - ten clinical trial applications for the treatment of COVID-19.
    - a paper for the treatment of COVID-19.

100. In November, the EAG discussed and made recommendations on:
    - a paper on the risk based approach to medicines control testing in the UK.
    - a paper on the independent batch release of COVID-19 vaccines – batch release in the event that one or more control tests is not performed by the NCL.

101. Also in November, the EAG provided written comments on:
    - a paper for the treatment of COVID-19.
    - four clinical trial applications for the treatment of COVID-19.

102. In December, the EAG provided written comments on:
    - eight clinical trial applications for the treatment of COVID-19.

COVID-19 Therapeutics Expert Working Group

103. 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.

104. The Expert Working Group met on 15 occasions in 2020, and discussed many items, some of the more high-profile topics included: dexamethasone, remdesivir, hydroxychloroquine, chloroquine, and vitamin D. The advice of the working group on the use of dexamethasone was further considered and discussed by the Commission on Human Medicines (CHM) leading to the issuance of guidance recommending its use in the management of hospitalised patients with COVID-19.

105. The Expert Working Group considered use of hydroxychloroquine / chloroquine in COVID-19 on multiple occasions, in order to promote decisions based upon the latest epidemiological data. The EWG's advice was shared with the CHM and the range of regulatory options for managing clinical trials involving hydroxychloroquine for treatment or prevention of COVID-19 were discussed. The CHM agreed with the recommendations and advised that all relevant trials should be systematically reviewed.

106. The CHM noted the Expert Working Group's advice on public statements on ibuprofen and angiotensin converting enzyme inhibitors (ACEi)/angiotensin receptor blockers (ARBs).

107. The Expert Working Group regularly invite representatives from other public and private bodies to furnish them with the latest information, this is integral to the group's ability to effectively fulfil their remit. Examples include representatives from the COVID-19 Genomics UK (COG-UK) consortium who provided and continue to provide critical information on the emergence of SARS-CoV-2 viral variants, specialists from King's College Hospital concerning both the use of anti-coagulants during the COVID-19 pandemic and the COVID symptom study (app), and WHO representatives who gave their perspectives on the Solidarity interim trial outcomes.

108. 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.

109. 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 Vaccine Benefit Risk Expert Working Group

110. 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.

111. The COVID-19 Vaccines Benefit-Risk Expert Working Group met on 18 occasions in 2020 and will continue regular as well as ad-hoc meetings as needed. The most important events advised on by the group included the authorisation under Regulation 174 of the HMR 2012 of the first vaccines shown to be effective against SARS-CoV-2 that included COVID-19 mRNA Vaccine BNT162b2 (Pfizer/BioNTech), COVID-19 Vaccine AstraZeneca and COVID-19 Vaccine Moderna. The group also advised on the safety of the vaccines following their administration based on reviews of reported suspected side effects.

112. 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 first COVID-19 vaccines, based on safety, quality and efficacy of the vaccines. Major topics of discussion and decisions reached by the group of vital clinical importance included:
    - Use of the vaccines in women of child-bearing age, pregnant women and breast-feeding women.
    - Recommended age groups for use of the vaccines.
    - Batch testing of the vaccines.
    - Close monitoring of emerging side effects following administration of the vaccines.
    - Extension of the dosing interval between doses for COVID-19 mRNA Vaccine BNT162b2.
    - Post-effectiveness studies to monitor the effectiveness of the vaccines.
    - Ad-hoc groups were convened to discuss individual topics e.g. quality aspects of COVID-19 mRNA Vaccine BNT162b2, theoretical risk of HLA sensitisation and COVID-19 Vaccine AstraZeneca.

113. 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, National Institute of Biological Standard and Control (NIBSC), Public Health England (PHE), representatives from NHS England, NHS Scotland, NHS Wales and NHS Northern Ireland, as well as the deputy CMO's office.

COVID-19 Vaccines Safety Surveillance Methodologies Expert Working Group

114. In May 2020, the CHM established an Expert Working Group (EWG) to advise the Medicines and Healthcare products Regulatory Agency (MHRA) on its safety monitoring strategy for COVID-19 vaccine(s). The EWG held four meetings from May to October 2020, during which it considered proposals and methodologies for MHRA-led vigilance activities. Based on this advice, the MHRA implemented a four-stranded approach to vigilance of COVID-19 vaccines in December 2020 with the first vaccine deployment; (i) Enhanced passive surveillance – 'observed vs expected' analysis; (ii) Rapid Cycle Analysis and Ecological analysis based on CPRD data; (iii) Targeted active monitoring, via the Yellow Card Vaccine Monitor; (iv) Formal, ad hoc epidemiological studies". This strategy was subsequently endorsed by the CHM.

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

115. In 2020, the GRIDEAG convened virtually three times and provided advice by written correspondence on seven occasions.

116. In June, the EAG discussed and made recommendations on:
    - a medicine indicated for the treatment of moderate to severe atopic dermatitis in adult patients who are candidates for systemic therapy.

117. In July, the EAG discussed and made recommendations on:
    - a medicine indicated for the treatment of adults with psoriatic arthritis that has not responded to other medicines.

118. Also in July, the EAG provided written comments on:
    - a medicine indicated for the treatment of moderate to severe chronic pain associated with a type of joint disease (osteoarthritis) in adult patients for whom treatment with non-steroidal anti-inflammatory drugs (NSAIDs) and/or an opioid is either ineffective, not tolerated or inappropriate.
    - a medicine indicated for the treatment of actinic keratosis, a chronic skin condition of the face or scalp in adults.

119. In August, the EAG provided written comments on:
    - a medicine for the treatment of arthritis associated with psoriasis, a skin condition in adult patients and is also indicated to treat ankylosing spondylitis, a condition associated with inflammation of the joints of the spine and other joints.
    - a medicine used for the treatment of moderate to severe house dust mite-induced allergic conditions.

120. In September, the EAG reviewed data from the MHRA Yellow Card scheme and literature regarding topical steroid withdrawal (colloquially referred to as red skin syndrome, a term for a severe reaction experienced on stopping treatment with topical corticosteroids (TCS).

121. Also in September, the EAG provided written comments on:
    - a medicine indicated for the treatment of acne.
    - a medicine indicated for the treatment of anaemia in adult patients with chronic kidney disease.

122. In October, the EAG provided written comments on:
    - a medicine used for the treatment of severe atopic dermatitis (that causes dry and itchy patches of skin that are often red and swollen). The medicine is used in adult and adolescent patients that have either not responded to other treatments or relapsed after other treatments, or those who are ineligible or intolerant to other treatments.

Infection Expert Advisory Group (IEAG)

123. In 2020, the IEAG provided written comments on 119 occasions.

124. In January, the EAG provided written comments on:
    - a medicine indicated for the treatment of long-term (chronic) hepatitis delta virus (HDV) infection in adults.
    - a medicine used for the treatment of several types of bacterial infections.

125. In February, the EAG provided written comments on:
    - a medicine indicated for the treatment of skin infections.
    - a paper on the use of antivirals and other agents for the treatment of COVID-19.
    - a paper on the risks of birth defects and medicines used to treat infections.
    - a medicine indicated in the treatment of tuberculosis.

126. In March, the EAG provided written comments on:
    - a medicine with a proposed indication for the treatment of COVID-19.
    - a medicine indicated for the treatment of preventing flu in adults and children from 12 years of age.

- four clinical trial applications for the treatment of COVID-19.

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

128. In May, the EAG provided written comments on:
    - 21 clinical trial applications for the treatment of COVID-19.

129. In June, the EAG provided written comments on:
    - a medicine indicated for the prevention and treatment of pneumonitis caused by the pathogen Pneumocystis jirovecii.
    - 16 clinical trial applications for the treatment of COVID-19.

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

131. In August, the EAG provided written comments on:
    - response letter to the initial MHRA review on a paper for the treatment of COVID-19.
    - five clinical trial applications for the treatment of COVID-19.

132. In September, the EAG provided written comments on:
    - ten clinical trial applications for the treatment of COVID-19.

133. In October, the EAG provided written comments on:
    - ten clinical trial applications for the treatment of COVID-19.

134. In November, the EAG provided written comments on:
    - four clinical trial applications for the treatment of COVID-19.

135. In December, the EAG provided written comments on:
    - eight clinical trial applications for the treatment of COVID-19.

Isotretinoin Expert Working Group (IEWG)

136. 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.

137. The IEWG held two meetings in March and September 2020. During these meetings the terms of reference were agreed along with a work plan and they began consideration of the available scientific data. The importance of patient's and other stakeholder's input in the review was recognised and a public call for information was launched in November to gather views from patients, their families and healthcare professionals.

138. The IEWG will consider all responses to the call for information and it is anticipated that there will be at least two further meetings, including a

meeting where patients and other stakeholders will present their views to the IEWG.

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

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

140. The MWHEAG considered the latest evidence and made recommendations on the following issues with marketed medicines:
    - risks of liver toxicity with use of ulipristal acetate 5mg for gynaecological conditions.
    - Rates of adverse events when switching between levothyroxine medicines used in the treatment of under active thyroid glands.

141. The MWHEAG considered the evidence and made recommendations on applications related to new uses of existing medicines or new medicinal products for contraception, prevention of premature birth, induction of labour, uterine fibroids, post-menopausal hormonal replacement therapy and treatment of under active thyroid glands.

142. The MWHEAG considered and made recommendations on Prescription Only Medicine (POM) to Pharmacy Only (P) reclassification of medicines for contraception and post-menopausal vaginal atrophy.

Safety of Medicines during pregnancy

143. During the year the MWHEAG monitored all reports of suspected ADRs associated with use of medicines in pregnancy received by MHRA. The MWHEAG reviewed 696 new reports of suspected ADRs associated with use of medicines in pregnancy received from September 2019 to September 2020. The majority of reports received during this period did not raise any new concerns.

144. The MWHEAG reviewed potential safety signals following use of the following medicines during pregnancy and recommended that no regulatory action was warranted in each case: paracetamol, venlafaxine, doxylamine succinate/ pyridoxine hydrochloride, prochlorperazine, and macrolide antibiotics.

145. The MWHEAG considered further review and/or regulatory action should be taken for use of the following medicines during pregnancy:

146. Pivmecillinam: a risk of false positive tests neonates for isovaleria acidaemia due to carnitine deficiency following prolonged maternal use of pivmecillinam was highlighted by a small number of reports. The EAG considered that relevant clinicians are likely aware of this risk following pivmecillinam use but noted the recommendation from the European Pharmacovigilance Risk Assessment Committee (PRAC) for updates to product information to remind healthcare professionals of this risk.

147. Aripiprazole: The EAG considered the evidence for possible lactation suppression after taking aripiprazole. The EAG considered that some women may experience lactation suppression after taking aripiprazole and it should be considered how best to communicate this.

148. SSRI/SNRI antidepressant medicines: The EAG noted the PRAC recommendation to update the Product Information for some antidepressants to include information on small increased risk of postpartum haemorrhage (PPH) associated with use in the last month before delivery. The EAG recommended that this should be communicated in the context of other risks for postpartum bleeding and a small increased risk of PPH when used in the month before delivery and supported the provision of this information via Drug Safety Update.

Neurology, Pain and Psychiatry Expert Advisory Group (NPPEAG)

149. In 2020, the NPPEAG convened virtually four times and provided advice by written correspondence on nine occasions.

150. In January, the EAG discussed and made recommendations on:
    - a medicine indicated to calm emotions particularly in the case of restlessness and agitation.

151. Also in January, the EAG was provided with an oral update on the status of an antidepressant medicine to be used in combination with oral antidepressant therapy, for the rapid reduction of depressive symptoms in adult patients with a moderate to severe episode of major depressive disorder who have active suicidal ideation with intent that was considered at the previous meeting in November 2019.

152. In March, the EAG discussed and made recommendations on:
    - a gene therapy medicine indicated for the treatment of metachromatic leukodystrophy in patients from birth to before 17 years and in older patients for whom disease onset occurred before 17 years.
    - a medicine indicated for the treatment of adults with depression, neuropathic pain, chronic tension headache and migraine.

153. Also in March, the EAG was presented with an analysis of UK Yellow Card data and published literature relating to cases of antipsychotic toxicity in patients taking high doses of antipsychotics long-term.
    - antipsychotic drug level monitoring for people on long-term high-dose treatment. Recommendations were based on an analysis of UK Yellow Card data and published literature.
    - blood level monitoring for an antipsychotic drug in people with pneumonia and other inflammatory conditions. Recommendations were based on an analysis of Yellow Card reports of fatal cases of heart conditions, pneumonia and overdose.

154. In April, the EAG provided written comments on the antidepressant medicine reviewed by the EAG in January 2020.

155. In May, the EAG provided written comments on:
    - a medicine indicated for the treatment of depression, especially if phobic symptoms are present or if other types of antidepressants have failed.
    - a gene therapy medicine indicated for the treatment of adults and children with L-amino acid decarboxylase deficiency.

156. In June, the EAG provided written comments on:
    - a medicine indicated for the treatment of seizures associated with Dravet syndrome, a rare, drug-resistant epilepsy in children aged 2 years to 17 years and adults.

157. In July, the EAG provided written comments on:
    - an antiepileptic medicine indicated for the treatment of focal seizures in adults aged 18 to 65 years.
    - a medicine indicated for the treatment of symptoms of depressive illness, especially where sedation is required.

158. In September, the EAG met twice to discuss and make recommendations on:
    - the antidepressant medicine reviewed by the EAG in January and April 2020.
    - a signal of restless legs syndrome associated with an antihistamine medicine.
    - the safety of antiepileptic medicines during pregnancy.

159. In November, the EAG provided written comments on:
    - a proposed extension of the indication for the antidepressant medicine reviewed by the EAG in January, April and September 2020.
    - a medicine indicated for the treatment of depression.
    - a medicine indicated for the treatment of schizophrenia in patients currently stabilised with oral antipsychotics.

Oncology and Haematology Expert Advisory Group (OHEAG)

160. In 2020, the OHEAG convened virtually eight times and provided advice by written correspondence on eight occasions.

161. In March, the EAG provided written comments on:
    - a paper proposing to amend the pregnancy prevention programmes for patients taking certain medicines to allow home pregnancy testing for women of childbearing potential.

162. In April, the EAG discussed and made recommendations:
    - on a medicine indicated for the treatment of patients with a certain type of cancer called chronic lymphocytic leukaemia/small

cell lymphocytic lymphoma that were not responding to one prior treatment and patients with a certain type of cancer called follicular lymphoma that were not responding to one prior treatment.

- on a medicine indicated for the treatment of patients with a type of bile duct cancer (with a defect in the FGFR2 protein) that has come back after previous treatment(s).
- on a medicine indicated for the treatment of patients with a certain type of cancer called hairy cell leukaemia that comes back or is no longer responding after two prior treatments.
- on a medicine indicated for the treatment of patients with a disorder of blood clotting called Haemophilia A (severe form).
- a medicine indicated for the treatment of a type of pancreatic cancer (BRCA-mutated) that has responded to the first treatment with standard platinum-based chemotherapy.

163. Also in April, the EAG made recommendations on Early Access to Medicine Scheme (EAMS) procedures for;
    - a medicine indicated for the treatment of a certain type of liver cancer called hepatocellular carcinoma.
    - a medicine indicated for the treatment of adult patients with unresectable (unable to be removed) advanced, recurrent or metastatic (cancer which has spread) oesophageal squamous cell cancer after prior fluoropyrimidine- and platinum-based chemotherapy.

164. Also in April, the EAG provided written comments on:
    - safety referral recommendations on testing for Dihydropyrimidine Dehydrogenase (DPD) deficiency.

165. In May, the EAG discussed and made recommendations on:
    - a medicine indicated for the treatment of patients with a certain type of blood cancer called multiple myeloma that is not responding to three prior treatments.
    - a medicine used in combination with trastuzumab and capecitabine for the treatment of patients with locally advanced unresectable or metastatic HER2-positive breast cancer that can either not be removed or has spread to other parts of the body, including the brain, who have received at least 2 prior anti-HER2 treatment regimens.
    - a medicine indicated for the treatment of adult patients with an enlarged spleen or with symptoms related to myelofibrosis, a rare form of blood cancer.
    - a medicine indicated for the treatment of adult patients with mantle cell lymphoma a type of cancer of the white blood cells that has either not responded to treatment or has come back after treatment.
    - a medicine indicated for the treatment of adult patients with a type of bowel cancer (BRAF V600E-mutated) who have received prior systemic therapy.

- a medicine used in combination with cetuximab, for the treatment of adult patients with a type of bowel cancer (BRAF V600E-mutated) that has spread to other parts of the body, who have received prior systemic therapy.

166. In June, the EAG discussed and made recommendations on:
    - a medicine indicated in combination with other medicine for the treatment in men and postmenopausal women who have advanced breast cancer with a gene defect that has progressed after prior treatment.
    - a medicine indicated for the treatment in children aged 3 years and above with plexiform neurofibromas (benign tumour of peripheral nerves) that cannot be completely removed by surgery.
    - a medicine indicated for the treatment of adult patients with a type of prostate cancer (with defects in gene repair mechanisms) that has spread from where it started into different areas of the body and is no longer responding to treatment to lower testosterone and who have already been treated with specific hormonal agents (abiraterone acetate or enzalutamide).

167. Also in June, the EAG provided written comments on:
    - a medicine used to treat adult patients with a type of bone marrow cancer of the white blood cells, multiple myeloma, that has relapsed after treatment.
    - a medicine indicated for the treatment of endometrial cancer (cancer of the lining of the womb) where it has spread or cannot be removed by surgery.
    - a medicine indicated for the treatment of relapsed or recurrent acute myeloid leukaemia, a cancer of white blood cells, in adult patients.

168. In July, the EAG discussed and made recommendations on:
    - a medicine indicated for the treatment of adult patients with a cancer that affects the bladder (called urothelial carcinoma) when it has gone through the bladder wall or spread to other parts of the body.
    - a medicine indicated for the treatment of adults with bladder cancer that has spread and has progressed after recent chemotherapy.
    - a medicine indicated for the treatment of adult patients with a cancer that affects the bladder, called urothelial carcinoma when it has gone through the bladder wall or spread to other parts of the body.

169. In August, the EAG discussed and made recommendations on:
    - a medicine indicated for the treatment of adult patients with acute myeloid leukaemia, a type of blood cancer.

- a medicine indicated for the treatment of adult patients who have advanced lung cancer with a gene defect and progressed on prior treatment.
- a medicine indicated for the treatment of type of cancer in the bladder or urinary tract called urothelial carcinoma.

170. Also in August, the EAG provided written comments on:
    - a medicine indicated for the prevention of deep vein thrombosis (blood clots) in patients undergoing general or orthopaedic surgery.
    - a medicine indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, a type of blood cancer, and who are not eligible for or refuse autologous stem cell transplant.

171. In September, the EAG discussed and made recommendations on:
    - a medicine indicated for the treatment of patients with multiple myeloma (a type of blood cancer).
    - a medicine indicated for the treatment of adult patients with a rare type of blood cancer (Waldenström's macroglobulinaemia).
    - a medicine indicated for the treatment of patients with breast cancer that has either spread to other parts of the body or cannot be removed by surgery.
    - a medicine as additional treatment for patients with familial adenomatous polyposis.
    - a medicine indicated for the maintenance treatment of patients with ovarian, fallopian tube or peritoneal cancer after chemotherapy.
    - a medicine indicated for the treatment of acute myeloid leukaemia.

172. Also in September, the EAG provided written comments on:
    - a medicine indicated for the prevention of painful crises, including sudden chest pain and severe chronic anaemia, in patients with a blood disorder called sickle cell anaemia.

173. In October, the EAG discussed and made recommendations on:
    - a medicine indicated for patients with lung cancer and thyroid cancer.

174. In November, the EAG made recommendations on Early Access to Medicine Scheme (EAMS) procedures for;
    - a medicine indicated for the treatment of mesothelioma.
    - a medicine indicated for the treatment of a type of bile duct cancer (metastatic/ advanced cholangiocarcinoma with FGFR2 fusion or rearrangement) in adults who have received at least one previous chemotherapy treatment.

Optimising Data on Medicines used in Pregnancy Expert Working Group

175. The EWG was set up to consider better ways to collect and monitor data on the safety of medicines during pregnancy and breastfeeding in response to the recommendations of the Report of the EWG on Hormone Pregnancy Tests published in November 2017[1]. The Group convened in July 2019 and met three times in 2019 and a further two times in June and August 2020.

176. The Group put together a comprehensive summary of key UK sources of observational data on medicines used in pregnancy and breastfeeding including ongoing and proposed developments for improved data. This summary formed the basis for the Group to identify gaps in the currently available data and make recommendations for how these might be addressed using existing data sources or using novel approaches to data collection.

177. Gaps in available data relevant to medicines used in pregnancy identified by the Group related to both exposure and outcome data. Gaps in exposure data include: medicines dispensed and administered in secondary care, use of over-the-counter medicines, and medication details such as dosage, duration and indication. Gaps in outcome data include: early miscarriage prior to a maternity booking appointment, and long-term physical and neurodevelopmental outcomes in children. The Group also identified a number of other important considerations for data on medicines used in pregnancy including: the importance of data quality, data linkage, the need for public and professional engagement with secondary use datasets and information governance.

178. The Group made recommendations to address the gaps in data collection, on optimising the linkage of existing datasets, on improving data quality and to encourage research on the safety of medicines used in pregnancy and breastfeeding. The CHM fully endorsed the conclusions and recommendations of the EWG at its meeting in November. The report of the EWG was published on 11 January 2021 and formed part of a Written Ministerial Statement on an update on the government's response to the Independent Medicines and Medical Devices Safety Review.

Paediatric Medicines Expert Advisory Group (PMEAG)

179. The PMEAG advises the CHM on the safety, quality and efficacy of medicines for paediatric use, including all matters relating to the implementation of the European Paediatric Regulation. The PMEAG met seven times in 2020 and provided advice through written correspondence

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

for an additional sixteen papers. Below are summarised the papers discussed during the meetings.

Paediatric Work-sharing procedures

180. The PMEAG considered one product assessed under Article 45 of the EU Regulation (coordinated at European level by Member States) in the therapeutic area of epilepsy.

New Paediatric Drugs

181. The PMEAG considered three applications for new medicinal products with paediatric indications including, a new gene therapy medicine indicated to treat adult and paediatric patients for a genetic condition affecting the way signals are passed between certain cells in the nervous system, a medicine indicated for a genetic condition in which aging appears in childhood and lastly a medicine indicated for the treatment of seizures associated with a complex form of epilepsy in children and adults.

Marketing authorisation applications supported by paediatric data

182. The PMEAG advised on eight applications for variation requests on existing products. The products covered a range of indications including, two medicines intended for the treatment of venous thromboembolism in paediatric patients, a medicine intended for the control of status epilepticus and for the prevention and treatment of seizures in paediatric patients, a medicine intended for weight loss in adults and adolescents, a medicine intended for the treatment of schizophrenia, a medicine intended for the treatment of ulcerative colitis - an inflammatory disease of the large bowel, a medicine intended for treatment of juvenile idiopathic arthritis, an inflammation of joints, and lastly a medicine for the treatment of interrupted breathing in premature babies.
The PMEAG advised on a paper reviewing a medicine used for bladder condition and depression and agreed to the proposed update of the paediatric indications.

Safety of medicines in children

183. In 2020 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 for a product used in allergic conditions in children, the use of opioids in the treatment of paediatric chronic non-cancer pain, and the risk of neurobehavioral reactions in association with an asthma drug in children and adolescents. The PMEAG was also presented with a review on storing medicines safely away from children, including ensuring child resistant caps are replaced correctly. Lastly, the experts discussed and advised on a paper on updating a Drug Alert for a drug used for the treatment of infections in neonates.

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

184. The PMEAG discussed a paper concerning coronavirus infections (COVID-19) in children and an additional paper on the Paediatric Inflammatory Multisystem Syndrome Temporally Associated With SARS-CoV-2 (PIMS-TS). The EAG commented on a review of paediatric studies conducted in UK in the last 5-years.

185. Finally, the PMEAG heard an update on Brexit and the Agency's plans with regards to supporting the regulation of paediatric medicines in the UK after exit day.

Pharmacovigilance Expert Advisory Group (PEAG)

186. The CHM'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.

187. The PEAG met eleven times in 2020, including eight times by teleconference, and provided advice by written procedure on four further occasions.

188. During 2020, the PEAG considered papers and advised on the following:
    - risk of major congenital malformations following maternal use of macrolide antibiotics during the first trimester of pregnancy.
    - a review of the evidence on the possible impact of Angiotensin Converting Enzyme (ACE) inhibitor medicines and Angiotensin Receptor Blockers (ARBs) on SARS-CoV-2 infection and severity of COVID-19 symptoms.
    - COVID-19 virus acquisition and outcomes in patients using proton pump inhibitors.
    - risk of acute kidney injury with remdesivir indicated for the treatment of COVID-19 in patients with pneumonia requiring supplemental oxygen.
    - COVID-19 and INR test results in patients taking vitamin K antagonists including warfarin.
    - Risk of neural tube defects including spinal bifida, with first trimester exposure to Xoneva (doxylamine succinate/pyridoxine hydrochloride), indicated for nausea and vomiting in pregnancy.
    - risk of neural tube defects following use of dolutegravir during pregnancy.
    - risk of microcephaly following use of efavirenz during pregnancy
    - Possible drug-drug interaction between hydroxychloroquine/chloroquine and macrolide antibiotics.
    - cardiovascular risks and bleeding risk with non-vitamin K antagonist oral anticoagulants versus warfarin.

- a review of cases of e-cigarette or vaping associated lung injury (EVALI) in the UK.
- increased risk of hearing impairment with aminoglycoside antibiotic use in people with the m.1555A>G mitochondrial genetic mutation.
- use of nebulisers at home for delivery of asthma rescue medication to children and adolescents.
- risk of dependence and misuse with diphenhydramine.

189. The PEAG also considered matters raised by Coroners under Regulation 28 of the coroners (investigations) regulations 2013 to Prevent Future Deaths. In 2020, these included matters relating to the need for routine plasma drug level monitoring for antipsychotics to prevent toxicity when used long term at high doses; the need for therapeutic plasma drug level monitoring for fluoxetine; and the risk of psychosis with doxycycline.

190. The PEAG considered and gave advice on the Risk Management Plan for Spravato (esketamine hydrochloride) indicated for treatment-resistant depression; and for risdiplam which was made available under the UK Early Access to Medicines Scheme in September 2020 for the treatment of spinal muscular atrophy types 1 and 2.

191. The Group also gives advice on the need for active risk communications, their format and appropriate recipients. During 2020 the PEAG advised on communications for fluorouracil, tegafur and capecitabine and the need to test patients for dihydropyrimidine dehydrogenase (DPD) deficiency prior to their use; on denosumab and the risk of multiple vertebral fractures on stopping treatment; as well as on communications to raise awareness of the neuropsychiatric side effects of montelukast.

192. In accordance with its responsibility for oversight of the UK Yellow Card scheme, the PEAG considered Yellow Card reporting statistics at each of its meetings in 2020. The PEAG also gave advice on one application for access to Type II Yellow Card data for research purposes.

193. 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).

Real World Data Ad Hoc Working Group

194. The remit of the group was to review the guidance produced by MHRA internal group on Real-World Evidence (RWE) 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.

195. In 2020, the Real World Data Ad Hoc Group met twice.

196. In September, the group discussed the draft guideline on randomised controlled trials generating real-world evidence to support regulatory decisions. Proposals were made which were to be incorporated into the document to produce a revised draft. The group also discussed the plan for the public consultation for the guideline. The remit of the group was also discussed and agreed.

197. In October, the group discussed the revised guideline and subject to further revisions agreed that it could go out for public consultation. The consultation materials were discussed and agreed. The group also discussed an early draft of the guideline on using real-world evidence as an external control in trials to support a regulatory decision.

REPORTING OF SUSPECTED ADVERSE DRUG REACTIONS 2020

198. 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 via the European Medicines Agency (EMA). To note in 2021, following the UK's exit from the EU, pharmaceutical companies will be legally obliged to 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.

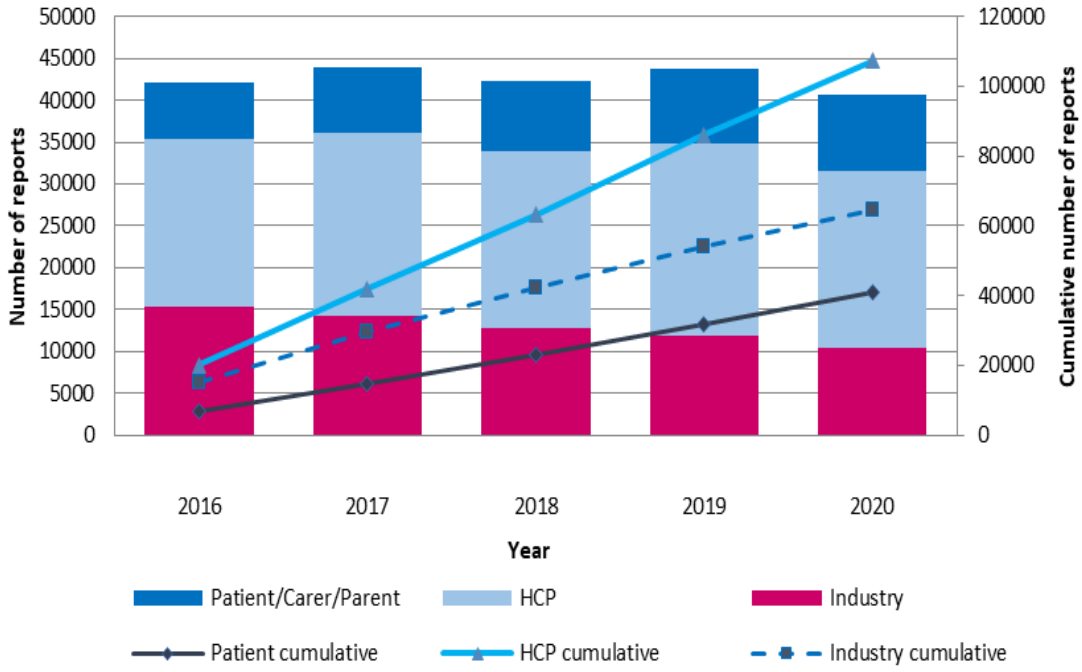
199. The total number of UK spontaneous suspected ADR reports received from all sources over the last five years shows a stable and robust system with an average of 42,560 reports per year as shown in figure 1 below. As expected with lockdown and social distancing measures introduced in the NHS and across the UK in March 2020, the overall total numbers of Yellow Card reports decreased by 7% in 2020 compared to 2019 (3,012 less reports). Similarly, a decreasing trend in patient safety incidents reported by healthcare professionals was also seen across the NHS compounded by factors such as a greater focus on COVID-19 pandemic, changes in clinical care, and less face to face interaction between healthcare professionals and patients. Due to the additional focus on the pandemic, to reinforce the Yellow Card scheme and support patients, the MHRA ran four major campaigns in 2020.

200. Overall direct Yellow Card reporting from healthcare professionals accounted for 52% (21,246 reports) of all suspected ADR reports received in 2020 and 22% (9,109 reports) of all reports were received

from members of the public (including patients, parents and carers). In 2020, Yellow Card reports from members of the public increased by 4% and healthcare professionals decreased by 8% compared to the previous year, due to the implications of the pandemic.

201. In 2020, suspected ADR reported from the pharmaceutical industry accounted for 25% (10,372 reports) of all reports received by the MHRA. This represents a decline of 12% (1423 reports) in relation to 2019 figures. The decrease in reports follows no particular trends. Pharmaceutical companies have been contacted and we are assured that they are reporting appropriately.

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



Year	2016	2017	2018	2019	2020
Number of Reports	42,085	43,935	42,240	43,776	40,764

202. In response to the pandemic, MHRA launched a dedicated Coronavirus Yellow Card reporting site in May 2020 for healthcare professional and patients to report suspected side effects to a medicine and incidents involving medical devices associated with Covid-19 treatment but also in preparedness for roll out of any future Covid-19 vaccines. Administration of the first COVID-19 vaccine started in early December 2020 and MHRA received 2,737 reports associated with the vaccine up to the end of the year. Based on previous experience, the launch of new vaccines, global attention and national mass vaccination programme, exponential

increases in Yellow Card reporting are expected in 2021 and have begun to be seen.

Patient ADR Reporting

203. In 2020 we received the highest number of reports from the public since the scheme was established over 50 years ago with 9,008 Yellow Card reports received. These reports accounted for 22% of all ADR reports received over the year. There has been a 33% (2,257 reports) increase in patient, parent and carer reports over five years, since 2016. Promotion and education are key pillars of the MHRA's Yellow Card strategy with the five Yellow Card Centres where significant efforts have been made to proactively encourage reporting from healthcare professionals and patients.

204. In early 2020, credit card sized information cards for the public were distributed to various patient organisations. These were also disseminated via our five Yellow Card Centres alongside new pharmacy bag stickers to promote reporting and encourage the discussion about side effects at point of dispensing medicines.

205. The MHRA's collaboration continued with the Community Pharmacy Patient Safety Group, which represents the 18 largest pharmacy chains across UK; in particular, a new partnership with Superdrug Ltd was established. A number of activities included distribution of healthcare professional Yellow Card forms, information on e-learning and attending their annual clinical conference for their pharmacy and nursing teams. To encourage patient reporting there were new stickers for pharmacy bags, credit card sized information cards and Yellow Card forms for the public distributed to over 204 Superdrug pharmacies and their health clinics for nurses. This was supported by materials that were distributed in a pack with a joint letter, and internal communications, for example in their clinical newsletter and intranet.

206. Following consultation seeking views on how the MHRA engages and involves patients in 2019, campaign messages used in 2020 were tested with patient groups.

207. The MHRA ran four campaigns in 2020, three of which were during the pandemic lockdown. The MHRA held an ADR awareness week campaign which took place from 17-23 February 2020 on social media to encourage patients and healthcare professionals to report to the Yellow Card scheme. The theme was to report when using or giving multiple medicines (polypharmacy). During the campaign week, there was a 57% increase in direct reporting compared to the same week a year before. This contributed to February 2020 showing a 21% increase in direct suspected adverse drug reactions reported to the Yellow Card scheme compared to the previous year. This campaign reached approximately 250,000 people on social media during the week. Each campaign was supplemented with a Drug Safety Update Article and an MHRA press release.

208. The MHRA continues to work with the Cross UK partnership of devolved administrations, National Institute for Clinical Excellence (NICE) and the Royal Pharmaceutical Society for campaigns. Approximately 40,000 Yellow Card materials were distributed to various patient and healthcare professional stakeholders. Further engagement included through the chair of Community Pharmacy Patient Safety Group which resulted in the Chemist+Druggist publishing a social media blog from the Chair to encourage pharmacy and patients to report.

209. Due to Covid-19 and the MHRA working remotely, electronic reporting was encouraged with messages added to the website. The Yellow Card freephone line hours were extended to 9am-5pm each weekday. In May, the MHRA held a second campaign to launch the Covid-19 reporting site to streamline reporting relating to Covid-19 treatment and in readiness for future vaccines coupled with ADR messages to encourage reporting. This was spearheaded with a 'Dear Healthcare Professional letter' which went to all healthcare professionals in June 2020.

210. A number of activities took place to encourage reporting in 2020 during the pandemic, the MHRA and its Yellow Card Centres adapted to promote the scheme online, and organised virtual and recorded presentations to raise awareness of the scheme. MHRA also worked with providers such as Attend Anywhere, a virtual waiting room for patients, and devolved administrations to include messages about reporting to maintain awareness. Work continues in this area.

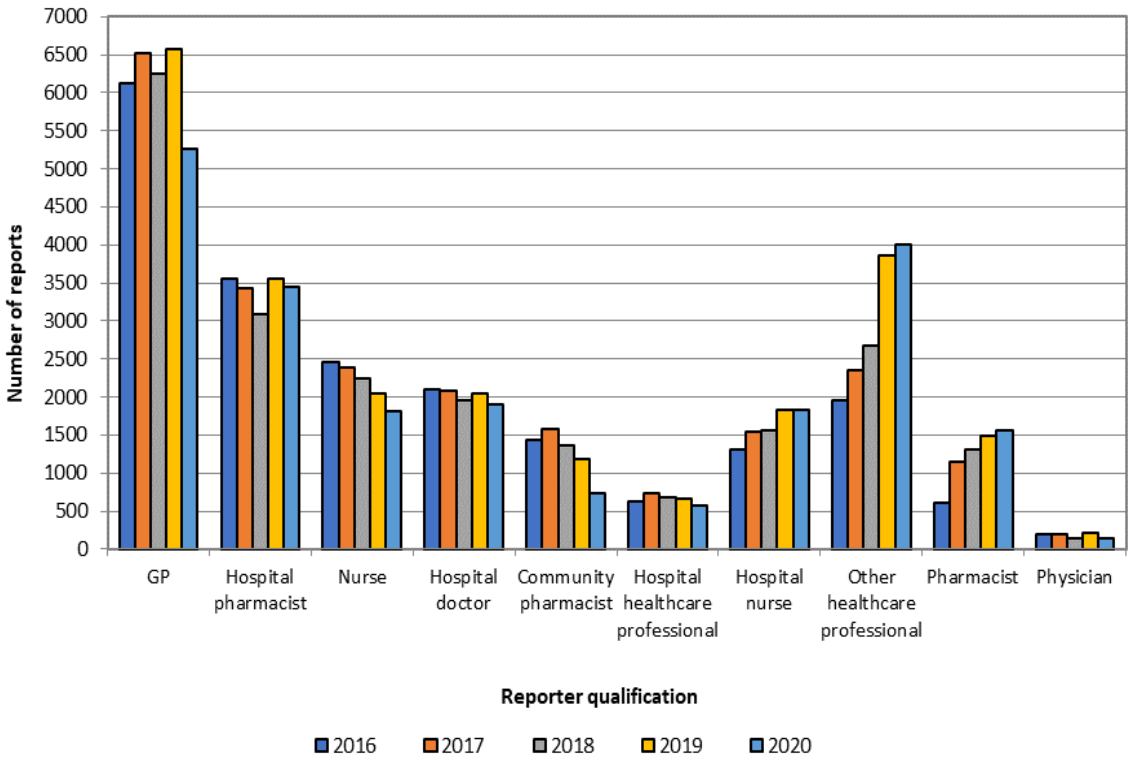
211. The third week long campaign was held around World Patient Safety Day 2020 (17 September 2020). The campaign was marked with a new campaign strapline *'Every report counts',* emphasising that collectively, every report helps to build a bigger picture of patient safety and can lead to action to protect others. The campaign featured insights from patient and healthcare professionals who have previously reported and helped lead to MHRA acting to improve the safe use of medicine and medical devices. For example, the MHRA developed animations and a video of a pharmacist in Liverpool, who shared their experience of reporting and what happens to a report and subsequent signal, which the MHRA took regulatory action on. The video, in addition to previous Yellow Card promotional videos, is hosted on the MHRA's YouTube channels. It was added to the Yellow Card reporting website in a number of places as well as on the MHRA GOV.UK pages.

212. The MHRA also ran #MedSafetyWeek from 2–8 November 2020. A Drug Safety Update article for the campaign as well as a press release was published, copy for stakeholders to help promote the campaign week alongside the use of the materials. As a result, there were small increases in reporting seen in hospital pharmacy, patient reporting, general pharmacy (speciality not specified), pre-reg pharmacy and radiographers. This followed after general increase seen as a result of patient safety day efforts which improved reporting from healthcare professionals.

Healthcare professional ADR reporting

213. In 2020 the decline in healthcare professional reporting has been seen across most reporting qualifications and reporting routes. Yellow Card reports received directly from healthcare professionals in 2020 decreased by 8% (1,865 reports) when compared to 2019. A breakdown of direct healthcare professional reports by reporter qualification between 2016 and 2020 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.*

214. In previous years GPs reported the most suspected ADR reports compared to all other healthcare professionals to the Yellow Card scheme. For the majority of healthcare professional reporter groups, reporting to the scheme decreased in 2020 due to the pandemic as outlined earlier in this section, GP reporting decreased by 20%. Overall, in 2020 reports from GPs accounted for 25% of all direct healthcare professional reports.

215. Figure 2 shows a slight increase in the number of reports received compared to last year from pharmacists and other healthcare professionals, with increases of 4% and 5% respectively. Reporting from other healthcare professionals has continued to increase over the last 5 years, in 2020 other healthcare professional reports accounted for 19% of all direct reports received. The most frequently reported professions within this group were unspecified other healthcare professionals (51%), followed by pharmacy assistants (15%), radiographers (10%), and pre-registration pharmacists (10%).

216. We have continued to work with stakeholders such as General Pharmaceutical Council, Royal Colleges, professional associations and groups of networks such as the National Medication Safety Network to reverse the small decline seen in healthcare professional reporting.

217. The trends within these reporter qualifications for 2020 highlight the impact the pandemic has had, positives in certain reporter groups that are reflected in a change in clinical care but also highlight a need to re-engage as part Yellow Card strategic efforts in 2021, including how care is being delivered through social distancing measures and virtually in healthcare settings.

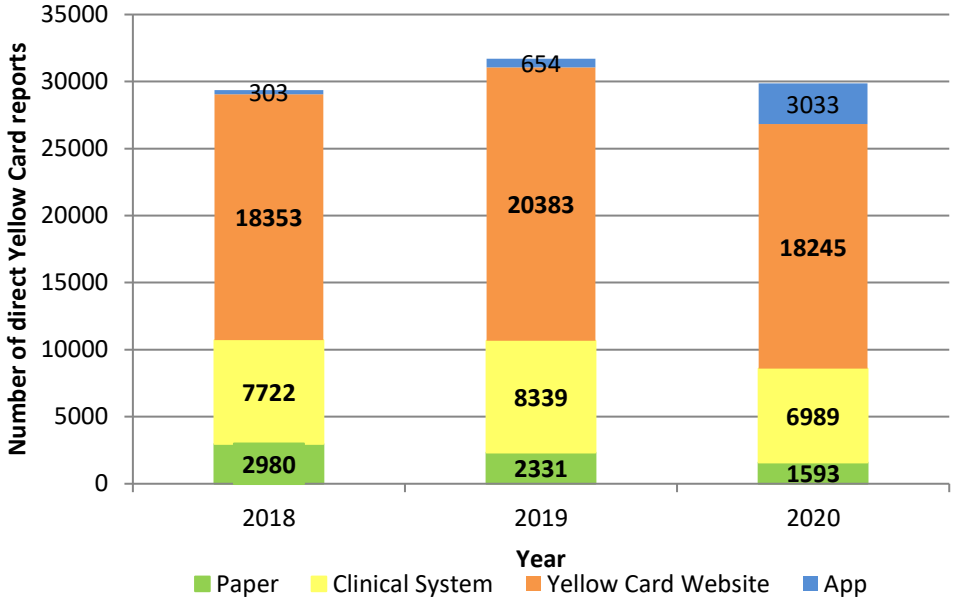
Electronic ADR Reporting

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

219. In 2020, 93% (9,109 reports) of all ADR reports from patients, parents and carers were reported electronically, with a 7.5% (580 reports) decrease in reports via the Yellow Card website compared to 2019.

220. In 2020, 93% (21,246 reports) of all direct healthcare professional reports were received electronically, with 52.4% (11,142 reports) through the Yellow Card website, which is promoted the most, and 33% (6,987) via clinical systems. Paper reports formed the majority of the remaining 8% (1,704 reports) of direct healthcare professional reports. A breakdown of the methods of reporting from healthcare professionals can be found in Figure 3.

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

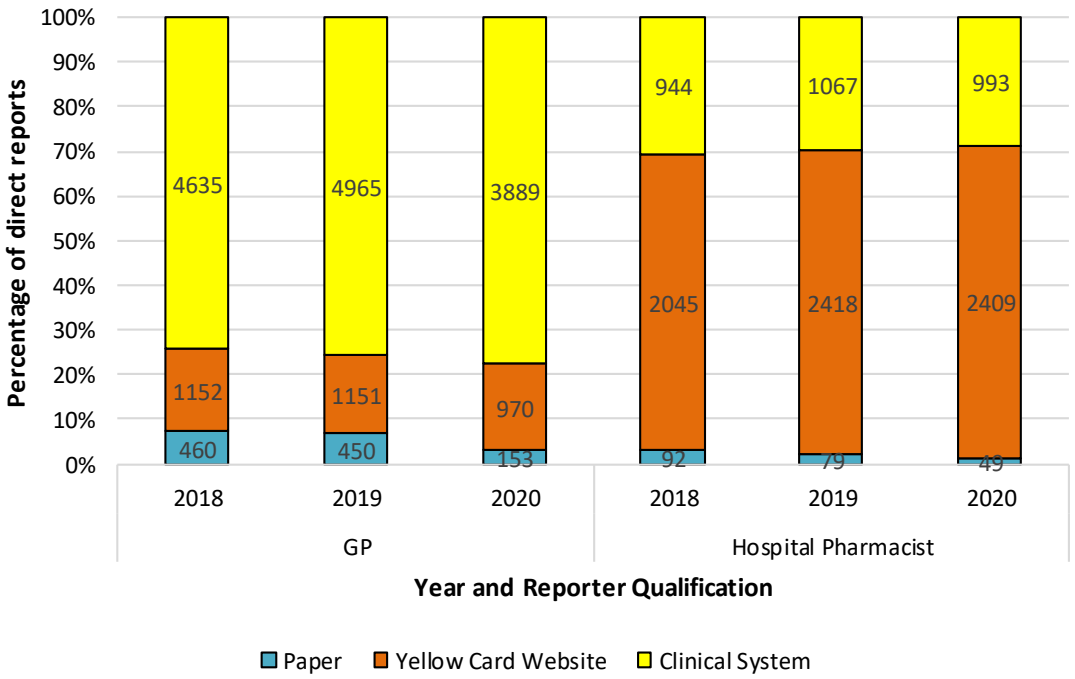


221. The number of suspected ADR reports received directly from the Yellow Card form being integrated into clinical IT systems has increased by 8.5% (654 reports) compared to 2018. A key part of the MHRA's Yellow Card strategy is a focus on making Yellow Card reporting easier and more accessible to healthcare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

222. Reports from all clinical systems formed 32% of all direct reports from healthcare professionals. Further work continues to engage other clinical system providers to integrate Yellow Card reporting functionality and further extend this proven method of increasing reporting.

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

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



224. In 2020, 97% of all GP reports were received electronically, with GP reports via clinical systems accounting for 78% (3,889 reports) of all reports from GPs. Of this, SystmOne accounted for 62.5% (3,292 reports) of suspected ADR reports from GPs. Reports from Vision accounted for 15% (597 reports) of all GP reports in 2020.

225. Reports received via hospital pharmacists via clinical systems (MI Databank) decreased by 6.5% (69 reports), as well as through the Yellow Card website with a decrease of 7% (164 reports).

226. The increase in electronic 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

227. The Yellow Card app was initially designed with both healthcare professionals and patients as target users, however reporting trends have shown that the app is particularly used by patients as a route of reporting. Suspected ADR reporting through the app has increased significantly in 2020 with a 362% increase in reporting from 2019 (658 reports) to 2020 (3041 reports). Of these reports, 43% (1331 reports) were from members of public.

228. The MHRA has been further exploiting the app and these benefits through the WEB-RADR 2 project, based on patient and healthcare professional feedback. Enhancements implemented in 2020 include the

inclusion of the COVID-19 reporting form for both vaccines and medicines used to treat coronavirus symptoms. There are also features such as unit conversions (i.e., height and weight) which make it more accessible and easier for reporters to fill in this information along with pop-up notifications so that users are able to see any news or updates about their medicines and reports.

UK Yellow Card Centres

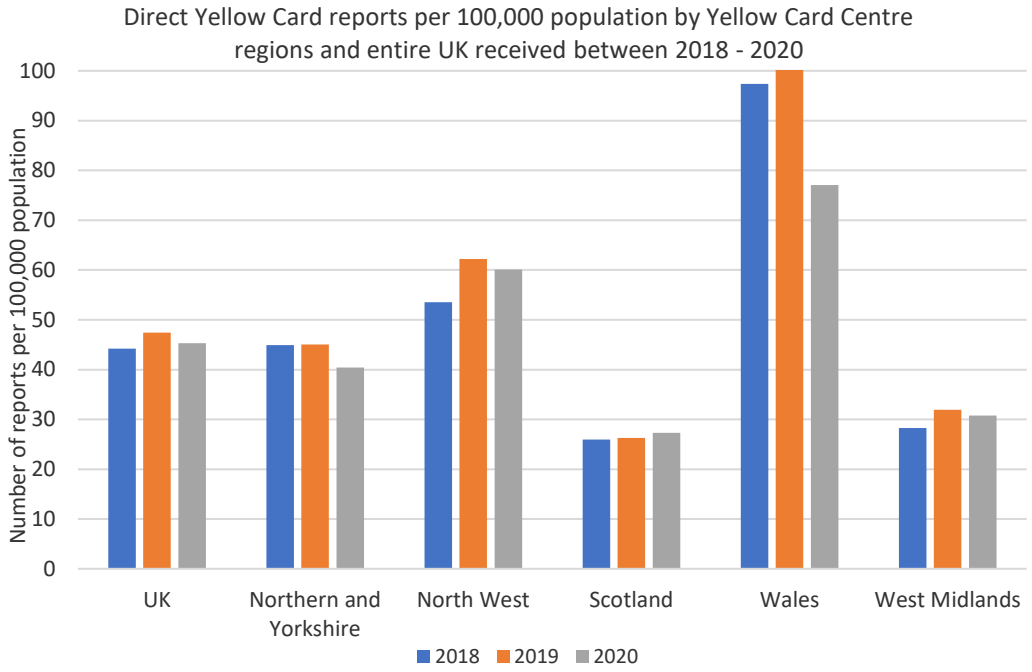
229. The MHRA works with five Yellow Card Centres (YCCs) based in the United Kingdom to increase awareness of the Yellow Card scheme and increase ADR reporting rates within their regions. The YCCs operate in Wales, Scotland, Northern & Yorkshire, North West and the West Midlands. The YCCs are involved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

230. Despite the current Pandemic the YCCs continue to promote the Yellow Card scheme by adapting training and developing online content to ensure this can be carried out virtually in order to educate both undergraduate and postgraduate healthcare students, as well as qualified healthcare professionals. The YCCs play an important part in social media campaigns by supporting through their YCC social media pages.

231. Many events and conferences have been cancelled or postponed due to the pandemic, however for those that were able to go ahead virtually YCCs were able to discuss the importance of ADR reporting with attendees. YCC Northern and Yorkshire have engaged with a number of various patient groups i.e. Crohn's and Colitis UK, Epilepsy Action and the Migraine Trust. YCC North West attended conferences to increase engagement, these included the British Dental Associated Conference, Superdrug conference as well as the University of Bradford. YCC Scotland's Twitter has seen an increase in the number of followers, also having new patient representation on their Advisory Group has helped to increase awareness among community groups. YCC West Midlands have been recruiting champions in primary care networks to improve engagement. YCC Wales attended a number of conferences such as the Welsh Immunisation Conference, Breast Test Wales and the UK Renal Pharmacy Group Conference.

232. The YCCs dedication and continued support of the Yellow Card scheme can be seen by the steady ADR reporting rates in Figure 5. It is important to note that reporting rates overall in 2020 are generally lower than last year, mainly impacted by the current Pandemic. In 2020 two YCCs had a higher reporting rate per 100,000 people than the UK average (45): North West (60) and Wales (77).

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

233. The MHRA signal management system is designed for the timely detection of new and changing drug safety issues. Changes in the frequency of ADRs already known to be associated with medicines are also closely monitored through the MHRA's signal detection process. The drug-event combinations from Yellow Card reports are assessed on a weekly basis to identify potential safety signals.
In 2020, there were a total of 113 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 2020

	Signal Priority		
	Top	**Increased**	**Standard**
Number of signals	2	4	107

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

234. In 2020, information (ADR reports, enquiries) received directly from members of the public contributed towards multiple signals being detected. Of these signals 27 were initiated for investigation from information from members of the public. Pharmacovigilance Information received from health care professionals also contributed to a number of safety signals, of which 31 reports were the index case.

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

236. Some examples of signals which stimulated regulatory action in 2020 include secukinumab use and associated facial paralysis, which was reviewed following receipt of a patient report. This review resulted in the signal being raised in Europe, leading to a Marketing Authorisation Holder (MAH) review within their Periodic Safety Update Report (PSUR) procedure. A further example is of trimethoprim and drug reaction with eosinophilia and systemic symptoms (DRESS). This signal was raised following case reports of DRESS following long term use of trimethoprim – the Marketing Authorisation Holder was requested to conduct a review of DRESS associated with long-term use of trimethoprim with a view to adding the DRESS to both the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) in relation to such use.

237. Signals were also raised in 2020 that involved well established drugs and known side effects, but following new information received via the Yellow Card scheme it was felt the product information could better reflect the potential risks. For example, a signal of warfarin and the increased risk of haemorrhage with head trauma was raised following correspondence from a patient. Upon review, it was concluded the PIL could better reflect this risk so it was subsequently updated with a warning to seek medical attention after a fall or injury whilst on treatment; especially involving any blow to the head.

238. Following the finalisation of the Pregnancy Signal Meeting pilot in 2019, the Pregnancy Signal Meeting was incorporated into the MHRA's routine signal detection processes, with Standard Operating Procedures developed. The Pregnancy Signal Meeting continued in 2020 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.

239. In 2020, 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 has proposed a number of topics in 2020, 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 high profile UK drug safety issues such as isotretinoin and sexual dysfunction and misuse of opioids.

240. During 2020, and continuing in to 2021, the MHRA has adapted its signal management system in response to the COVID-19 pandemic. A pharmacovigilance strategy was developed for medicines, and vaccines, to manage the response to the COVID-19 pandemic. Initially this involved conducting pharmacovigilance activities surrounding medicines used in the treatment of COVID-19, but further developed following the introduction of vaccinations and the national rollout of the vaccination programme. Further detail on the MHRA's response to the pandemic can be seen in the COVID-19 EWG section of the report.

E-Cigarette Reporting

241. 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 2020 there have been 149 adverse reaction reports (ADRs). This includes all spontaneous reports submitted to the MHRA by consumers and healthcare professionals (24) as well as reports of adverse reactions received from industry (125). 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. This explains the notable increase in reports over the last year (27 adverse reaction reports in 2019). We also received 1 report of a product safety concern and 1 report of a product quality concern relating to nicotine containing e-cigarettes. We continue to liaise closely with Trading Standards authorities to share information regarding product device-related safety and quality concerns.

MEMBERSHIP OF THE COMMISSION ON HUMAN MEDICINES

Chair

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[2] End of appointment 14/12/2020
[3] Reappointed 07/07/2020

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Advanced Nurse Practitioner

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Personal Chair in Medical Statistics and Clinical Trials, Usher Institute, University of Edinburgh

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Consultant Paediatric Rheumatologist and Honorary Senior Lecturer, Alder Hey Foundation NHS Trust and University of Liverpool

Professor David Baldwin
Professor of Psychiatry, Academic Lead for General Adult Psychiatry for Clinical Academic Training at University of Southampton

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

[4] Appointed 06/07/2020
[5] End of appointment 31/12/2020
[6] Appointed 06/07/2020
[7] End of appointment 31/03/2020
[8] Appointed 06/07/2020
[9] Reappointed 08/03/2020

Professor Mike Bennett MD FRCP FFPMRCA
St. Gemma's Professor of Palliative Medicine
Academic Unit of Palliative Care

Professor Kristien Boelaert MD, PhD, MRCP
Professor of Endocrinology and Honorary Consultant Endocrinologist

Dr Rebecca Bromley
Neuropsychologist at University of Manchester, Clinical Psychologist in NHS

Mr Kevin Brown
Public Health England (PHE)

Professor Wendy Burn
Professor of Psychiatry and President of the Royal College of Psychiatrists

Mr Andrew Evans
NHS Wales

Mr Christopher Garland
NHS Northern Ireland

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

Dr Gillian Hawksworth
Academic Community Pharmacist, Visiting Fellow at University of Huddersfield & Past President of the Royal Pharmaceutical Society of Great Britain (RPSGB)

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Consultant Perinatal Psychiatrist
GM Trust Lead for Perinatal Services

Professor Helen J Lachmann
Professor of Medicine & Honorary Consultant Nephrologist
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Ms Emily Lawson
NHS England

Ms Claire Liew
Department of Health and Social Care (DHSC)

Mr Lois Lloyd
NHS Wales

Mr Jamie Lopez
Public Health England (PHE)

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Department of Health and Social Care (DHSC)

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Professor of Affective Disorders at Newcastle University

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Ms Kate Mitchell
Department of Health and Social Care (DHSC)

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

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Professor of Clinical Psychiatry, Edinburgh University

Professor Poulam M Patel
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Mr Steve Powis
NHS England

Mr Keith Ridge
NHS England

Mr Richard Roberts
NHS Wales

Professor Peter Sandercock
Chairman RECOVERY DMC

Ms Justine Scanlan
NHS England

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

Ms Alison Strath
NHS Scotland

Ms Josephine Tapper
Patient Representative

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Professor Angela E Thomas
Consultant Paediatric Haematologist, Royal Hospital for Sick Children, Edinburgh

Mr Gareth Paul Thomas
Public Health England (PHE)

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

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Toxicological Risk Assessor, Food Standards Agency

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Deputy Chief Executive, Epilepsy Action

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NHS England

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

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Observers of Commission Meetings

Mr Ian Bateman
Director of Quality, NHS Blood and Transplant

Ms Jenna Dilkes
National Institute for Health and Care Excellence (NICE)
(January, April, May, June, July, October, November, December)

Ms Kay Ellis
NHS Blood and Transplant Sponsor

Dr Aiden Fowler
NHS England

Mr Christopher Garland
Principal Pharmaceutical Officer, Northern Ireland

Professor Peter Groves
Chair of the MHRA Devices Expert Advisory Committee, Chair of the National Institute for Health and Social Care Excellence (NICE) Medical Technologies Advisory Committee

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Assistant Director Strategic Business Transformation, NHS Blood and Transplant

Dr Sonia Macleod
Independent Medicines and Medical Devices Safety Review

Mr Eric Power
Programme Director, National Institute for Health and Social Care Excellence (NICE)

Ms Jenniffer Prescott
National Institute for Health and Social Care Excellence (NICE)

Dr Keith Ridge
Chief Pharmaceutical Officer, NHS

Ms Ellie Rose
Head of Flu Policy

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

Ms Alison Strath
Interim Chief Pharmaceutical Officer, Scotland

Mrs Madeleine Wang
Lay Member

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

Remit

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

Chair

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

Members

Professor Amanda Adler MD PhD FRCP
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Deputy Medical Director Welsh Health Specialised Services Committee

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Honorary Professor of Experimental Cardiology, Papworth and Addenbrooke's Hospitals Cambridge & Research Group Head, Department of Biochemistry, University of Cambridge

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Professor of Nephrology & Honorary Consultant Nephrologist, University of Glasgow and Glasgow Renal and Transplant Unit, Queen Elizabeth University Hospital, Glasgow

[10] End of appointment 11/11/2020
[11] End of appointment 11/11/2020
[12] Reappointed 08/12/2020

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

Professor Pallav L Shah MD MBBS FRCP
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Professor Hilary Pinnock[13] MB ChB (Hons) MRCGP MD
Professor of Primary Care Respiratory Medicine, Asthma UK Centre for Applied Research, Allergy and Respiratory Research Group, Usher Institute of Population Health Sciences and Informatics, University of Edinburgh; General Practitioner, Whitstable Medical Practice

Dr Caroline Vaughan[14] PhD
Lay Representative of MHRA EAGS. Governor of the Surrey and Sussex Hospital

Professor Sarah Wild[15] MB BChir MSc PhD FRCPE FFPH
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[13] End of appointment 14/02/2020
[14] Resigned 16/03/2020
[15] Reappointed 17/07/2020

MEMBERSHIP OF THE CHEMISTRY, PHARMACY AND STANDARDS EXPERT ADVISORY GROUP

Remit

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

Chair

Professor Kevin M G Taylor[16] BPharm PhD FRPharmS
Chair of the British Pharmacopoeia Commission and Professor of Clinical Pharmaceutics, UCL School of Pharmacy, London

Vice Chair

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Pharmaceutical Microbiologist

Professor Ben Forbes[18] BPharm PhD
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Professor Geoffrey W Hanlon BSc PhD
Emeritus Professor of Pharmaceutical Microbiology, School of Pharmacy & Bio-Molecular Sciences, University of Brighton

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

[16] Reappointed 01/01/2020
[17] End of appointment 12/10/2020
[18] Appointed 18/06/2020

Miss Carol E Knott[19] MRPharmS MBA MIHM
Lay Member. Director of Windcliff Management Ltd

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

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

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Ms Hilary A Shenton[21] CPFA
Lay Representative. Retired Secretary to the School of Medicine, University of Sheffield

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

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Emeritus Professor of Pharmaceutics, Bradford University

[19] End of appointment 07/12/2020
[20] Appointed 19/03/2020
[21] End of appointment 29/02/2020
[22] Appointed 19/03/2020
[23] End of appointment 10/11/2020

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

Remit

To advise the Commission on:

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

Chair

Dr Siraj Misbah[24] MBBS (Hons) MSc FRCP FRCPath
Consultant Clinical Immunologist, Lead for Clinical Immunology, Oxford University Hospitals

Vice Chair

Professor Helen J Lachmann MD FRCP FRCPath
Professor of Medicine & Honorary Consultant Nephrologist
Clinical Lead National Amyloidosis Centre, Clinical Service Lead Immunity & Rare Diseases Division, University College London & Royal Free Hospital London NHS Foundation Trust

[24] Reappointed in line with CHM post 07/07/2020

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

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

Professor Marc Turner[27] MBBS PhD MBA FRCP FRCPath FHEA
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Lay Member. Patient Advocate

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[25] Reappointed 03/11/2020
[26] Reappointed 19/05/2020, Retired 31/12/2020
[27] Reappointed 08/12/2020
[28] End of appointment 08/12/2020

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

Remit

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

Chair

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Professor of Rheumatology, Medical School, University of Sheffield

Members

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Associate Professor, University of Southampton and Consultant Dermatologist

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Mr David Chandler[29]
Lay Member. Chief Executive, Psoriasis and Psoriatic Arthritis Alliance, Hertfordshire

Professor Kevin Moore 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

[29] Reappointed 17/10/2020

MEMBERSHIP OF THE INFECTION EXPERT ADVISORY GROUP

Remit

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

Chair

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

Members

Professor David Dockrell[30] MB BCh MD FRCPI FRCP (Glas) FACP
Professor of Infection Medicine, University of Edinburgh

Dr Andrew Freedman B.A M.B,B.Chir M.A M.D 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 Richard Hobson MB BS MRCP (UK) FRCPath PhD LLM
Consultant Microbiologist and Honorary Senior Lecturer, Harrogate and District NHS Foundation Trust/University of Leeds

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

Dr Katie Jeffery[31] FRCP FRCPath
Director of Infection Prevention and Control, and Consultant Microbiologist, Oxford University Hospitals NHS Foundation Trust

Dr Hermione Lyall[32] BSc Hons MB ChB Hons MD FRCPCH
Consultant in Paediatric Infectious Diseases, St Mary's Hospital, Imperial College Healthcare NHS Trust, London

[30] End of appointment13/01/2020
[31] End of appointment 08/09/2020
[32] End of appointment 16/09/2020

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

Dr Matthias Schmid[33] MD FRCP DTMH
Consultant Physician, Head of Department of Infection & Tropical Medicine, Directive of Elective Studies Newcastle University, Royal Victoria Infirmary, Newcastle upon Tyne

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

[33] Reappointment 09/09/2020

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

Remit

To advise the Commission on the safety and efficacy of medicines related to endocrinology and women's reproductive health from menarche to menopause and conditions related to menopause, such as osteoporosis. The medicines covered will include medicines for contraception, emergency contraception and termination of pregnancy; medicines for infertility and assisted conception; HRT and non-hormonal treatments for osteoporosis.

Chair

Professor Philip Hannaford[34], FRSE
Emeritus Professor of Primary Care, University of Aberdeen

Vice Chair

Dr Diana Wellesley FRCP
Head of Prenatal Genetics, Consultant and Honorary Senior Lecturer in Clinical Genetics, Wessex Clinical Genetics Service, Princes

Members

Dr Ailsa Gebbie[35] MB ChB FRCOG FRCPE FFSRH
Consultant Gynaecologist and Director of the Clinical Effectiveness Unit of the Faculty of Sexual and Reproductive Health, Chalmers Centre, Edinburgh

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

Professor Siobhan Quenby[36] MBBS BSc MD FRCOG
Professor of Obstetrics, Warwick University

Ms Julia Louise Tassano-Edgecombe[37]
Nurse Consultant, Department of Sexual Health, Royal Berkshire NHS Foundation Trust

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

[34] Appointed as Chair 11/04/2020
[35] End of appointment 31/08/2020
[36] End of appointment 11/11/2020
[37] End of appointment 18/09/2020

MEMBERSHIP OF THE NEUROLOGY, PAIN AND PSYCHIATRY EXPERT ADVISORY GROUP

Remit

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

Chair

Professor 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

Professor Thomas R. E. Barnes[38] MD FRCPsych DSc
Emeritus Professor of Clinical Psychiatry, Imperial College London

Professor Naomi Fineberg[39] BA Hons MB BS MA MRCPsych
Consultant in General Adult Psychiatry, Hertfordshire Partnership NHS

Dr David Hunt[40] MBMS MRCP PhD
Honorary Consultant Neurologist/Wellcome Trust Senior Clinical Fellow, Anne Rowling Clinic, University of Edinburgh

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

Dr Fergus Rugg-Gunn[41] MB BS MRCP PhD
Consultant Neurologist, National Hospital for Neurology and Neurosurgery, Queen Square, London

Dr Aditya Sharma MBBS MD MRCPsych PhD
Clinical Senior Lecturer and Honorary Consultant in Child and Adolescent Psychiatry at Newcastle University and Cumbria, Northumberland Tyne and Wear NHS Foundation Trust

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

[38] End of appointment 07/12/2020
[39] Reappointed 08/12/2020
[40] Reappointed 08/12/2020
[41] Reappointed 21/01/2020

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

MEMBERSHIP OF THE ONCOLOGY AND HAEMATOLOGY EXPERT ADVISORY GROUP

Remit

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

Chair

Professor Poulam M Patel[42] PhD, MBBS, FRCP
Professor of Clinical Oncology, Academic Unit of Clinical Oncology, University of Nottingham

Professor Angela E Thomas[43] OBE MB BS PhD FRCPE FRCPath
University of Edinburgh

Members

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

Professor Stephen Devereux[44] PhD FRCP FRCPath
Consultant Haematologist and Professor of Lymphoma Biology, Kings College Hospital

Dr Hugo Ford[45] MA MB BChir MD FRCP
Director of Cancer Services, Cambridge University Hospitals Foundation Trust

Dr Robert Marcus MA FRCP FRCPath
Consultant Haematologist, HCA Healthcare

[42] Appointed as Chair 24/09/2020
[43] End of appointment 31/12/2020
[44] Reappointed 17/07/2020
[45] Reappointed 03/11/2020

MEMBERSHIP OF THE PAEDIATRIC MEDICINES EXPERT ADVISORY GROUP

Remit

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

Chair

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

Vice Chair

Professor Steven Cunningham[46] MBChB PhD FRCPCH (Vice Chair)
Professor of Paediatric Respiratory Medicine, University of Edinburgh and Honorary Consultant, Royal Hospital for Sick Children, NHS Lothian, Edinburgh

Members

Dr Eileen M Baildam[47] MB ChB DRCOG DCH RCP FRCP FRCPCH
Consultant Paediatric Rheumatologist and Honorary Senior Lecturer, Alder Hey Foundation NHS Trust and University of Liverpool

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

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

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

Dr Daniel Hawcutt[48] BSc (Hons), MB ChB (Hons), MD, MRCPCH
Senior Lecturer Paediatric Clinical Pharmacology, Women's and Children's Health, Institute of Translational Medicine, University of Liverpool

Professor Meriel Jenney MBChB MRCP MD FRCPCH
Deputy Medical Director, Cardiff and Vale University Health Board
Consultant Paediatric Oncologist

[46] End of appointment 11/11/2020
[47] End of appointment 11/11/2020
[48] Appointment 23/04/2020

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

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

Dr Rubin Minhas MB ChB MBA
GP Principal

Professor Marie-Louise Newell[49] MB MSc PhD FMedSci
Emeritus Professor of Global Health, School of Human Development and Health, Faculty of Medicine University of Southampton

Ms Sara Payne BA CPE LPC
Lay Member. Solicitor

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

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

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

[49] End of appointment 11/12/2020

MEMBERSHIP OF THE PHARMACOVIGILANCE EXPERT ADVISORY GROUP

Remit

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

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

Chair

Professor Sir Munir Pirmohamed[50] MB ChB (Hons) PhD FRCP (Edin) FBPhS, FFPM (Hon) FMedSci
David Weatherall Chair of Medicine, University of Liverpool, NHS Chair of Pharmacogenetics, Director of the Wolfson Centre for Personalised Medicine, Director of the MRC Centre for Drug Safety Science

Members

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

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

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

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

Dr Daniel Hawcutt 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

Ms Susan Hunneyball BSc (Hons)
Lay Member

[50] End of appointment 31/2/2020

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

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

Ms Christine Randall[51] BPharm MRPharmS
Assistant Director, North West Medicines Information Centre

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)

[51] End of appointment 06/10/2020

MEMBERSHIP OF THE ADRENALINE AUTOINJECTORS WORKING GROUP

Chair

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

Members

Mr Andy Collen DipHE MSc FCPara
College Paramedic, Medicines and Prescribing Project Lead

Professor Adam Fox MA(Hons) Cantab., MSc, BS, DCH, FRCPCH, FHEAm Dip.
President, British Society for Allergy and Clinical Immunology (BSACI), Professor in Paediatric Allergy, Guy's and St Thomas' Hospitals.

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

Mr Trevor Povey
Ethics and Compliance, Community Pharmacy- ASDA

Dr Jasmeet Soar MA, MB BChir, FRCA, FFICM, FRCP
Consultant in Anaesthetics & Intensive Care Medicine, Southmead Hospital, Bristol, past Chair UK Resuscitation Council

Wing Tang
Head of Support and Guidance, Royal Pharmaceutical Society

Mr Robbie Turner (Director of Pharmacy and Member Experience
Royal Pharmaceutical Society

Mrs Madeleine Wang BA (Hons)
Lay representative

Dr Bruce Warner
NHS England & NHS Improvement

Invited Experts

Dr Liz Angier
General Practitioner, Primary Care Group, BSACI

Dr Carla Jones
CEO, Allergy UK

Ms Lynne Regent
CEO, Anaphylaxis Campaign

Mrs M Harvey
Patient representation

Mr S Harvey
Patient representation

MEMBERSHIP OF THE COVID-19 THERAPEUTICS EXPERT WORKING GROUP

Chair

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

Members

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

Ms Susan Bradford
Lay Member

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

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

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

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

Sir Michael Jacobs MA PhD MB BS FRCP Edin DTM&H
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 (Edin) FBPhS, FFPM (Hon) FMedSci
David Weatherall Chair of Medicine, University of Liverpool, NHS Chair of Pharmacogenetics, Director of the Wolfson Centre for Personalised Medicine, Director of the MRC Centre for Drug Safety Science

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

Invited Experts

Dr Claire Steves
Senior Clinical Lecturer, King's College London

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

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

Ms Ana Maria Henao Restrepo
World Health Organization

Sir Richard Peto
World Health Organization

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

Chair

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

Members

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

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

Professor Neil French MB ChB FRCP PhD
Head Department of Clinical Infection Microbiology and Immunology, Chair of Infectious Diseases & Global Health, Hon Consultant Infectious Diseases, Royal Liverpool & Broadgreen University Hospitals Trust

Professor David Goldblatt MB ChB FRCPCH FRCP PhD
Professor of Vaccinology and Immunology, Consultant in Paediatric Immunology, NIHR Senior Investigator, Great Ormond Street Hospital & University College London

Ms Susan Hunneyball BSc(Hons)
Lay Member

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

Sir Michael Jacobs MA PhD MB BS FRCP Edin DTM&H
Clinical Director of Infection, Royal Free London NHS Foundation Trust, Hon. Senior Lecturer, Liverpool School of Tropical Medicine

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

Professor Paul J Lehner PhD FRCP FMedSci
Professor of Immunology and Medicine, Wellcome Trust Principal Research Fellow
Honorary Consultant Infectious Diseases, Cambridge Institute of Therapeutic Immunology and Infectious Disease (CITIID), Jeffrey Cheah Biomedical Centre Cambridge Biomedical Campus

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

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

Dr Andrew Riordan MD FRCPCH DTM&H
Consultant in Paediatric Infectious Diseases and Immunology, Honorary Clinical Lecturer, University of Liverpool, Alder Hey Children's NHS Foundation Trust, Liverpool

Professor Chris Robertson PhD MSc BSc
Professor of Public Health Epidemiology, University of Strathclyde

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

Professor Tom Solomon FRCP PhD
Chair, Neurological Science and Director, NIHR Health Protection Research Unit in Emerging and Zoonotic Infections, University of Liverpool, Hon Consultant Neurologist, Walton Centre NHS Foundation Trust

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

Mrs Madeleine Wang BA (Hons)
Lay Member

Professor Christopher Weir BSc MSc PhD FRSS Cstat Professor of Medical Statistics & Clinical Trials, Edinburgh Clinical Trials Unit, Usher Institute, University of Edinburgh

Invited Members of CTBVEAG

Professor B Kevin Park BSc, PhD, Hon FRCP, FMedSci, FBTS, HonFBPhS
Professor of Pharmacology, Department of Pharmacology, University of Liverpool

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

Invited Members of CPSEAG

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

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

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

Professor Yvonne Perrie BSc Hons MRPharmS FAPS FSB PhD
Chair in Drug Delivery, Strathclyde Institute of Pharmacy and Biomedical Sciences, University of Strathclyde, Glasgow. Scotland

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

MEMBERSHIP OF THE COVID-19 VACCINES SAFETY SURVEILLANCE METHODOLOGIES EXPERT WORKING GROUP

Chair

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

Members

Professor Ian J Douglas BSc MSc PhD
Senior Lecturer in Pharmacoepidemiology, London School of Hygiene & Tropical Medicine & Member of the Pharmacovigilance Expert Advisory Group (PEAG)

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

Sir Michael Jacobs MA PhD MB BS FRCP Edin DTM&H
Clinical Director of Infection, Royal Free London NHS Foundation Trust & Hon. Senior Lecturer, Liverpool School of Tropical Medicine

Professor Simon De Lusignan
Professor of Primary Care and Clinical Informatics, University of Oxford

Dr Rupert Payne PhD MRCGP FRCPE FBPhS
Consultant Senior Lecturer in Primary Care, University of Bristol

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

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

Professor Chris Robertson
Professor of Public Health Epidemiology, University of Strathclyde

Professor Calum Semple PhD FRCPCH FRCPE FHEA
Professor of Outbreak Medicine
University of Liverpool

MEMBERSHIP OF THE DESOGESTREL AD HOC STAKEHOLDER GROUP

Remit

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

Chair

Professor Kevin M G Taylor BPharm PhD FRPharmS
Chair of Chemistry, Pharmacy & Standards (CPS) EAG
Chair of the British Pharmacopoeia Commission and Professor of Clinical Pharmaceutics, UCL School of Pharmacy, London

Members

Medical Profession

Dr Martin Duerden RCGP
Medical Adviser in Therapeutics, Centre for Medical Education, Cardiff University
Royal College of Obstetricians & Gynaecologists

Gynaecologist

Edward Morris
RCOG new president
Royal College of Obstetricians & Gynaecologists

Pharmacist

Joanne Jenkins
Specialist Pharmacist, National lead for Patient Group Directions, Medicines Use and Safety Division

Community Pharmacist

Raymond Anderson BSc(Hons) FPSNI FCPA FFRPS AMRPS
Community Pharmacist, Portadown, Co. Armagh

Specialist Healthcare Professional

Rita Jenner BSc (Hons)
School Nurse & Practice Teacher, Suffolk

Faculty of Sexual and Reproductive Healthcare (FSRH) representative
Dr Asha Kasliwal President FSRH
Faculty of Sexual & Reproductive Healthcare

Practice Nurse
Mrs Elia C Monteiro BSc PGDip MSc
Practice Nurse, General Practice Nursing, Royal College of Nursing, London

British Pregnancy Advisory Service (BPAS) Representative
Tracey Forsyth
Remote Contraception and Sexual Health Nurse – Manager, BPAS Healthcare

MEMBERSHIP OF ISOTRETINOIN EXPERT WORKING GROUP

Chair

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

Members

Professor Darren Ashcroft BPharm, MSc, PhD, FRPharmS
Professor of Pharmacoepidemiology, Head, Drug Usage and Pharmacy Practice Group, University of Manchester

Dr Susannah Baron
Consultant Dermatologist, St Thomas' Hospital

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

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

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

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

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

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

Dr George Millington (Norfolk and Norwich)
Officer of BAD, Academic Vice President

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

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

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

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

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 Member

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

Invited Expert

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

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

Chair

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

Members

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

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

Ms Caroline Cake
Chief Operating Officer at Health Data Research UK

Dr Rachel Charlton
Dept of Pharmacy and Pharmacology
University of Bath

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

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

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

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

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

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

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

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

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

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

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

Mrs Madeleine Wang BA (Hons)
Lay Member

MEMBERSHIP OF THE REAL WORLD DATA WORKING GROUP

Chair

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

Members

Ms Susan Bradford
Lay Representative

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

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

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

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

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

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

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

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

MEMBERSHIP OF THE AD HOC STAKEHOLDER GROUP TO CONSIDER A PRODUCT TO TREAT VAGINAL ATROPHY

Remit

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

Chair

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

Members

Medical Profession

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Medical Adviser in Therapeutics, Centre for Medical Education, Cardiff University
Royal College of Obstetricians & Gynaecologists

General Practitioner

Dr Rubin Minhas MB ChB MBA
GP Principal

Gynaecologists

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Clinical Lead Menopause Service King's College Hospital, Chairman British Menopause Society

Tim Hillard DM FFSRH FRCOG
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Specialist Pharmacist (PGD)

Emma Anderson BPharm
Regional tutor, East Midlands, Centre for Pharmacy Postgraduate Education, University of Manchester, Oxford

Joanne Jenkins
Specialist Pharmacist, National lead for Patient Group Directions, Medicines Use and Safety Division

Community Pharmacist
Raymond Anderson BSc(Hons) FPSNI FCPA FFRPS AMRPS
Community Pharmacist, Portadown, Co. Armagh

Faculty of Sexual and Reproductive Healthcare (FSRH) representative
Dr Asha Kasliwal President, FSRH
Faculty of Sexual & Reproductive Healthcare

Practice Nurse
Mrs Elia C Monteiro BSc PGDip MSc
Practice Nurse, General Practice Nursing, Royal College of Nursing, London

Generalist Nurse
Ruth Bailey
Practice Nurse, currently works in Sexual Health & Deputy Chair of the Woman Health Forum, Royal College of Nursing

MEMBERSHIP OF THE OPHTHALMIC PANEL

Dr Sajjad Ahmad MB BS PhD FRCOphtp
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Director, National Institute for Health Biomedical Research Centre for Ophthalmology,
Moorfields Eye Hospital and UCL Institute of Ophthalmology, London, UK
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Mr Martin M^{c}Kibbin MB BS FRCOphth
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Mr David P.S. O'Brart MD FRCS FRCOphth
Consultant Ophthalmic Surgeon, St Thomas' Hospital, London. President Elect for the UK and Ireland Society of Cataract & Refractive Surgeons (UKISCRS)

Professor Sunil Shah MB BS FRCOphth FRCSE FBCLA
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Miss Laura Steeples MBChB (Hons) FRCOphth
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COMMISSION ON HUMAN MEDICINES

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

AAI	Adrenaline Auto-Injector
ABRHP	Advisory Board on the Registration of Homeopathic Products
ACE	Angiotensin Converting Enzyme
ADHD	Attention deficit hyperactivity disorder
ADR	Adverse Drug Reaction
AED	Anti-epileptic drug
ARB	Angiotensin Receptor Blocker
ARSA	Arylsulphatase A
BPC	British Pharmacopoeia Commission
BPF	Bronchopleural Fistula
CDRRA	Cardiovascular, Diabetes, Renal, Respiratory and Allergy
CHM	Commission on Human Medicines
CMDh	Co-ordination group for Mutual recognition and Decentralised procedures (human)
COPD	Chronic Obstructive Pulmonary Disease
CPS	Chemistry, Pharmacy and Standards
CTBV	Clinical Trials, Biologicals & Vaccines
DHSC	Department of Health and Social Care
DLBCL	diffuse large B-cell lymphoma
DOAC	Direct Oral Anticoagulant
DPD	Dihydropyrimidine Dehydrogenase
DRESS	drug reaction with eosinophilia and systemic symptoms
DSU	Drug Safety Update
EAG	Expert Advisory Group
EAMS	Early Access to Medicines Scheme
EMA	European Medicines Agency
EWG	Expert Working Group
FDA	Food and Drug Administration
FMF	Familial Mediterranean Fever
GI	Gastrointestinal
GP	General Practitioner

GRID	Gastroenterology, Rheumatology, Immunology & Dermatology
GSL	General Sales List
HAE	a condition that causes swelling and pain
HAS	Health Sciences Authority
HDV	Hepatitis Delta Virus
HIV-1	Human Immunodeficiency Virus
HMAC	Herbal Medicines Advisory Committee
HZ	Herpes Zoster
IEAG	Infection Expert Advisory Group
IEWG	Isotretinoin Expert Working Group
IPMS	International Post-Market Surveillance
LA	Licensing Authority
MAH	Marketing Authorisation Holder
MDS	Myelodysplastic syndrome
MED	Opioid medicines and morphine equivalent dose
MHRA	The Medicines and Healthcare products Regulatory Agency
MLD	Metachromatic Leukodystrophy
MWH	Medicines for Women's Health
NHS	National Health Service
NIBSC	National Institute for Biological Standards and Control
NICE	The National Institute for Health and Care Excellence
NMOSD	Neuromyelitis Optica Spectrum Disorder
NPP	Neurology, Pain & Psychiatry
NSAID	Non-Steroidal Anti-Inflammatory Drug
NSCLC	Non-Small Cell Lung Cancer
OA	Osteoarthritis
OH	Oncology and Haematology
P (medicine)	Pharmacy only medicine
PD	Parkinson's disease
PEAG	Pharmacovigilance Expert Advisory Group
PFD	Prevention of Future Death
PH1	Primary Hyperoxaluria Type 1
PHE	Public Health England

PIL	Patient Information Leaflet
PMEAG	Paediatric Medicines Expert Advisory Group
PNA	Purine Nucleoside Analogue
POM	Prescription Only Medicine
PPH	Postpartum Haemorrhage
PPP	Pregnancy Prevention Plan
PRAC	Pharmacovigilance Risk Assessment Committee
PSUR	Periodic Safety Update Report
RMS	Relapsing Multiple Sclerosis
RWD	Real World Data
RWE	Real-World Evidence
SmPC	Summary of Product Characteristics
TCS	Topical Corticosteroids
TGA	Therapeutic Goods Administration
TRPR	Tobacco and Related Product Regulations
VTE	Venous Thromboembolism
YCC	Yellow Card Centres

BRITISH PHARMACOPOEIA COMMISSION

ANNUAL REPORT FOR 2020

INTRODUCTION

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

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 AND COVID-19

3. During the year, the British Pharmacopoeia has been committed to maintaining 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) stock levels to ensure the availability of BPCRS supportive to the medicines supply chain. The BP has also worked with other pharmacopoeias across the globe to identify existing monographs for medicinal substances and products under investigation for the treatment of COVID-19, culminating in the publication of a comprehensive list on the WHO website.

MEMBERSHIP

4. A list of members of the British Pharmacopoeia Commission during 2020 is shown in **Appendix I**.

5. Following a review carried out in collaboration with the Department of Health and Social Care Appointments and Honours Team during 2019, eight members were successfully re-appointed for periods between two to four years with effect from 1st January 2020. The appointment of new members was delayed due to the impact of the COVID-19 pandemic. Four new members were appointed for a period of four years with effect from 22nd June 2020.

6. A list of members of the supporting Expert Advisory Groups, Panels of Experts and Working Parties for 2020 is given in **Appendix II**. In order to further support the work arising from the MHRA strategy for pharmacopoeial standards for biological medicines, a new Working Party on Advanced Therapy Medicinal Products (ATMP) was established and its inaugural meeting was held in April. The Working Party identified several areas where the provision of non-mandatory guidance in the BP would be useful; two sub-groups consisting of experts from WP ATMP were subsequently established on Flow Cytometry and Vector Copy Number. In light of overlapping areas of responsibility for the Expert Advisory Groups on Nomenclature and Pharmacy, the BP Commission endorsed a proposal to incorporate the role and remit of the two groups into a single, merged Expert Advisory Group including all current members with effect from 1st January 2021.

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

MEETINGS

8. The British Pharmacopoeia Commission met three times during 2020. Fifteen meetings of the Expert Advisory Groups, Panels of Experts and Working Parties were also held during the year, together with several meetings of the WP ATMP sub-groups on Flow Cytometry and Vector Copy Number. Due to the impact of the COVID-19 pandemic, all

meetings from March onwards 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. However, from 17th March 2020 onwards all staff worked from home due to the pandemic. 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 during the year with staff working in shifts to ensure 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 2020

13. Following publication of the British Pharmacopoeia 2020, three online updates were issued providing users with the text of the 10th Edition of the European Pharmacopoeia and Supplements 10.1 and 10.2.

British Pharmacopoeia 2021

14. The British Pharmacopoeia 2021 was published in August 2020. This new edition is available as a package containing the five volumes of the British Pharmacopoeia 2021, the one volume of the British

Pharmacopoeia (Veterinary) 2021 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 2021 is 1st January 2021.

16. All monographs published within the 10th Edition of the European Pharmacopoeia, as amended by Supplements 10.1 and 10.2, 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 2021 contains 30 new monographs of national origin which were not published in previous editions. These include one new monograph for Traditional Herbal Medicines and eight new monographs for unlicensed formulations. Over 170 monographs were amended in respect of technical or editorial content and three new infrared reference spectra were added to this edition.

18. The titles of 10 monographs were amended in the British Pharmacopoeia 2021. These involved changes to those national monographs which still contained split standard terms and changes to several European Pharmacopoeia monographs. 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. Progress was made in implementing the new policy on Dissolution Testing in Finished Product Monographs for Solid Oral Dosage Forms, with several monographs being updated in the British Pharmacopoeia 2021 to replace the acceptance criteria with harmonised Q-values.

20. Four new Appendices were added to harmonise with the European Pharmacopoeia: Appendix II N - Process Analytical Technology; Appendix XIV O2 – Quantification and Characterisation of Residual Host-cell DNA; Appendix XVII N2 – Powder Flow Properties by Shear Cell Methods; Appendix XVII O2 – Scanning Electron Microscopy.

21. The Supplementary Chapter on Aseptic Preparation of Unlicensed Medicines was updated following publication of the new monograph for Parenteral Nutrition Solutions.

22. Further to the comprehensive review of published monographs undertaken during 2019, a further 30 national monographs were omitted

from the British Pharmacopoeia 2021 following consultation. In accordance with Regulation 252(2)(c) of the Human Medicines Regulations 2012, omitted monographs continue to remain in force.

British Pharmacopoeia (Veterinary) 2021

23. The British Pharmacopoeia (Veterinary) 2021 was published as a companion volume to the British Pharmacopoeia 2021 in August 2020. 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) 2021 is 1st January 2021.

24. The British Pharmacopoeia (Veterinary) 2021 contains two new monographs of national origin which were not published in previous editions.

25. One new Appendix was added to harmonise with the European Pharmacopoeia: Appendix XV J (Vet) 3 – Principles for the Detection of Extraneous Viruses in Immunological Veterinary Medicinal Products using Culture Methods.

26. Two national monographs were omitted from the British Pharmacopoeia (Veterinary) 2021, following consultation.

British Approved Names 2017

27. The fourth Supplement to British Approved Names 2017 (Supplement No. 4) was published in August 2020. The Supplement identifies and defines 45 new chemical and biological entities that are used in medicines in the UK. The majority of the new names are for active substances used in medicinal products that have been licensed through the European Medicines Agency and have not previously been marketed in the UK.

Digital Publications

28. Access to the online version (https://www.pharmacopoeia.com) and the offline download edition of the publications is provided as a component of the complete British Pharmacopoeia 2021 package. The offline download edition is updated to include the European Pharmacopoeia Supplement updates at the same time as the online BP.

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

30. Following the regular public consultation schedule for new and revised monographs, four three-month consultation periods were held during 2020. The opportunity to contribute to the monograph development and revision process is appreciated by users and the comments received help to ensure that the monographs are robust.

31. In addition to the consultations on draft monographs, the opportunity was taken this year to seek the views of users on proposed technical changes for the BP publications relating to the introduction of new technologies and the approach to expressing impurity limits in monographs. The responses received were broadly positive and will support improvement and modernisation initiatives in future editions of the BP.

32. A regular programme of user research has continued to further support development of the BP website and products. Undertaken in January, this research supported the development of Tracked Changes functionality, which is now available to enable users to identify how a monograph has been revised using easy to understand symbols. In addition, several enhancements were made to improve the accessibility of the website. A feature is in development for a future update, which will identify why changes have been made within individual monographs.

Prices and Availability

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

34. 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

35. By the end of 2020 work was progressing on the preparation of the next editions of the British Pharmacopoeia and British Pharmacopoeia (Veterinary). These will be published during 2021 and will have an effective date of 1st January 2022.

36. A digital update to the British Pharmacopoeia 2021 was issued in December 2020 providing users with the text of Supplement 10.3 to the 10th Edition of the European Pharmacopoeia, which came into effect on 1st January 2021. Further updates will be issued to coincide with the implementation of Supplements 10.4 and 10.5 on 1st April and 1st July 2021 respectively. These updates will only be available via the online BP and the offline download. The texts will subsequently be included in the BP 2021 publications as appropriate.

OTHER PHARMACOPOEIAL MATTERS

Biological Medicines

37. Substantial progress has been made in implementing the MHRA strategy on pharmacopoeial public quality standards for biological medicines.

38. The BIO-DPS Working Party, which was established in 2018 to explore the potential of performance and class-based standards for biotechnological products identified within the strategy work programme, has continued to develop its work throughout 2020. The Working Party, which includes international experts, has developed a deeper understanding of these concepts, which are to be evaluated through real-world case studies coupled with supporting laboratory evaluation. The project is on track to deliver robust, evidence-based recommendations to the Agency, the BP Commission and wider stakeholders. A report of findings is expected by 2022.

39. The BP Advanced Therapy Medicinal Products (ATMP) Working Party was established in March 2020. The objectives of the Working Party include the consideration of previously undertaken work by the Agency around how standards could support the development of ATMPs and their associated analytics and the development of recommendations and advice to the BP Commission and MHRA on actions that could be undertaken to support quality and innovation in these medicines. The work has recognised the importance of stakeholder contributions and systems wide approaches 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 established to support the work and contributed to continued staff development in both organisations. The Working Party has established two sub-groups to develop specific supportive guidance around specific analytical technologies, with a view to publishing this guidance for stakeholder comments in spring 2021 and finalised for publication in summer 2021.

40. In addition to the work described related to standards development, the Agency has also recognised and continued to support broader engagement across the biopharmaceutical and ATMP landscape. The Agency and BP remains active within the 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

41. 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.

42. Ready-to-use infusions are increasingly being prepared from licensed products for use in the home environment. The Expert Advisory Group on Unlicensed Medicines are preparing non-mandatory guidance on these formulations, together with developing specific monographs.

Herbal and Complementary Medicines

43. The BP has continued to focus on developing monographs for herbal drugs that are widely used in the UK and for those known to be used in the preparation of traditional herbal medicines. One new BP monograph for a traditional herbal medicine was included in the BP 2021 and two monographs were updated to improve the control of these materials.

44. The Expert Advisory Group on Herbal and Complementary Medicines is comprehensively reviewing the work programme to identify future candidate monographs that will provide value to users.

Nomenclature

45. The BP continued to provide advice and comments to the World Health Organization (WHO) Committee on International Nonproprietary Names (INN). Recommended INN (rINN) for products licensed in the UK are formally adopted as British Approved Names when they are first included in licensed medicines. UK Experts provided input into two meetings during the year and contributed to the evaluation of INN requests and the development of WHO policies on drug nomenclature. Two rINN Lists (83 and 84) were published by WHO during the year.

46. The BP Secretariat is also responsible for advising on proposed invented names for medicines in the UK and providing the UK input to the European Medicines Agency (EMA) Names Review Group. During the year 600 proposed invented names were assessed on behalf of the EMA for use in the UK. Members of the BP staff provided advice and recommendations to the EMA Names Review Group for discussion at their meetings. BP staff 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

47. The Analytical Quality by Design (AQbD) Working Party finalised the official response to the MHRA consultation on the application of Analytical Quality by Design Principles to Pharmacopoeial Standards during the

year. The response included the opinions of stakeholders, which had been gathered in 2019, as well as detailing the MHRA's response and strategy for the implementation of the learnings from the consultation. The report also detailed the future work programme for the Working Party.

48. The AQbD Working Party held a meeting in December to consider future areas of work and the next phases of the project. This will include the publication of guidance and supporting information for the incorporation of AQbD into the BP, future laboratory projects and building the capability of the MHRA and the Working Party to maximise the benefits of the project.

49. 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. The BP intends to build on the relationships developed through our engagement to maximise the impact of any external publications, including an impending joint Webinar with the United States Pharmacopeia in February 2021.

Liaison with Other UK Organisations

50. Whilst the opportunity for practical collaborations between academic institutions and the BP was more challenging this year, a number of methods to be included in new and revised monographs are currently being jointly investigated. These include an investigation into a potential revision to the monograph for Paroxetine Tablets which is ongoing with the University of Sunderland, investigations into methodology for new monographs for Carvedilol Oral Suspension and Clomipramine Oral Suspensions with Aston University and the revision of identification tests which specify the use of chloroform with Robert Gordon University.

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

Laboratory

52. The Laboratory has continued to support the work of the British Pharmacopoeia Commission and the wider MHRA remit relating to public health throughout 2020.

53. Activities were somewhat impacted by the COVID-19 pandemic. However, the Laboratory was able to remain operational throughout by implementing social distancing and by adjustments to working arrangements including enhanced cleaning and laboratory protocols.

54. Despite the pandemic, laboratory work on twenty-two new and revised BP monographs was undertaken during the year for inclusion in future

publications. The Laboratory Services group completed the Agency's response to the detection of nitrosamines in drug substances, as part of the cross-European laboratory network to develop methods to detect these contaminants in active substances and in drug products. The data obtained from this work was used to inform the Agency's risk assessment and regulatory actions and was also shared with other regulators.

BP Reference Materials

55. Thirteen new British Pharmacopoeia Chemical Reference Substances (BPCRS) were established to support the British Pharmacopoeia and British Pharmacopoeia (Veterinary) publications, 76 were replaced and 170 were re-tested to ascertain their continued stability.

56. All new BPCRS that were introduced into the BP 2021 and BP (Vet) 2021 were made available to coincide with publication in August 2020, ensuring that users were ready to comply with the new and revised monographs before they came into force.

57. The demand for these reference materials remained high throughout the year. 35905 vials were sold within the UK and to countries worldwide, representing an increase of about 17% from the previous year. This increase is across the range of BPCRS, including some priority items related to potential COVID-19 medicines.

European Pharmacopoeia

58. The third and fourth Supplements to the 10th Edition of the European Pharmacopoeia (Supplements 10.3 and 10.4) were published in July 2020 and October 2020 respectively. Supplement 10.3 came into effect on 1st January 2021 and Supplement 10.4 will come into effect on 1st April 2021. The fifth Supplement (10.5) was published in January 2021 and will come into effect on 1st July 2021. The text of these publications will be included in the next editions of the British Pharmacopoeia or British Pharmacopoeia (Veterinary), as appropriate.

59. 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. Due to the pandemic, all meetings of the European Pharmacopoeia Commission and its Expert Groups and Working Parties were held remotely from March.

60. Regular meetings between representatives from the National Pharmacopoeial Authorities were held during the year to discuss ways in which the pharmacopoeias could respond to the COVID-19 pandemic.

61. The BP had presented proposals outlining best practices for carrying out pilot studies at the annual meeting of National Pharmacopoeial Authorities. By sharing experiences, this should help to ensure the success of future pilot studies undertaken by the European and other pharmacopoeias

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

63. 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.

64. 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 2020, is included in **Appendix V**.

International Liaison and Collaboration

65. 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.

66. Due to travel restrictions imposed by the COVID-19 pandemic, most international meetings that were able to go ahead during the year were held remotely. BP staff and experts participated in a large number of meetings either as attendees or participants.

67. BP Staff attended the Eleventh International Meeting of World Pharmacopoeias (IMWP) which was organised by the World Health Organization (WHO) and was held in Strasbourg 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, together with opportunities to hold meetings with representatives from other pharmacopoeia to discuss mutual areas of interest and potential collaborations. The final day of the meeting had been open to stakeholders. Many representatives from industry had attended and areas of discussion had included pharmacopoeial harmonisation/convergence, implementation of monographs and communication. The White Paper on the “Value of Pharmacopoeial Standards for Access to Quality Medicines” had been approved at the meeting and was published on the WHO website in October.

68. Regular meetings were held during the year between representatives of the IMWP participating pharmacopoeias, including the BP. These meetings had focussed on steps the pharmacopoeias could take to assist in the response to the global pandemic and on other public health issues such as nitrosamine contamination.

69. 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.

70. The BP attended the WHO Consultation on Screening Technology, Laboratory Tools and Pharmacopoeial Specifications for Medicines in May and the 55th meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations in October. Draft documents relating to general texts and monographs for the International Pharmacopoeia were discussed, including a draft monograph for Zanamivir Inhalation Powder, which is being developed collaboratively between the BP and the International Pharmacopoeia.

71. BP staff attended the 70th and 71st WHO Consultations on International Non-proprietary Names in April and October and a large number of new names were successfully discussed at both meetings. In line with the trend observed in recent years, the number of names requested for biological substances continued to form a major part of the discussions.

72. A member of the BP staff provided information on behalf of the MHRA to the European Medicines Agency Names Review Group throughout the year. The invented names for medicinal products are used in Centralised Licence Applications and must be acceptable in all Member States and the UK during the transition period (1st February to 31st December 2020).

73. BP staff had attended the 2020 Parenteral Drug Association Pharmacopoeia Conference which had been held over three days in September and October. The conference had been well attended by stakeholders and there had been a wide-ranging agenda including items relating to pharmacopoeias and on wider challenges for medicines.

74. 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 and the pharmacopoeial response to the global pandemic.

75. A member of the BP staff participated in the USP Emerging Technologies Workshop & Roundtable discussions on Quantitative NMR and Digital Data Applications held in November which explored developments and different perspectives on quantitative NMR applications with global speakers and attendees.

76. The BP continued to work with the Chinese Pharmacopoeia and the Indian Pharmacopoeia to develop Memoranda of Understanding between these two pharmacopoeias and the BP which will facilitate future collaboration activities.

77. The BP had participated in an MHRA visit to India in February and had attended a number of meetings with regulators and stakeholders. These included the 5th India Pharmaceutical Forum, at which the BP had presented on Analytical Quality by Design, and the Industry Round Table meeting at which a range of issues had been discussed including the future of the BP. These meetings provided an opportunity to engage with stakeholders and to raise the international profile of the BP.

78. Following the end of the transition period on 31st December 2020, the British Pharmacopoeia continues to be part of the Medicines and Healthcare products Regulatory Agency's public health role. The UK was a founding member of the Convention on the Elaboration of a European Pharmacopoeia and continues to be a member of the European Pharmacopoeia as the UK continues to be a member of the Council of Europe in its own right. The European Pharmacopoeia text will continue to be reproduced in the BP for the convenience of users.

79. Information on BP operations from 1st January 2021 was published on the BP website in December. This includes details of those instances in the BP that refer to EU requirements and how these have been transposed into domestic UK law. It also includes advice to BPCRS customers to ensure that they can continue to receive the essential reference materials required to demonstrate compliance with BP monographs in a timely manner.

ACKNOWLEDGEMENTS

80. 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.

81. The British Pharmacopoeia Commission also wishes to record its immense gratitude to the staff of the British Pharmacopoeia and Laboratory Services Group of the Medicines and Healthcare products Regulatory Agency concerned with the business of the Commission and its Expert Advisory Groups, Panels of Experts and Working Parties. Significant input to the work of the British Pharmacopoeia Commission continued to be received from members of staff from the Licensing Division, the Vigilance & Risk Management of Medicines Division, the Inspection, Enforcement & Standards Division, the Technology, Digital, Data & Delivery Division and the Communications Division of the Agency.

Significant input has also been received from the BP and MHRA Laboratories, from the Department of Health and Social Care, from the National Institute for Biological Standards and Control, from the Cell and Gene Therapy Catapult and from the Veterinary Medicines Directorate.

82. The Commission wishes to acknowledge the advice of the publishing team at The Stationery Office in the production of the British Pharmacopoeia 2021, the British Pharmacopoeia (Veterinary) 2021 and Supplement No. 4 to British Approved Names 2017.

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

OBITUARIES

84. Members were saddened to learn of the deaths of Mr Thomas Chapman, a former member of the Expert Advisory Group on Herbal and Complementary Medicines, and of Mr Roy Cowell, who had been a member of the Working Party on Advanced Therapy Medicinal Products.

APPENDIX I

MEMBERSHIP OF THE BRITISH PHARMACOPOEIA COMMISSION DURING 2020

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 & Nordics, Akcea Therapeutics

Dr Andrew Barnes BSc PhD FRSC
Quality Assurance Pharmacist, Pharmacy Manufacturing Unit, East Suffolk and North Essex NHS Trust

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

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

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

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

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

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

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

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

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

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

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

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

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

Secretary and Scientific Director

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

APPENDIX II

MEMBERSHIP OF EXPERT ADVISORY GROUPS, PANELS OF EXPERTS AND WORKING PARTIES OF THE BRITISH PHARMACOPOEIA COMMISSION DURING 2020

EXPERT ADVISORY GROUPS

ABS: Antibiotics	R L Horder (**Chair**), G D Cook (**Vice Chair**), G Blake, G Clarke, E Flahive, V Jaitely, W Mann, J Miller, M Pires, J Sumal, I R Williams
BIO: Biological and Biotechnological Products	P Varley (**Chair**), A-M Brady (**Vice-Chair**), E Amirak, L Bissett*, C Braxton*, C Burns, K Chidwick*, A Cook*, J Cook*, B Cowper, S Gill, C Jones*, A Kippen, V Loh, K Nordgren*, B Patel, A M Pickett*, T Pronce*, L Randon, I Rees*, S Schepelmann*, P Sheppard[1], P Stickings*, R Thorpe, L Tsang, M Wadhwa*, W Zunic
HCM: Herbal and Complementary Medicines	M Simmonds (**Chair**), R Middleton (**Vice-Chair**), L A Anderson[1], P Anderson, A Booker, C Etheridge, C Leon, B Moore, M Pires, E Reich, M Rowan, A Slater, K Strohfeldt-Venables, J Sumal*, C Welham, E Williamson, K Zhao (*Corresponding members* SS Handa, A Krauss, Z-T Wang)
MC1: Medicinal Chemicals	A G Davidson (**Chair**), D Cairns (**Vice-Chair**), S Bale, H Batchelor, J C Berridge, E Bush, A J Caws, D Deutsch, P Fleming, E Gray, W J Lough, D J Malpas, 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
NOM: Nomenclature	J K Aronson (**Chair**), A McFarlane, D Mehta, G P Moss, R Thorpe (*Corresponding member* R G Balocco Mattavelli)

PCY: Pharmacy	R L Horder (**Chair**), R A Lowe (**Vice-Chair**), M Ahmed*, E Baker, J Beach, D Elder, J Lim*, J MacDonald, A McFarlane, J F McGuire, T Purewal, K M G Taylor, S Wicks (*Corresponding member* J Churchill)
ULM: Unlicensed Medicines	M G Lee (**Chair**), V Fenton-May (**Vice-Chair**), A 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, J Salt, C Stirling, R Woodland

WORKING PARTIES

AQbD: Analytical Quality by Design	G Cook (**Chair**), P Borman, S Brown, M Chatfield, S Ellison, C Gray, M Hanna-Brown, S Jones, P Nethercote, E Razzano (*Corresponding members* K Barnett, B Harrington, W Sherwin)
ATMP: Advanced Therapy Medicinal Products *(incorporating the sub-groups on Flow Cytometry and Vector Copy Number)*	J Barry (**Chair**), E Abranches, C Blue, J Campbell, D Caulfield, R Cowell[2], K Gilmour, J Glassford, A Lovatt, A Niewiarowska, J Norton, A Nowocin, L Pattenden, J Rattu, I Rees, R Rego, V Robertson, I Santeramo, F Schnetzinger, I Searing, B Surmacz-Cordle, J Towler, C Trento, 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, A Ramzan, B Rellahan, M Wild

AD-HOC GROUP

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

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

MEMBERS OF THE BRITISH PHARMACOPOEIA COMMISSION STAFF DURING 2020

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 (*from November*)
Mr M Whaley

Secondees from the Cell and Gene Therapy Catapult

Dr M Francois
Dr R McCoy

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*)
Ms L Johnson (*Key Accounts Manager, LGC*)
Mr P Bedson (*Operations Director, LGC*)
Dr D Craston (*Chief Scientific Officer, LGC*)

Administrative

Ms F Chughtai
Ms N Begum (*from December*)
Mr B Delahunty
Miss J Paine
Ms U Rothna

APPENDIX IV

BRITISH PHARMACOPOEIA COMMISSION PUBLICATIONS DURING 2020

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

British Pharmacopoeia 2021 package

Consisting of:-

British Pharmacopoeia 2021

British Pharmacopoeia (Veterinary) 2021

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

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

Individual BP Monograph (only supplied electronically)

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

British Approved Names

British Approved Names 2017: Supplement No. 4
(*Price £20*)

APPENDIX V

EUROPEAN PHARMACOPOEIA COMMISSION

MEMBERS OF THE UNITED KINGDOM DELEGATION DURING 2020

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 2020

Group 1	Microbiology	M Whaley
Group 6	Biological Substances	B Cowper
Group 6B	Human Blood and Blood Products	C Thelwell
Group 7	Antibiotics	J Sumal
Group 9G	Medicinal Gases	P Henrys (***Chair***)
Group 10A	Organic Chemistry (Synthetic Products)	D J Malpas
Group 10B	Organic Chemistry (Synthetic Products)	E Bush
Group 10C	Organic Chemistry (Synthetic Products)	J McKendrick
Group 10D	Organic Chemistry (Synthetic Products)	C T Goddard
Group 11	Organic Chemistry (Natural Products)	H Corns
Group 12	Dosage Forms and Methods	R L Horder (***Chair***), E Gray
Group 13B	Phytochemistry (B)	P Anderson
Group 14	Radioactive Compounds	R D Pickett
Group 15	Sera and Vaccines	S Schepelmann, P Stickings
Group 15V	Veterinary Sera and Vaccines	A-M Brady *(Specialist*), R Cooney
Group 17	Medicinal Products Containing Chemically Defined Active Substances	S Young
Group P4	Procedure 4	A Evans

MEMBERS OF WORKING PARTIES FROM THE UNITED KINGDOM DURING 2020:

Bacterial Endotoxins Test	K Nordgren
Cell Therapy Products	K Cornish
Chromatographic Separation Techniques	S Young
Extracts	L Anderson[1], M Pires
Gene Therapy Products	Y Zhao
General Methods	E Gray, O McPolin (*Specialist*)
Host-cell Proteins	A Kippen
Inhalanda	K M G Taylor
Monoclonal Antibodies	P Varley, S Prior, M Wadhwa
Mycoplasmas	R Hawkins
Paediatric Formulary	K Boon
Procedure 4 for Biologicals	M Wadhwa, L Both
Pyrrolizidine Alkaloids	S MacDonald
Raw Materials for the Preparation of Cellular and Gene Therapy Products	L Bisset
Rules of Procedure	A Gibb
Special Revision Programme	A Evans
Standard Terms	M Ahmed
Statistics	R Gaines Das

[1]*Retired during the year.*

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

INTRODUCTION

Purpose of the Code

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

Importance of impartiality

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

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

SCOPE

Committees and groups to which this Code applies

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

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

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

DEFINITIONS

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

Pharmaceutical Industry

3.2 "Pharmaceutical industry" means:

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

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

Immediate family

3.3 "Immediate family" means:

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

INTERESTS WHICH NEED TO BE DECLARED

Summary of interests that need to be declared

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

- Their own financial interests in the pharmaceutical industry; (financial interests are either personal or non-personal, and either specific to the product being discussed, or non-specific);
- Financial interests in the pharmaceutical industry held by members of their immediate family;
- Any other matter that could affect their impartiality, or that could reasonably be perceived as affecting their impartiality. Some examples of interests that are relevant in the context of this Code of Practice, not all associated with the pharmaceutical industry, are set out in section 4.7 below.

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

Personal interests

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

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

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

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

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

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

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

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

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

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

Non-personal interests

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

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

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

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

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

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

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

Other relevant interests

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

- An individual, or his department, has done research work relating to a particular product, or class of products. Although the research has not been funded by any particular pharmaceutical company, the research has taken a particular line e.g. in relation to the safety of the products, or their efficacy;
- An individual has made public statements (either favourable or unfavourable) about a particular company, or product, or class of products or about a competitor's product or class of product;
- The relevant committee is considering whether a product should be reclassified e.g. from prescription only, to a pharmacy medicine, and the individual has a particular interest in the reclassification being made e.g. because he is a retail pharmacist and he will benefit financially;
- An individual participates in, or is connected with, a charity or pressure group that would have an interest in the outcome of the advice being given;
- An individual has a family member who suffers from an illness who would benefit from treatment if a product under discussion were to be authorised;

- An individual has a family member who has suffered a severe reaction or other problem as a result of treatment with a product under discussion;
- Matters relating to persons who are not immediately family members, but are closely connected with the committee expert e.g. adult child no longer living in the same household, or non-family member whose work or other interests are closely associated with the pharmaceutical industry and which could reasonably be perceived as affecting the individual's impartiality. An example might be where a committee is giving advice in relation to a product and a close family member or friend has had a major development responsibility for that product;
- Interests in a company manufacturing the delivery system (e.g. syringes or other medical equipment) for a particular medicinal product;

Attendance at conferences, scientific meetings and similar

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

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

4.10 In order that the chairmen and members of CHM, HMAC, ABRHP and the three EAG chairmen specified in paragraph 4.8 above should be able to attend appropriate scientific events to keep their knowledge up to date, the MHRA has established a discretionary fund to meet the reasonable expenses (e.g. travel and accommodation costs) incurred in their attendance. The relevant MHRA committee secretariat will administer the fund, and chairmen and members wishing to claim the costs of

attendance at such events must make an application in good time to enable appropriate travel and other arrangements to be made. The fund will cover educational events that are relevant to maintaining the expertise of individuals serving on the CHM, HMAC, ABRHP and the three specified EAGs, where acceptance of financial support from industry (for example a single pharmaceutical company) would not be appropriate. Separate guidance on the allocation of resources from the fund has been developed for use by the MHRA secretariat.

4.11 In some cases it will permissible for members of CHM, HMAC, ABRHP or the EAG chairmen to attend events sponsored by the pharmaceutical industry (and accept the payment of their expenses) without recourse to the MHRA discretionary fund. For example, where a learned society holds an international conference that is sponsored by a number of different pharmaceutical companies, it will generally be acceptable for the member to accept such an invitation and to receive payment of expenses, although in such instances declaration of attendance and receipt of funding must be declared in the normal way.

4.12 If funding and/or expenses are paid specifically for an individual's attendance but nevertheless paid to his department rather than the individual himself, it will not normally be acceptable for the individual to attend.

4.13 Benefits of this nature paid to an immediate family member that also benefit the committee chairman or member (e.g. a company pays his or her flight costs so that the he or she can attend a conference with a family member) must be declared as the individual's own interest. However, there is no requirement to declare educational conferences and similar events attended by immediate family members.

4.14 If an individual attends an educational conference or similar, he or she should avoid participation in, for example, "satellite" meetings sponsored and arranged by specific companies or focusing on specific products where involvement in discussions might reasonably be perceived as affecting his or her impartiality. If in doubt, this must be raised with the MHRA Secretariat at the earliest possible opportunity, who will be able to provide further guidance.

4.15 The rules for holding personal interest in the pharmaceutical industry do not apply to the chairmen and members of EAGs, apart from the chairmen of the three EAGS described at paragraph 4.8 above, and for the reasons set out in paragraph 4.4 above. Therefore, these experts may attend meetings sponsored by the pharmaceutical industry and accept funding of expenses, but these must be declared.

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

declarations will be published annually in the report of the work of the committees.

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

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

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

DECLARATION OF INTERESTS

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

Annual declaration

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

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

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

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

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

Declarations at meetings

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

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

PARTICIPATION IN DISCUSSIONS WHEN AN INTEREST HAS BEEN DECLARED

7.1 "Taking part in discussions" means speaking at meetings or voting. Where an individual is not to take part in a discussion, he or she should

leave the room before the discussion commences and return only when that agenda item is complete.

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

Personal Interests

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

7.4 If an individual has declared a personal non-specific interest the individual must take no part in discussions on that agenda item, except at the Chairman's discretion to answer questions from other members. If the personal non-specific interest relates to shares that have been disposed of, the individual will generally be permitted to take part in discussions once three months have elapsed from the date of the disposal of them If the personal non-specific interest relates to other matters, such as a payment received from a pharmaceutical company, the individual will generally be permitted to take part in discussions once 12 months has elapsed from the date of receipt of payment. However, in some cases it will not be appropriate for the individual to take part even though 12 months have elapsed – for example, where he has an ongoing consultancy or other financial relationship with the pharmaceutical company.

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

Non-Personal Interests

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

which he has responsibility has carried out specific work on the product under discussion.

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

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

Other Interests

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

Rival Products

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

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

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

Consideration of Classes of Products

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

RECORD OF INTERESTS

8.1 A record is kept in the MHRA of:

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

PUBLICATION

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

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

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

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Stuart H Ralston	None	None	Abbvie Alexion Amgen Bristol Myers-Squibb Celgene	Sponsorship of clinical meeting	No	None
			Consilient Health Janssen Eli-Lilly Novartis Pfizer	Sponsorship of clinical meeting	No	
			Roche Sandoz Sanofi-Genzyme Thornton &Ross UCB	Sponsorship of clinical meeting		
			Astra-Zeneca	Research funding to institution (registry study)		
			Kyowa Kirin	Research funding		
			Kyowa Kirin	to institution (clinical trial) Research funding to institution (registry study)		
			Eli Lilly	Donation of IMP for a clinical trial		
Ms Susan Bradford	None	None	Roche	Speaker at event sponsored by	No	None

				Roche. Not renumerated.		
Professor Jamie Coleman	None	None	None	None	No	None
Dr Jamie Fraser	None	None	None	None	No	None
Professor Jonathan S Friedland	None	None	Astra Zeneca	The commercial company is a sponsor / funder of research at St. George's University of London which does not involve me (and of which I am generally unaware of the topic)	Yes	I am a member of the UK-CTAP Covid-19 Prophylaxis subgroup. My family member, at UCL/UCLH leads a trial in Covid-19 and is involved in another trial for Covid-19.
			Chiesi Limited	As above	Yes	
			EDIXOMED LIMITED	As above	Yes	
			FairCourt Capital	As above	Yes	
			Penta ID Innovation SRL	As above	Yes	
			GlaxoSmithKline	As above	Yes	
			Gilead Sciences Ltd.	As above	Yes	
			Bristol-Myers Squibb International Corp	As above	Yes	
			LDN Pharma	As above	Yes	
			Merck Serono Ltd	As above	Yes	
			Oxford Gene Technology (Operations) Ltd	As above	Yes	
			Takeda UK Ltd	As above	Yes	

			Celgene Corporation	As above	Yes	
			Pfizer UK	As above	Yes	
			St Jude Medical, AFD Inc.	As above	Yes	
			Jay Pharma Inc.	As above	Yes	
			VBI Vaccines Inc	As above	Yes	
			Boston Scientific Limited	As above	Yes	
			Helperby Therapeutics	As above	Yes	
			Kuok Brothers Sdn Bhd	As above	Yes	
			Beckman Coulter Genomics Inc.	As above	Yes	
			Attune Medical Inc	As above	Yes	
			Merk Sharp & Dohme Ltd	As above	Yes	
Professor Richard Gilson	None	None	ViiV	My department is a collaborating site in 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)	No	None
			Pfizer	My department is a collaborating site in clinical trials sponsored by Pfizer, who have	No	

	provided research funds to the department (received by UCL and by Central and North West London NHS Foundation Trust)	
Gilead Sciences	My department is a collaborating site in clinical trials sponsored by Gilead Sciences, who have provided research funds to the department (Central and North West London NHS Foundation Trust)	No
Janssen	My department is a collaborating site in clinical trials sponsored by Janssen, who have provided research funds to the department (Central and North West London NHS Foundation Trust)	No
Merck	My department is a collaborating site in clinical trials sponsored by Merck, who have provided research funds to the department	No

				(Central and North West London NHS Foundation Trust)		
			Mylan	My department was a collaborating site in a clinical trial using a product supplied by Mylan, funded by NHS England. Research funds to the department (Central and North West London NHS Foundation Trust were received from Public Health England)	No	
			GSK	My department is a collaborating site in clinical trials sponsored by GSK, who have provided research funds to the department (received by Central and North West London NHS Foundation Trust)	No	
Professor Malcolm Macleod	None	None	Janssen Pharmaceuticals	Part funding for PhD students in Centre for Clinical Brain Sciences	No	None
Dr Rebecca Mann	None	None	Sanofi	Local PI for vaccination study	No	None
			Sanofi		No	

Professor Sarah Meredith	None	None	Abbott	Grant & Product donated for a trial	No	None
			Astellas	Grant & Product donated for a trial	No	
			AstraZeneca	Grant & Product donated for a trial Product donated for a trial Drug supply and financial support	No	
			Bayer	Grant & Product donated for a trial Product donated for a trial	No	
			Boehringer Ingelhein, Bristol-Myers Squibb	Grant &Product donated for a trial Product donated for a trial	No	
			Cipla	Product donated for a trial	No	
			Gilead Sciences	Grant & Product donated for a trial Product donated for 4 trials: Grant for the Proud study	No	
			GlaxoSmithKline	Grant & Product donated for a trial Product donated for a trial	No	
			Janssen	Grant & Product donated for a trial Product donated for a trial	No	
			Janssen-Cilag	Grant & Product donated for a trial	No	

Lilly	Product donated for a trial	No
Merck	Product donated for a trial Grant & Product donated for a trial	No
Pilatus	Product donated for a trial	No
Roche	Grant & Product donated for a trial	No
Sanofi-Aventis	Grant & Product donated for a trial	No
Sanofi Pasteur	Product donated for a trial	No
Tibotec	Product donated for a trial	No
Viiv	Grant and product donated for a trial	No
Emergent Biosolutions	Product donated for a trial	No
Emcure	Product donated for a trial	No
FIT Biotech	Product donated for a trial	No
INSERM-ANRS	Product donated for a trial	No
Merck-Serono	Grant & Product donated for a trial	No
Takeda	Product donated for a trial	No
Amgen	Product donated for a trial	No
Novartis	Grant & Product donated for a trial	No

			TB Alliance	Grant and product donated for a trial	No	
Dr Siraj Misbah	None	None	None	None	N/A	None
Professor Poulam M Patel	EUSA	Sponsored attendance to ASCO GU annual Conference (Feb 2020)	Pfizer	Co-Investigator/Co-supervisor for translational research project into hepatotoxicity. Project part funded by educational grant from Pfizer	No	None
			Scancell	Co- supervisor for translational research project into hepatotoxicity. Project part funded by grant from Scancell	No	None
			Calithera Biosciences	Local PI for multicentre company sponsored trial	No	None
			BMS	Local PI for multicentre company sponsored trial	No	None
			Scancell	Chief Investigator for company sponsored clinical trial	No	None
			Pfizer	Local PI for multicentre company sponsored trial	No	None
			Astra Zeneca	Collaboration on research project	No	None

				and prospective phase 1 trial where AZ are providing drug to be added during preparation of dendritic cell vaccine		
Professor Sir Munir Pirmohamed	None	None	Eli Lilly	Research grant to University of Liverpool (UoL) to support clinical training fellowships jointly with the Medical Research Council (MRC)	No	In November 2020, I became a member of Innovative Medicines Initiative-funded consortium called Accelerating research & development for advanced therapies (ARDAT: www.ardat.org). As part of this the UoL will receive research funding directly from the EU Commission. Like all IMI consortia, this is a public-private partnership, and academic and clinical members of the consortium will work in collaboration with industry partners (Pfizer, Bayer, Janssen, Lonza, Novartis, Novo Nordisk, Sanofi-Anetis, Spark Therapeutics, Takeda, Viscofan and Astella Pharma), but will not receive direct funding from the industry partners.
			Novartis	Research grant to UoL to support clinical training fellowships jointly with MRC	No	

			Roche	Research grant to UoL to support clinical training fellowships jointly with MRC	No	
			UCB Pharma	Research grant to UoL to support clinical training fellowships jointly with MRC	No	
			Astra Zeneca	Research grant to UoL to support PhD in drug-drug interactions co-funded by the EPSRC	No	
			BMS (Bristol Myers Squibb)	Unrestricted educational grant to UoL to support UK Pharmacogenetics and Stratified Medicine network open meeting	No	
			Vistagen	Research grant evaluating the role of L-amino acid transporter	No	
Professor Shirley Price	None	None	GSK	This NPNS interest relates to donations provided by GSK to the British Toxicology Society (BTS) to support their Annual Congress and Education and Training of which I	Yes	None

				am currently President of the Society (2020-2022)		
			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)	Yes	None
Professor Marc Turner	None	None	Cell and Gene Therapy Catapult	Non-Executive Director (non-renumerated)	No	Medical Director, Scottish National Blood Transfusion Services
			Global Alliance on iPSC Therapies	Non-Executive Director (non-renumerated)	No	Professor of Cellular Therapy, University of Edinburgh
Mrs Helen Ward	None	None	None	None	None	None
Professor Christopher Weir	None	None	AB Science	DSMB membership for two trials (in ALS and mastocytosis), with income to my department (no work done or payment received to date)	Yes	None

			Eli Lilly	Research grant to institution, on which I am co-applicant	Yes	
Dr Martin Wilson	None	None	None	None	N/A	None

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

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Jamie Coleman	None	None	None	None	N/A	None
Professor Amanda Adler	BI	Grant to cover salary of colleagues; Grant awarded to my predecessor	None	None	No	None
Professor Iolo Doull	None	None	None	None	N/A	None
Dr John Firth	None	None	Amgen	Occasional support of renal unit educational meetings	No	None
			Astellas	Occasional support of renal unit educational meetings	No	
			Genzyme	Occasional support of renal unit educational meetings	No	
			Roche	Occasional support of renal unit educational meetings	No	
			Shire	Occasional support of renal unit	No	

				educational meetings		
Professor Andrew Grace	None	None	None	None	N/A	None
Dr Phillip Ind	None	None	None	None	N/A	None
Professor Patrick Mark	Napp	Consultancy, Lecture fee	Astellas	Consultancy (fee to employer)	No	None
	Astrazeneca	Consultancy, Lecture fee	Boehringer Ingelheim	research grant	Yes	
	Boehringer Ingelheim	Consultancy	None	None	No	
Professor Theresa McDonagh	Astra Zeneca	Consultancy Fee	None	None	No	None
	Corpus	Honoraria for talk-Corpus receives funding form Novartis	None	None	No	
Professor Hilary Pinnock	Boehringer Ingelheim	Honorarium			Yes	Primary Care Respiratory Society-UK. (A registered charity that receives financial support from a number of pharmaceutical and respiratory device companies). I am a member of the research sub-committee - some of the projects are supported by unrestricted grants from respiratory interested Pharmaceutical Companies International Primary Care Respiratory Group. (A registered charity that receives financial support

from a number of pharmaceutical and respiratory device companies). I am education lead - some of the projects are supported by unrestricted educational grants from respiratory interested Pharmaceutical Companies.
Scottish Allergy and Respiratory Academy. (A national training programme and resource in allergic and respiratory disorders for healthcare professionals in primary, secondary and tertiary care and other interested individuals). I am course co-ordinator for this initiative which is supported by unrestricted educational grants from respiratory interested Pharmaceutical Companies.
European Respiratory Society. (A professional society that receives financial support from a number of pharmaceutical and respiratory device companies). I am Head of Assembly 1 - some of the societies activities are supported by unrestricted educational grants from respiratory interested Pharmaceutical Companies.

Professor Pallav Shah	Olympus	consultancy	ERBE, Medtronic, Olympus, PneumRX/BTG, Pulmonx, Boston Scientific, Nuvaria, Broncus	sponsor Imperial college for bronchoscopy course	No	None
	Pulmonx	consultancy/ lecture	Pulmonx	RCT with endobronchial valves Royal Brompton Hospital reimbursed for clinical trial expenses	Yes	
	Creo	consultancy	Nuvaira	RCT with vagal nerve ablation Royal Brompton Hospital and Chelsea & Westminster Hospital reimbursed for clinical trial expenses	Yes	
	None	None	CSA	RCT with RejuvenAir Chelsea & Westminster Hospital reimbursed for clinical trial expenses	Yes	
Dr Caroline Vaughan	None	None	None	None	N/A	None
Professor Sarah Wild	Novo Nordisk	Accommodation, subsistence and contribution to registration fees	None	None	Yes	None

Gilead	provided as part of unrestricted educational grant during attendance at biannual meetings of the Scottish Study Group for Care of Diabetes in the Young in role as member of Steering Group Honorarium paid to research account for attending advisory board discussing epidemiological data	No

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

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Kevin Taylor	None	None	None	None	N/A	None
Professor Graham Buckton	Teva	Consulting	None	None	Yes	None
	Silvergate	Consulting				
	Lupin	Consulting				
	Apotex	Consulting				
	Sandoz	Consulting				
	Anachem	Consulting				
	Alvogen	Consulting				
	Wockhardt	Consulting				
	Macleods	Consulting				
	Zydos	Consulting				
	Sun	Consulting				
	MSN	Consulting				
	Novartis	Consulting				

	Accord	Consulting				
	DRL	Consulting				
Professor Brian Clark	None	None	None	None	N/A	None
Mr V'Iain Fenton-May	None	None	None	None	N/A	None
Professor Ben Forbes	None	None	Vectura	Sponsorship of a research student	Yes	None
			AstraZeneca	Secondment - grant	Yes	
Professor Geoffrey Hanlon	None	None	None	None	N/A	None
Dr Gillian Hawksworth	None	None	None	None	N/A	None
Miss Carol E Knott	Windcliff Management Ltd	Owner and Director of company providing consultancy services to the NHS and private healthcare	None	None	No	None
	Baxter Healthcare	Shares purchased whilst an employee from 1982 to 1995			No	
	INFAI UK	Acting as Contract Responsible Person			Yes	
Dr Majella Eileen Lane	None	None	None	None		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
Mr Robert Lowe	None	None	None	None	N/A	None
Professor Christopher Marriott	Remedica Ltd	Directorship, Shares.	None	None	Yes	Family members holds shares in Halation Ltd and Vectura Ltd.
	Vectura Ltd	Shares				
	Halation Ltd	Company Secretary, Directorship, Fees, Shares.				
Professor Darragh Murnane	Fluid Pharma Ltd. LS2 3AA	University Director, non-specific, no guaranteed personal benefit.	Chiesi Ltd.	Sponsored PhD Studentship	Yes	Organization - Reviral Date - 06/2020- present Detail: Research Collaboration between Fluid Pharma (company of which I hold Directorship) and Reviral
	Adare Pharmaceuticals Inc. (New Jersey)	Consultancy - Specific	GlaxoSmithKline	In-kind support for research project, and sponsored PhD studentships	Yes	
	Aptar Pharma (India)	Honorarium for conference contribution at RDD Asia - Non-specific.	AstraZeneca	In-kind support for research project	Yes	
			3M Ltd. (now called) Kindeva Drug Delivery Ltd	In-kind support for research project	Yes	
			Philips Respironics	Sponsored PhD studentship	Yes	
			Clement Clarke International	Contract research and in-kind support for research projects	Yes	

			Bespak (now called Bespak Recipharm)	Funding for a collaborative Research Project, co-funded by Innovate UK.	Yes	
Professor Yvonne Perrie	None	None	GSK	EU Grant to University of Strathclyde. Grant now completed but publications still being written and funding from EU finalised.	No	Controlled Release Society, President-elect Jan 2020 – June 2020. President June 2020 – Dec 2020. This is a non-salaried volunteer position for a scientific society.
			AMRI	Knowledge exchange research contracts from company to University of Strathclyde.	No	
			Encap/Capsugel/ Lonza	KTP and KE Grant to University of Strathclyde.	No	
			Lamellar Biomedical	KTP Grant to University of Strathclyde.	No	
			Pfizer Inc, Astrazeneca, Precision Nanosystems, Centre for process Innovation Ltd, Malvern Instruments, Croda.	Grant which includes contributions from listed companies to University of Strathclyde.	No	
			Microfluidics	Equipment loan to University of Strathclyde and in-kind research	No	

				support (consumables).		
			Precisions Nanosystems Inc	Equipment loan to University of Strathclyde. SmartScotland Grant with PNI. PhD studentship funding.	No	
			Janssen Pharmaceuticals	PhD funded studentship with Janssen	No	
			Haver Pharmaceuticals	Knowledge exchange research contracts from company to University of Strathclyde.	No	
			Mologic	Knowledge exchange research contracts from company to University of Strathclyde.	No	
			Everna	Knowledge exchange research contracts from company to University of Strathclyde.	No	
Ms Hilary Shenton	None	None	None	None	N/A	None
Professor Kevin Taylor	None	None	None	None	N/A	None
Professor Michael Threadgill	None	None	None	None	N/A	None

Professor Susannah Walsh	Pal International	Grants and in kind contribution	Waymade	My employer has received a large alumni contribution from VJ Patel who is connected to Waymade.	Yes	None
	Better Vision Solutions	I am an inventor on patents licensed to BVS	None	None	Yes	None
Professor Peter York	Nektar Therapeutics	Shares	None	None	Yes	None
	CrystecPharma	Director, shares			Yes	
	Bayer AG	Consultancy			No	

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

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Dr Siraj Misbah	None	None	None	None	N/A	None
Professor Farzin Farzeneh	Cellectis, France	Consultancy, Contract Manufacture and R & D Collaborations	None	None	Yes	None
	Autolus Therapeutics	Shares, Consultancy Payments, Contract Manufacture and R & D Collaborations				
	Apterna	Consultancy				
	Servier	Contract Manufacture				
	Orchard Therapeutics	Consultancy - Member of “Cell and Gene Therapy Scientific Advisory Board”.				
	Centre Hospitalier Universitaire Vaudois	Shares and Consultancy				

Professor Helen J Lachmann	SOBI	Speakers fees/consultancy	SOBI	Support for research nurse salary, unrestricted grant to support UKSAID national meetings,	Yes	None
	Novartis	Speakers fees/consultancy			Yes	
	UPTODATE	Editor payments			Yes	
Professor Kevin Park	None	None	2. Medical Research Council (MRC)	2. A systems medicine approach for the stratification of CLL patients: Biomarkers and therapeutic opportunities	Yes	None
			3. Medical Research Council (MRC)	3. Centre for Drug Safety Science (CDSS) Renewal	Yes	
			4. L'Institut De Recherches Internationales Servier (France)	4. Defining the molecular mechanisms underlying the complex role of mitochondrial dysfunction in the onset of drug-induced cholestatic injury		
			5. Medical Research Council (MRC)	5. Definition of the naturally-processed drug-peptide adducts that can act as functional T-cell	Yes	

	antigens	
6. Biotechnology & Biological Science Research Council (BBSRC)	6. Development of screening approaches to assess to intrinsic immunogenicity of drugs and novel chemicals	
7. European Commission	7. Improving the survival of transplanted kidneys using a novel regenerative medicine therapy	Yes
8. GlaxoSmithKline Research & Development Limited (UK)	8. North West England MRC Fellowships in Clinical Pharmacology and Therapeutics	
9. European Commission	9. Novel technologies for evaluating the efficacy and safety of cell-based therapies for kidney disease RenalToolBox	Yes
10. Pancreatic Cancer Research Fund (UK)	10. Preclinical evaluation of Nrf2 inhibition as a means to improve chemotherapeutic efficacy in patients with pancreatic cancer	

11. GlaxoSmithKline Research & Development Limited (UK)	11. Quantitative assessment of drug-protein adduct formation and function
12. Merck & Co., INC. (USA)	12. To examine the potential preclinical value of mechanism-based biomarkers of DILI over more established and widely accepted clinical diagnostics related to liver histopathology. Development and qualification of the use of a combination of established and mechanism-based biomarkers (HMGB1(+Ac/-Ac); cytokeratin 18 or ccK18; Mir122) for DILI assay in preclinical studies (CDSS DILI Project)
13. European Commission	13. Translational Safety Biomarker Pipeline (TransBioLine): Enabling development and implementation of

				novel safety biomarkers in clinical trials and diagnosis of disease		
			14. European Commission	14. TransQST: Translational quantitative systems toxicology to improve the understanding of the safety of medicines		
Professor Andrew Pollard	None	None	None	None	N/A	Chair of UK Dept. Health and Social Care's (DHSC) Joint Committee on Vaccination & Immunisation (JCVI), and member of the WHO's SAGE. Chair of EMA, SAG on vaccines until 31/1/2020 Chief investigator on NIHR funded oxford covid19 vaccine development . The University of Oxford has entered into a partnership with AstraZeneca on coronavirus vaccine development.
Dr Robin Thorpe	None	None	None	None	N/A	None
Professor Marc Turner	None	None	Cell and Gene Therapy Catapult	Non-Executive Director (non-renumerated)	No	Medical Director, Scottish National Blood Transfusion Services

			Global Alliance on iPSC Therapies	Non-Executive Director (non-renumerated)	No	Professor of Cellular Therapy, University of Edinburgh
Mrs Madeleine Wang	None	None	None	None	N/A	None
Professor Christopher Weir	None	None	AB Science	DSMB membership for two trials (in ALS and mastocytosis), with income to my department (no work done or payment received to date)	Yes	None
			Eli Lilly	Research grant to institution, on which I am co-applicant		

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

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Anthony G Wilson	None	None	None	None	N/A	None
Dr Michael Ardern-Jones	Sanofi-Genzyme	Conference attendance, Speaker fees	Abbvie	UHS Commercial clinical trial	No	Biotechnology and Biological Sciences Research Council iCASE industrial studentships have been funded at my institution with Unilever. I have supervised 3 PhDs. Unilever is a consumer goods manufacturer, with an interest in skin science.
Dr Michael Ardern-Jones	Leo Pharma	Consultancy, Advisory board fees	Leo Pharma	UHS Commercial clinical trial	Yes	None
	AbbVie	Consultancy, Advisory board fees	Amgen	UHS Commercial clinical trial	Yes	
	Pfizer	Consultancy, Advisory board fees	None	None	Yes	
Professor Qasim Aziz	None	None	Allergan	Site PI for phase 3 clinical trial.	No	None
			Symprove	Academic collaboration	Yes	
			Clasado	Site PI for phase 3 clinical trial in set up	Yes	

Mr David Chandler	None	None	None	None	N/A	I am employed by a patient charity, but the charity has a policy not to receive any funding or financial support whether monetary, in kind or via a third parties from pharmaceutical companies or other commercial organisations. Any events or meetings I attend in relation to my work for the charity are funded by the charity, this includes: registration fees, travel, subsistence and accommodation. Family member also works for the same charity, and the above, applies to them. Family member works within the NHS as a diagnostic radiographer with nuclear medicine specialty, but has no personal or financial connections in the pharmaceutical industry. No other members of my immediate household have any financial interests in the pharmaceutical industry or associated organisations.
Professor Kevin Moore	Salutare Group Ltd	Director	None	None	No	I am the director of Edgegilding Ltd, but this has no connection with the pharmaceutical industry, and is related to bookbinding.
	Mallinckrodt	Consultancy	None	None	Yes	None

Professor Celia Moss	None	None	None	None	N/A	None

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

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Jonathan S Friedland	None	None	Astra Zeneca	The commercial company is a sponsor / funder of research at St. George's University of London which does not involve me (and of which I am generally unaware of the topic)	Yes	I am a member of the UK-CTAP Covid-19 Prophylaxis subgroup. My family member, at UCL/UCLH leads a trial in Covid-19 and is involved in another trial for Covid-19.
			Chiesi Limited	As above	Yes	
			EDIXOMED LIMITED	As above	Yes	
			FairCourt Capital	As above	Yes	
			Penta ID Innovation SRL	As above	Yes	
			GlaxoSmithKline	As above	Yes	
			Gilead Sciences Ltd.	As above	Yes	
			Bristol-Myers Squibb International Corp	As above	Yes	
			LDN Pharma	As above	Yes	
			Merck Serono Ltd	As above	Yes	
			Oxford Gene Technology (Operations) Ltd	As above	Yes	

			Takeda UK Ltd	As above	Yes	
			Celgene Corporation	As above	Yes	
			Pfizer UK	As above	Yes	
			St Jude Medical, AFD Inc.	As above	Yes	
			Jay Pharma Inc.	As above	Yes	
			VBI Vaccines Inc	As above	Yes	
			Boston Scientific Limited	As above	Yes	
			Helperby Therapeutics	As above	Yes	
			Kuok Brothers Sdn Bhd	As above	Yes	
			Beckman Coulter Genomics Inc.	As above	Yes	
			Attune Medical Inc	As above	Yes	
			Merk Sharp & Dohme Ltd	As above	Yes	
Professor David Dockrell	None	None	ViiV	Fees paid to University Fee paid to department with proportion paid to investigator by University. fees for developing talks related to roles of inflammation. Also by nature providing some consultancy type activity in preparing talks and advising company on contemporary	Yes	Grant funding from MRC for SHIELD consortium which I lead representing a partnership of UK universities and investigators developing host based therapy to combat antimicrobial resistance. Ongoing input to GSK on results relating to investigational Nrf2 agonists for which my lab previously received grant funding to examine effects on immune responses of Investigator on DEFINE protocols a platform

				issues for people living with HIV		for clinical trials involving community and non-critically ill hospital patients that has included a galectin 3 inhibitor (TD139) from (Astra Zeneca) and nafamostat (Tokyo Chemical Industry). I am chair of the DSMB for a related protease inhibitor in the SPIKE Trial in the community and member of the DMSB for a planned Covid-19 chhuman challenge model being developed by Imperial College London
Dr Andrew Freedman	Viiv Healthcare	Sponsorship to attend national/ international HIV conferences	None	None	N/A	None
Professor Richard Gilson	None	None	ViiV	My department is a collaborating site in 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)	No	None
			Pfizer	My department is a collaborating site in clinical trials sponsored by Pfizer, who have provided research funds to the department	No	

	(received by UCL and by Central and North West London NHS Foundation Trust)	
Gilead Sciences	My department is a collaborating site in clinical trials sponsored by Gilead Sciences, who have provided research funds to the department (Central and North West London NHS Foundation Trust)	No
Janssen	My department is a collaborating site in clinical trials sponsored by Janssen, who have provided research funds to the department (Central and North West London NHS Foundation Trust)	No
Merck	My department is a collaborating site in clinical trials sponsored by Merck, who have provided research funds to the department (Central and North West London NHS Foundation Trust)	No

			Mylan	My department was a collaborating site in a clinical trial using a product supplied by Mylan, funded by NHS England. Research funds to the department (Central and North West London NHS Foundation Trust were received from Public Health England)	No	
			GSK	My department is a collaborating site in clinical trials sponsored by GSK, who have provided research funds to the department (received by Central and North West London NHS Foundation Trust)	No	
Dr Richard Hobson	None	None	None	None	N/A	None
Dr Susan Hopkins	None	None	None	None	N/A	None
Dr Katie Jeffrey	None	None	None	None	N/A	None
Dr Hermione Lyall	None	None	None	None	N/A	None
Professor Kevin Moore	Salutare Group Ltd	Director	None	None	No	I am director of Edgegilding Ltd, but this has no connection with the pharmaceutical industry, and is related to bookbinding.

	Mallinckrodt	Consultancy			Yes	
Dr Matthias Schmid	None	None	None	None	N/A	The ID department has occasional support for meetings from various drug companies sponsoring a sandwich lunch. However I have not had any personal gains or remuneration from any company.
Ms Hilary Shenton	None	None	None	None	N/A	None

MEDICINES FOR WOMEN'S HEALTH EXPERT ADVISORY GROUP MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Philip Hannaford	None	None	None	None	N/A	None
Dr Ailsa Gebbie	None	None	None	None	N/A	None
Ms Linda Pepper	None	None	None	None	N/A	None
Professor Siobhan Quenby	None	None	None	None	N/A	None
Julia Tassano-Edgecombe	None	None	None	None	N/A	None
Professor Jonathan H Tobias	None	None	None	None	N/A	None
Dr Diana Wellesley	None	None	None	None	N/A	None

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

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Malcolm Macleod	None	None	Janssen Pharmaceuticals	Part funding for PhD students in Centre for Clinical Brain Sciences	No	I am academic coordinator of the EQIPD IMI consortium (funded period Oct 2017 to Sept 2020, now in no cost extension. Consortium partners include: AbbVie Inc. (ABBVIE) Arlenda SA (Arlenda) Boehringer Ingelheim International GmbH (BI) concentris research management GmbH (concentris) Eberhard Karls Universität Tübingen (EKUT) F. Hoffmann-La Roche AG (ROCHE) Institut de Recherches Servier (SERVIER) Janssen Pharmaceutica NV (JANSSEN) Noldus Information Technology BV (NOLDUS) Novartis Pharma AG (NOV) Orion Corporation (ORION) PAASP GmbH (PAASP) Pfizer Ltd. (Pfizer)Porsolt SAS (Porsolt) PsychoGenics Inc. (PGI) Sanofi-Aventis Recherche & Développement (SARD) Science Exchange Inc. (SE)

						Stichting Buro ECNP (ECNP) Synaptologics BV (SYLICS) Ucb Biopharma SPRL (UCB)
Professor Thomas R.E.Barnes	Gedeon Richter	Member of Advisory Board	None	None	No	None
Professor Naomi Fineberg	None	None	None	None	N/A	I work as a medical lead of an NHS England service providing pharmacological treatment for obsessive compulsive disorders. I act as an unpaid medical adviser and trustee to national consumer charities for OCD and related disorders. I chair the world psychiatric association scientific section on anxiety, OCD and related disorders. I have contributed to the British association for psychopharmacology (bap) treatment guidelines for anxiety disorders (2014) and the nice treatment guidelines including the most recent update (2013). I have received research grants from the NIHR and horizon2020 (cost). I receive an honorarium from Elsevier for editorial duties for the journal comprehensive psychiatry.
Dr David Hunt	None	None	None	None	N/A	None
Dr Waqar Rashid	MS Society - Advisor	Medical advisor to MS charity	None	None	Yes	I took part as an advisor in two paid webinars (Merck and Biogen) on the following

						non-product specific topics in the last 12 months: Delivering neurology services during the Covid-19 pandemic. Implications and implementation of Covid-19 vaccination on people with MS
	Association of British Neurologists	MS committee member	None	None	Yes	None
Dr Fergus Rugg-Gunn	None	None	None	None	N/A	None
Dr Aditya Sharma	None	None	Lundbeck	Unrestricted medical educational grant towards a study	Yes	None
Dr Catherine Stannard	None	None	None	None	N/A	None
Professor Christopher Weir	None	None	AB Science	DSMB membership for two trials (in ALS and mastocytosis), with income to my department (no work done or payment received to date)	Yes	None
			Eli Lilly	Research grant to institution, on which I am co-applicant	Yes	None

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

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Angela E Thomas	None	None	None	None	N/A	Non-Executive Director of the CTG Catapult from October 2020.
Professor Poulam M Patel	EUSA	Sponsored attendance to ASCO GU annual Conference (Feb 2020)	Pfizer	Co-Investigator/Co-supervisor for translational research project into hepatotoxicity. Project part funded by educational grant from Pfizer|	Yes	None
			Scancell	Co- supervisor for translational research project into hepatotoxicity. Project part funded by grant from Scancell	No	
			Calithera Biosciences	Local PI for multicentre company sponsored trial	No	
			BMS	Local PI for multicentre company sponsored trial	No	

			Scancell	Chief Investigator for company sponsored clinical trial	No	
			Pfizer	Local PI for multicentre company sponsored trial	No	
			Astra Zeneca	Collaboration on research project and prospective phase 1 trial where AZ are providing drug to be added during preparation of dendritic cell vaccine	No	
Professor David Bowen	Abbvie	Consultancy	None	None	Yes	None
	Syros	Consultancy			Yes	
	Silence Therapeutics	Consultancy			Yes	
	Eurocept	Advisory Board			No	
Professor Stephen Devereux	None	None	None	None	N/A	None
Dr Hugo Ford	None	None	None	None	N/A	My family member is the Conservative MP for Chelmsford and Parliamentary Under Secretary of State for Children and Families
Dr Robert Marcus	None	None	None	None	N/A	None

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

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Dr Rebecca Mann	None	None	Sanofi	Vaccination against Meningococcus ACWY	No	None
Dr Eileen Baildam	None	None	None	None	N/A	None
Mrs Catrin Barker	None	None	None	None	N/A	None
Dr Helen Burdett	None	None	None	None	N/A	None
Professor J Helen Cross	None	None	GW Pharmaceuticals	Epidyolex	Yes	None
			Zogenix	Fintepla		
			Vitaflo	Betashot		
			Stoke Therapeutics	Antisense Oligonucleotide STK-001		
			Marinius	Ganaxolone		
Professor Steven Cunningham	None	None	None	None	N/A	None

Dr Daniel Hawcutt	None	None	None	None	N/A	None
Professor Meriel Jenney	None	None	None	None	N/A	None
Dr Caroline Jones	None	None	None	None	N/A	None
Professor Nigel Klein	None	None	None	None	N/A	None
Dr Rubin Minhas	None	None	None	None	N/A	None
Professor Marie-Louise Newell	None	None	None	None	N/A	None
Ms Sara Payne	PHG Foundation (Cambridge)	Associate (PT)	None	None	Yes	Family member is a high court judge in intellectual property cases in the Chancery division of the high court concerning medicates and medical devices
Dr Guido Pieles	Canon Medical Systems Ltd	Consultancy (lecturing, strategy of sports cardiology imaging)	None	None	Yes	None
	Cardiac Health & Performance Ltd.	Director (clinical sports cardiology and sports medicine consulting)			Yes	
Professor Heather Wallace	None	None	Novabiotics	none	Yes	President of EUROTOX. The Society receives sponsorship from many sources for its annual congress. These funds go to the local

						organising committee (for 2020 Copenhagen) who run the conference.
			CellProTx			
Dr Morris Zwi	None	None	None	None	N/A	None

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

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Sir Munir Pirmohamed	None	None	Eli Lilly	Research grant to University of Liverpool (UoL) to support clinical training fellowships jointly with the Medical Research Council (MRC)	No	In November 2020, I became a member of Innovative Medicines Initiative-funded consortium called Accelerating research & development for advanced therapies (ARDAT: www.ardat.org). As part of this the UoL will receive research funding directly from the EU Commission. Like all IMI consortia, this is a public-private partnership, and academic and clinical members of the consortium will work in collaboration with industry partners (Pfizer, Bayer, Janssen, Lonza, Novartis, Novo Nordisk, Sanofi-Anetis, Spark Therapeutics, Takeda, Viscofan and Astella Pharma), but will not receive direct funding from the industry partners.
			Novartis	Research grant to UoL to support clinical training		

				fellowships jointly with MRC		
			Roche	Research grant to UoL to support clinical training fellowships jointly with MRC		
			UCB Pharma	Research grant to UoL to support clinical training fellowships jointly with MRC		
			Astra Zeneca	Research grant to UoL to support PhD in drug-drug interactions co-funded by the EPSRC		
			BMS (Bristol Myers Squibb)	Unrestricted educational grant to UoL to support UK Pharmacogenetics and Stratified Medicine network open meeting		
			Vistagen	Research grant evaluating the role of L-amino acid transporter		
Professor Darren Ashcroft	None	None	AbbVie, Becton Dickinson, Celgene (Bristol Myer Squibb/Amgen)	MRC Stratified Medicine Research Grant: Psoriasis Stratification to Optimise Relevant Therapy (PSORT)	No	None

			Medimmune (Astra Zeneca), Novartis (Sandoz), Pfizer, Qiagen, Stiefel-GSK	MRC Stratified Medicine Research Grant: Psoriasis Stratification to Optimise Relevant Therapy (PSORT)		
			Eli Lilly,Janssen, LEO Pharma,	MRC Stratified Medicine Research Grant: Psoriasis Stratification to Optimise Relevant Therapy (PSORT)		
			LEO Foundation, Eli Lilly, Novartis (Sandoz),	Research grant to support the development of the Global Psoriasis Atlas		
			Abbvie, Amgen (was Celgene), Janssen	Research grant to support the development of the Global Psoriasis Atlas		
			Mundipharma	Research grant		
Professor Ann Daly	None	None	None	None	N/A	President, International Society for the Study of Xenobiotics until December 2021 Senior Editor, British Journal of Clinical Pharmacology Investigator on IMI-H2020 project entitled LITMUS which is concerned with identification and qualification of biomarkers for non-alcoholic liver disease.

Professor Ian Douglas	Glaxo SmithKline	None	GlaxoSmithKline	Research Grant	Yes	None
Dr Mark Glover	None	None	None	None	N/A	None
Dr Daniel Hawcutt	None	None	None	None	N/A	None
Ms Susan Hunneyball	None	None	None	None	N/A	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
Dr Karen Miller	None	None	None	None	N/A	None
Dr Rupert Payne	None	None	None	None	N/A	I am consultant editor (remunerated position) for the journal Prescriber (John Wiley & Sons publishers) which carries pharmaceutical industry advertising. I am not involved in decisions around advertisements for the journal. I receive funding from the National Institute for Health Research (NIHR) to undertake research on polypharmacy, medicines optimisation and pharmacoepidemiology.

Ms Christine Randall	None	None	None	None	N/A	None
Dr Ruben Thanacoody	None	None	None	None	N/A	None

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

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Kevin Taylor	None	None	None	None	N/A	None
Mr Andy Collen	None	None	None	None	N/A	None
Professor Adam Fox	None	None	Mylan & ALK	I am president of the British Society for Allergy & Clinical Immunology and Chair of the Healthcare Advisory Board of Allergy UK. Both of these organisations receiving commercial sponsorship for educational activities from Mylan & ALK. I have been involved in consultancy work for Mylan (one occasion 18/2/21), as a representative	Yes	None

				of Guy's & St Thomas' Hospitals NHS Foundation Trust, for which I receive no personal fee.		
Dr Siraj Misbah	None	None	None	None	N/A	None
Mr Trevor Povey	None	None	None	None	N/A	None
Dr Jasmeet Soar	None	None	None	None	N/A	None
Wing Tang	None	None	None	None	N/A	None
Mr Robbie Turner	None	None	None	None	N/A	None
Mrs Madeleine Wang	None	None	None	None	N/A	None
Dr Bruce Warner	None	None	None	None	N/A	None
Dr Carla Jones Dr Liz Angier	None	None	ALK	Sponsorship for activities developed and delivered by Allergy UK, my employer	No	None
Ms Lynne Regent	None	None	Mylan ALK	Mylan BSACI filming Sept 2020 subsequently given to Anaphylaxis Campaign	None	None

COVID-19 THERAPEUTICS EXPERT WORKING GROUP MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Jonathan S Friedland	None	None	Astra Zeneca	The commercial company is a sponsor / funder of research at St. George's University of London which does not involve me (and of which I am generally unaware of the topic)	Yes	I am a member of the UK-CTAP Covid-19 Prophylaxis subgroup. My family member, at UCL/UCLH leads a trial in Covid-19 and is involved in another trial for Covid-19.
			Chiesi Limited	As above	Yes	
			EDIXOMED LIMITED	As above	Yes	
			FairCourt Capital	As above	Yes	
			Penta ID Innovation srl	As above	Yes	
			GlaxoSmithKline	As above	Yes	
			Gilead Sciences Ltd.	As above	Yes	
			Bristol-Myers Squibb International Corp	As above	Yes	
			LDN Pharma	As above	Yes	
			Merck Serono Ltd	As above	Yes	

			Oxford Gene Technology (Operations) Ltd	As above	Yes	
			Takeda UK Ltd	As above	Yes	
			Celgene Corporation	As above	Yes	
			Pfizer UK	As above	Yes	
			St Jude Medical, AFD Inc.	As above	Yes	
			Jay Pharma Inc.	As above	Yes	
			VBI Vaccines Inc	As above	Yes	
			Boston Scientific Limited	As above	Yes	
			Helperby Therapeutics	As above	Yes	
			Kuok Brothers Sdn Bhd	As above	Yes	
			Beckman Coulter Genomics Inc.	As above	Yes	
			Attune Medical Inc	As above	Yes	
			Merk Sharp & Dohme Ltd	As above	Yes	
Dr Kenneth Baillie	None	None	None	None	N/A	None

Ms Susan Bradford	None	None	Roche	August 2020 - Speaker at event sponsored by Roche. Not renumerated.	No	None
Professor David Dockrell	None	None	GSK	Past funding from GSK for research (not in current year)	No	Investigator for RECOVERY Trial
			ViiV	Lecture fees and Meeting attendance sponsorship from ViiV	No	
Professor Richard Gilson	None	None	Janssen	non-personal non-specific interest in COVID-19 vaccine. My department is a collaborating site in clinical trials of other products sponsored by Janssen, who have provided research funds to the department through funding to Central and North West London NHS Foundation Trust.	No	None
			Mylan	non-personal non-specific interest in lopinavir/ritonavir. My department was a collaborating site in a clinical trial using another product supplied by		

	Mylan. The trial was funded by NHS England and research funds to the department were provided through funding to Central and North West London NHS Foundation Trust.
Gilead Sciences	non-personal specific interest in remdesivir. I was a local site sub-investigator on a remdesivir trial sponsored by Gilead Sciences.
Oxford University	non-personal, specific other interest in the AZ/Oxford University COVID-19 vaccine. Members of my research group at UCL were local investigators or sub-investigators on trials of the vaccine; I am not directly involved.
Astra Zeneca	non-personal, specific other interest in the AZ/Oxford University COVID-19 vaccine.

			Novavax	Members of my research group at UCL were local investigators or sub-investigators on trials of the vaccine; I am not directly involved. non-personal, specific other interest in the Novavax COVID-19 vaccine.		
			Imperial College London	Members of my research group at UCL were local investigators or sub-investigators on trials of the vaccine; I am not directly involved. non-personal, specific other interest in the Imperial College COVID-19 vaccine.		
Dr Susan Hopkins	None	None	None	Members of my research group at UCL were investigators on trials of the vaccine; I am not directly involved. None	N/A	None

Dr Katie Jeffery	None	None	None	None	N/A	None
Sir Michael Jacobs	None	None	None	None	N/A	None
Professor Nigel Klein	None	None	None	None	N/A	None
Dr Siraj Misbah	None	None	None	None	N/A	None
Professor Kevin Park	None	None	2. Medical Research Council (MRC)	2. A systems medicine approach for the stratification of CLL patients: Biomarkers and therapeutic opportunities	Yes	None
			3. Medical Research Council (MRC)	3. Centre for Drug Safety Science (CDSS) Renewal	Yes	
			4. L'Institut De Recherches Internationales Servier (France)	4. Defining the molecular mechanisms underlying the complex role of mitochondrial dysfunction in the onset of drug-induced cholestatic injury		
			5. Medical Research Council (MRC)	5. Definition of the naturally-processed drug-	Yes	

	peptide adducts that can act as functional T-cell antigens	
6. Biotechnology & Biological Science Research Council (BBSRC)	6. Development of screening approaches to assess to intrinsic immunogenicity of drugs and novel chemicals	
7. European Commission	7. Improving the survival of transplanted kidneys using a novel regenerative medicine therapy	Yes
8. GlaxoSmithKline Research & Development Limited (UK)	8. North West England MRC Fellowships in Clinical Pharmacology and Therapeutics	
9. European Commission	9. Novel technologies for evaluating the efficacy and safety of cell-based therapies for kidney disease RenalToolBox	Yes
10. Pancreatic Cancer Research Fund (UK)	10. Preclinical evaluation of Nrf2 inhibition as a means to improve	

	chemotherapeutic efficacy in patients with pancreatic cancer
11. GlaxoSmithKline Research & Development Limited (UK)	11. Quantitative assessment of drug-protein adduct formation and function
12. Merck & Co., INC. (USA)	12. To examine the potential preclinical value of mechanism-based biomarkers of DILI over more established and widely accepted clinical diagnostics related to liver histopathology. Development and qualification of the use of a combination of established and mechanism-based biomarkers (HMGB1(+Ac/-Ac); cytokeratin 18 or ccK18; Mir122) for DILI assay in preclinical studies (CDSS DILI Project)

			13. European commission	13. Translational Safety Biomarker Pipeline (TransBioLine): Enabling development and implementation of novel safety biomarkers in clinical trials and diagnosis of disease		
			14. European commission	14. TransQST: Translational quantitative systems toxicology to improve the understanding of the safety of medicines		
Professor Deenan Pillay	None	None	None	None	N/A	None
Professor Sir Munir Pirmohamed	None	None	AstraZeneca Roche, Eli Lilly, Novartis and UCB	Research grant to UoL to support PhD in drug-drug interactions. this relates to the MRC Clinical Pharmacology Training Scheme which is jointly funded by the MRC and these 4 companies. It trains medically qualified	No	None

	individuals to PhD level on a variety of projects. I am Director of the scheme.
Pfizer, Janssen, and Sanofi	I am part of an EU-funded IMI consortium on gene therapy, and these companies are partners in the project. The University of Liverpool will get funding from the EU (but not from the partners), this IMI project commenced on 3rd November 2020.
AGILE	this is a Liverpool early phase trial platform (between University of Liverpool and Liverpool School of Tropical Medicine). It is funded by the Wellcome Trust and UKRI/DHSC/NIHR. It is NOT evaluating vaccines, but only drugs to treat COVID-19. I was a co-applicant on the funding

applications to the UKRI and Wellcome Trust. I have no involvement with any of the developers of the compounds to be studied (academic or industrial).
I am a member of the UK COVID Therapeutics Advisory Panel (UK-CTAP), and Chair its Immune sub-group, which is advising the CMO on which compounds need to be prioritised for the COVID trial platforms including RECOVERY+, PRINCIPLE, AGILE, and HEAL (these trials are funded via NIHR/DHSC and UKRI)
I am a committee member of the DHSC Covid Immunology Group since April 2021

Professor Shirley Price Dr Claire Steves	None	None	GSK and AstraZeneca	These non-personal interests relate to donations provided by both companies to the British Toxicology Society (BTS) to support their Annual Congress and Education and Training initiatives. I am currently President of the Society (2020-2022).	Yes	None
Professor Angela E Thomas	None	None	None	None	N/A	Non-Executive Director of the CTG Catapult from October 2020.
Professor Stephen Devereux Ms Ana Maria Henao Restrepo	None	None	None	None	N/A	None
Sir Richard Peto	None	None	None	None	N/A	None

COVID-19 VACCINE BENEFIT RISK EXPERT WORKING GROUP MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Sir Munir Pirmohamed	None	None	AstraZeneca	Research grant to UoL to support PhD in drug-drug interactions.	No	None
			Roche, Eli Lilly, Novartis and UCB	this relates to the MRC Clinical Pharmacology Training Scheme which is jointly funded by the MRC and these 4 companies. It trains medically qualified individuals to PhD level on a variety of projects. I am Director of the scheme.		
			Pfizer, Janssen, and Sanofi	I am part of an EU-funded IMI consortium on gene therapy, and these companies are partners in the project. The University of Liverpool will get funding from the		

AGILE	EU (but not from the partners), this IMI project commenced on 3rd November 2020. this is a Liverpool early phase trial platform (between University of Liverpool and Liverpool School of Tropical Medicine). It is funded by the Wellcome Trust and UKRI/DHSC/NIHR. It is NOT evaluating vaccines, but only drugs to treat COVID-19. I was a co-applicant on the funding applications to the UKRI and Wellcome Trust. I have no involvement with any of the developers of the compounds to be studied (academic or industrial). I am a member of the UK COVID Therapeutics Advisory Panel (UK-CTAP), and

				Chair its Immune sub-group, which is advising the CMO on which compounds need to be prioritised for the COVID trial platforms including RECOVERY+, PRINCIPLE, AGILE, and HEAL (these trials are funded via NIHR/DHSC and UKRI) I am a committee member of the DHSC Covid Immunology Group since April 2021		
Professor Judith Breuer	None	None	None	None	N/A	None
Professor Gordon Dougan	None	None	None	None	N/A	None
Professor Neil French	None	None	Glaxo Smith Kline	As a named Investigator, I hold an award from Glaxo Smith Kline in relation to the evaluation of the effectiveness of RTS'S malaria vaccine in Malawi. Active from 1st March 2020 through to 30th June 2023.	Yes	I have held grants in the past from Glaxo Smith Kline as a named investigator to undertake work to evaluate the effectiveness of Rotarix vaccine. Impact of rotavirus vaccination on winter/ spring pressures at a large paediatric hospital in the UK: an ecological study. Co-Investigator GSK 2015-16

						Impact of national rotavirus vaccination on diarrhoea deaths among infants in rural Malawi, Co-Principal Investigator GSK 2014-16 Measuring of Rotavirus vaccine effectiveness in Merseyside Co-Investigator GSK 2014-16.
Professor David Goldblatt	None	None	None	None	N/A	None
Ms Susan Hunneyball	None	None	None	None	N/A	I have written articles for the Chemist and Druggist magazine which relate to Covid-19 vaccines generally. All the information reported in the articles has been in the public domain and I do not get paid. This activity was approved by MHRA.
Professor Kimme Hyrich	None	None	Abbvie	Period events between 1st January 2020 to 31st December 2020 Speaker's fees for participation in education conference in rheumatology (Abbvie) - paid to University of Manchester	Yes	For transparency, I am the Chief Investigator for the British Society for Rheumatology Biologics Register (www.bsrbr.org) and the UK JIA Biologiocs Register (sites.manchester.ac.uk/bcrdbspar/). Data from these patient registers have contributed to data supporting the RMP of many biologic therapies for arthritis although the university is not funded directly by any

						pharmaceutical company for this research. We are funded by Versus Arthritis and the British Society for Rheumatology. We undertake and publish independent comparative effectiveness research in my research group (all related to rheumatoid arthritis or juvenile idiopathic arthritis).
			Pfizer	1st January 2020 to 31st December 2020 for research in rheumatoid arthritis: Grant income (Pfizer) - paid to University of Manchester	Yes	
			Bristol Myers Squibb	1st January 2020 to 31st December 2020 for research in rheumatoid arthritis: Grant income (Bristol Myers Squibb) - paid to University of Manchester	Yes	
Sir Michael Jacobs	None	None	None	None	N/A	None
Professor Helen J Lachmann	SOBI	Speakers fees/consultancy	SOBI	Support for research nurse salary, unrestricted grant to support UKSAID national meetings,	Yes	None

	Novartis	Speakers fees/consultancy	None	None	Yes	
	UPTODATE	Editor payments	None	None	Yes	
Professor Paul J Lehner	None	None	None	None	N/A	None
Dr Siraj Misbah	None	None	None	None	N/A	None
Professor Shirley Price	None	None	GSK and AstraZeneca	These non-personal interests relate to donations provided by both companies to the British Toxicology Society (BTS) to support their Annual Congress and Education and Training initiatives. I am currently President of the Society (2020-2022).	Yes	None
Dr Andrew Riordan	None	None	Oxford University	Postgraduate External Examiner for Oxford University (Postgraduate Diploma in Paediatric Infectious Diseases)	No	Participant in University of Oxford's clinical trial
Professor Chris Robertson	None	None	None	None	N/A	None
Professor Pallav Shah	Olympus	consultancy	ERBE, Medtronic, Olympus,	sponsor Imperial college for	Yes	None

			PneumRX/BTG, Pulmonx, Boston Scientific, Nuvaria, Broncus	bronchoscopy course		
	Pulmonx	consultancy/ lecture	Pulmonx	RCT with endobronchial valves Royal Brompton Hospital reimbursed for clinical trial expenses	Yes	
	Creo	consultancy	Nuvaira	RCT with vagal nerve ablation Royal Brompton Hospital and Chelsea & Westminster Hospital reimbursed for clinical trial expenses	Yes	
	None	None	CSA	RCT with RejuvenAir Chelsea & Westminster Hospital reimbursed for clinical trial expenses	Yes	
Professor Tom Solomon	None	None	None	None	N/A	None
Dr Robin Thorpe	None	None	None	None	N/A	None
Mrs Madeleine Wang	None	None	None	None	N/A	None
Professor Christopher Weir	None	None	Lothian NHS Board	Other relevant interest arising	Yes	None

from link to the Lothian NHS Board. NHS Lothian R&D has partially funded Professor Weir's post at University of Edinburgh, since 2010, so that he could provide methodological advice on health services research studies and clinical trials.
I also have a non-personal, non-specific interest in Imperial College. Since 2018 my department has collaborated on clinical trials with Imperial College and receives grant income related to these collaborations. I am not involved in these collaborations.

COVID-19 VACCINES SAFETY SURVEILLANCE METHODOLOGIES EXPERT WORKING GROUP MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Dr Siraj Misbah	None	None	None	None	N/A	None
Professor Ian Douglas	GSK	Shares	GSK	Research grants from GSK	Yes	None
	Oxford University	Lecture fees			No	
Professor Jonathan S Friedland	None	None	Astra Zeneca	The commercial company is a sponsor / funder of research at St. George's University of London which does not involve me (and of which I am generally unaware of the topic)	Yes	I am a member of the UK-CTAP Covid-19 Prophylaxis subgroup. My family member, at UCL/UCLH leads a trial in Covid-19 and is involved in another trial for Covid-19.
			Chiesi Limited	As above	Yes	
			EDIXOMED LIMITED	As above	Yes	
			FairCourt Capital	As above	Yes	

Penta ID Innovation SRL	As above	Yes
GlaxoSmithKline	As above	Yes
Gilead Sciences Ltd.	As above	Yes
Bristol-Myers Squibb International Corp	As above	Yes
LDN Pharma	As above	Yes
Merck Serono Ltd.	As above	Yes
Oxford Gene Technology (Operations) Ltd.	As above	Yes
Takeda UK Ltd.	As above	Yes
Celgene Corporation	As above	Yes
Pfizer UK	As above	Yes
St Jude Medical, AFD Inc.	As above	Yes
Jay Pharma Inc.	As above	Yes
VBI Vaccines Inc	As above	Yes

			Boston Scientific Limited	As above	Yes	
			Helperby Therapeutics	As above	Yes	
			Kuok Brothers Sdn Bhd	As above	Yes	
			Beckman Coulter Genomics Inc.	As above	Yes	
			Attune Medical Inc	As above	Yes	
			Merk Sharp & Dohme Ltd.	As above	Yes	
Sir Michael Jacobs	None	None	None	None	N/A	None
Professor Simon De Lusignan	None	None	None	None	No	None
Dr Rupert Payne	None	None	National Institute for Health Research School for Primary Care Research (NIHR SPCR)	Funding received from NIHR SPCR to cover CPRD data costs for research project examining primary care risk factors for severe COVID-19 infection	N/A	None
Professor Sir Munir Pirmohamed	None	None	AstraZeneca Roche, Eli Lilly, Novartis and UCB	Research grant to UoL to support PhD in drug-drug interactions. this relates to the MRC Clinical Pharmacology	Yes	None

	Training Scheme which is jointly funded by the MRC and these 4 companies. It trains medically qualified individuals to PhD level on a variety of projects. I am Director of the scheme.
Pfizer, Janssen, and Sanofi	I am part of an EU-funded IMI consortium on gene therapy, and these companies are partners in the project. The University of Liverpool will get funding from the EU (but not from the partners), this IMI project commenced on 3rd November 2020.
AGILE	this is a Liverpool early phase trial platform (between University of Liverpool and Liverpool School of Tropical Medicine). It is funded by the Wellcome Trust and UKRI/DHSC/NIHR. It is NOT

evaluating vaccines, but only drugs to treat COVID-19. I was a co-applicant on the funding applications to the UKRI and Wellcome Trust. I have no involvement with any of the developers of the compounds to be studied (academic or industrial).
I am a member of the UK COVID Therapeutics Advisory Panel (UK-CTAP), and Chair its Immune sub-group, which is advising the CMO on which compounds need to be prioritised for the COVID trial platforms including RECOVERY+, PRINCIPLE, AGILE, and HEAL (these trials are funded via NIHR/DHSC and UKRI)

Professor Siobhan Quenby	None	None	None	I am a committee member of the DHSC Covid Immunology Group since April 2021 None	N/A	None
Professor Chris Robertson	None	None	None	None	N/A	None
Professor MG Calum Semple	None	None	Chiesi Farmaceutici SpA, Italy	Gift of Clinical Trial Investigational Material (to University of Liverpool as Trial sponsor) without encumbrance and distribution to trial sites (all NHS hospitals in UK).	No	None

DESOGESTREL AD HOC STAKEHOLDER GROUP MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Kevin M G Taylor	None	None	None	None	N/A	None
Dr Martin Duerden	None	None	None	None	N/A	None
Edward Morris	None	None	None	None	N/A	Chair of Advisory Board (one off) for Gedeon Richter potential new HRT to UK Market, March 2019, Personal;, unrelated HRT to this meeting
Joanne Jenkins	None	None	None	None	N/A	None
Raymond Anderson	None	None	None	None	N/A	None
Rita Jenner	None	None	None	None	N/A	None
Dr Asha Kasliwal		I have received fees from Bayer to speak about a product which is not in either of these two categories i.e. not an oral contraceptive or HRT.	None	None	N/A	Completed a questionnaire regarding risks and benefits of reclassification of Progestogen only pill in July 2019, No payment was received.

Mrs Elia C Monteiro	None	None	None	None	N/A	None
Tracey Forsyth	None	None	None	None	N/A	None

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

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Sir Munir Pirmohamed	None	None	AstraZeneca	Research grant to UoL to support PhD in drug-drug interactions.	Yes	None
			Roche, Eli Lilly, Novartis and UCB	this relates to the MRC Clinical Pharmacology Training Scheme which is jointly funded by the MRC and these 4 companies. It trains medically qualified individuals to PhD level on a variety of projects. I am Director of the scheme.		
			Pfizer, Janssen, and Sanofi	I am part of an EU-funded IMI consortium on gene therapy, and these companies are partners in the project. The University of Liverpool will get funding from the EU (but not from		

AGILE	the partners), this IMI project commenced on 3rd November 2020. this is a Liverpool early phase trial platform (between University of Liverpool and Liverpool School of Tropical Medicine). It is funded by the Wellcome Trust and UKRI/DHSC/NIHR. It is NOT evaluating vaccines, but only drugs to treat COVID-19. I was a co-applicant on the funding applications to the UKRI and Wellcome Trust. I have no involvement with any of the developers of the compounds to be studied (academic or industrial). I am a member of the UK COVID Therapeutics Advisory Panel (UK-CTAP), and Chair its Immune

				sub-group, which is advising the CMO on which compounds need to be prioritised for the COVID trial platforms including RECOVERY+, PRINCIPLE, AGILE, and HEAL (these trials are funded via NIHR/DHSC and UKRI) I am a committee member of the DHSC Covid Immunology Group since April 2021		
Professor Darren Ashcroft	None	None	AbbVie, Becton Dickinson, Celgene (Bristol Myer Squibb/Amgen)	MRC Stratified Medicine Research Grant: Psoriasis Stratification to Optimise Relevant Therapy (PSORT)	No	None
			Medimmune (Astra Zeneca), Novartis (Sandoz), Pfizer, Qiagen, Stiefel-GSK	MRC Stratified Medicine Research Grant: Psoriasis Stratification to Optimise Relevant Therapy (PSORT)		
			Eli Lilly,Janssen, LEO Pharma,	MRC Stratified Medicine Research Grant: Psoriasis Stratification to Optimise Relevant Therapy (PSORT)		

			LEO Foundation, Eli Lilly, Novartis (Sandoz),	Research grant to support the development of the Global Psoriasis Atlas		
			Abbvie, Amgen (was Celgene), Janssen	Research grant to support the development of the Global Psoriasis Atlas		
			Mundipharma	Research grant		
Dr Susannah Baron	None	None	None	None	N/A	I have been an author on the below 2 papers which includes information about treating patients with severe acne with oral Isotretinoin. Cunliffe WJ, Baron SE, Coulson IH A clinical and therapeutic study of 29 patients with infantile acne British Journal of Dermatology 2001; 145: 1-5 Archer CB, Cohen SN, Baron SE Guidance on the diagnosis and clinical management of acne. British Association of Dermatologists and Royal College of General Practitioners. Clin Exp Dermatol. 2012 May;37 Suppl 1:1-6. doi: 10.1111/j.1365-

						2230.2012.04335.x. Review. PMID: 22486762 [PubMed - indexed for MEDLINE]
Professor Amanda Drake	None	None	None	None	N/A	None
Professor Ian Nicol Ferrier	None	None	None	None	N/A	None
Dr Arianna Di Florio	None	None	None	None	N/A	None
Dr Clive Grattan	None	None	None	None	N/A	None
Professor David Gunnell	None	None	None	None	N/A	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). Isotretinoin was one of several medicines associated with high levels of reports of depression, suicidal behaviour and suicide.

Dr Karen Miller	None	None	None	None	N/A	None
Dr George Millington	None	None	None	None	N/A	None
Professor Rod Mitchell	None	None	None	None	N/A	None
Professor Gudrun Moore	None	None	None	None	N/A	None
Mr Giangiacomo Ollandini	None	None	None	None	N/A	None
Ms Linda Pepper	None	None	None	None	N/A	None
Dr Amr Raheem	None	None	None	None	N/A	None
Mrs Madeleine Wang	None	None	None	None	N/A	None
Professor Allan Young	Lundbeck Sunovion Livanova Janssen Allegan Bionomics Sumitomo Dainippon Pharma COMPASS Novartis	Paid lectures and advisory boards for the following companies with drugs used in affective and related disorders		UK Chief Investigator for Novartis Major Depression Disorder Study MIJ821A12201 as of February 2021 UK Chief Investigator for Compass Pathways Ltd Psilocybin Clinical Trials Portfolio Principal	Yes	None

		Investigator on the following current industry sponsored clinical trials.
		An Open-label Long-term Extension Safety Study of Intranasal Esketamine inTreatment-resistant Depression Safety and Sustenance of Esketamine Treatment Response With Repeated Doses at Intervals Determined by Symptom Severity (SUSTAIN-3)
	Young, A.	Janssen Pharmaceutica N.V.
		31/08/2017 → 31/12/2024
		A Global Prospective, Multi-center, Observational post-market Study to assess short, mid and long-term effectiveness and efficiency of VNS

				Therapy® as adjunctive therapy in real-world patients with difficult to treat depression Young, A. LivaNova plc: 13/09/2018 → 1/12/2025 A Double-Blind, Placebo-Controlled, Multi-Centre Study Investigating the Efficacy, Safety, and Tolerability of JNJ-61393215 as Adjunctive Treatment in Adults with Major Depressive Disorder with Anxious Distress with Suboptimal Response to Standard Antidepressants. Young, A. Janssen Cilag NV: 19/12/2019 → 30/08/2021		
Professor Peter C Hindmarsh	None	None	None	None	N/A	None

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

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Jane Norman	None	None	None	None	N/A	None
Professor Peter Brocklehurst	None	None	None	None	N/A	None
Mr Paul Brown	None	None	None	None	N/A	None
Ms Caroline Cake	None	None	None	None	N/A	None
Dr Rachel Charlton	Glaxo Smith Kline	Shares	University of Bath	In the past 12 months the Group within which I work at the University of Bath has held research grants from pharmaceutical companies for research on topics outside of those covered by this working group.	Yes	None
Mr Chris Dickson	None	None	None	None	N/A	None

Professor Helen Dolk	None	None	None	None	N/A	None
Professor Elizabeth S Draper	None	None	None	None	N/A	None
Dr Kenneth Hodson						
Dr Matthew Jolly						
Professor Neena Modi	None	None	Chiesi Pharmaceuticals and Takeda	Grant		None
Professor Joan Morris	None	None	GSK	Family member employed by		None
Dr Puja Myles	None	None	None	None	N/A	None
Ms Katharine Robbins						
Dr Sarah Stevens	None	None	None	None	N/A	None
Dr Sarah Stock	None	None	None	None	N/A	None
Mrs Madeleine Wang	None	None	None	None	N/A	None

REAL WORLD DATA WORKING GROUP MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Deborah Ashby	None	None	Merck Sharp & Dohme Limited	Consultancy for project on benefit-risk methodology, Merck Sharp & Dohme Limited (payments are made to Imperial College)	No	None
Ms Susan Bradford	None	None	Roche	August 2020 - Speaker at event sponsored by Roche. Not renumerated.	No	None
Professor Janet Darbyshire	None	None	None	None	N/A	None
Dr C Forfar	MyoKardia, UCB and Amgen	Consultancy services provided to MyoKardia, UCB and Amgen (personal, non-specific) during 2020	None	None	Yes	Mavacamten Romosuzumab Bimekizumab DSMB MRC Trial (STREAM 2) treatment of multidrug resistant TB
Dr Peter Hall	None	None	Pfizer Sanofi Novartis Flatiron Lilly	Institutional research funding	No	All 2020-2021 None

			Roche Eisai Daiichi-Sankyo			
Professor Andrew Hattersley	None	None	None	None	N/A	None
Dr Daniel Hawcutt	None	None	None	None	N/A	None
Professor Sarah Meredith	None	None	Abbott	Grant & Product donated for a trial	No	None
			Astellas	Grant & Product donated for a trial	No	
			AstraZeneca	Grant & Product donated for a trial Product donated for a trial Drug supply and financial support	No	
			Bayer	Grant & Product donated for a trial Product donated for a trial	No	
			Boehringer Ingelhein, Bristol-Myers Squibb	Grant &Product donated for a trial Product donated for a trial	No	
			Cipla	Product donated for a trial	No	
			Gilead Sciences	Grant & Product donated for a trial Product donated for 4 trials: Grant for the Proud study	No	
			GlaxoSmithKline	Grant & Product donated for a trial Product donated for a trial	No	

Janssen	Grant & Product donated for a trial Product donated for a trial	No
Janssen-Cilag	Grant & Product donated for a trial	No
Lilly	Product donated for a trial	No
Merck	Product donated for a trial Grant & Product donated for a trial	No
Pilatus	Product donated for a trial	No
Roche	Grant & Product donated for a trial	No
Sanofi-Aventis	Grant & Product donated for a trial	No
Sanofi Pasteur	Product donated for a trial	No
Tibotec	Product donated for a trial	No
Viiv	Grant and product donated for a trial	No
Emergent Biosolutions	Product donated for a trial	No
Emcure	Product donated for a trial	No
FIT Biotech	Product donated for a trial	No
INSERM-ANRS	Product donated for a trial	No
Merck-Serono	Grant & Product donated for a trial	No

			Takeda	Product donated for a trial	No	
			Amgen	Product donated for a trial	No	
			Novartis	Grant & Product donated for a trial	No	
			TB Alliance	Grant and product donated for a trial	No	
Professor Sir Munir Pirmohamed	None	None	AstraZeneca	Research grant to UoL to support PhD in drug-drug interactions.	Yes	None
			Roche, Eli Lilly, Novartis and UCB	this relates to the MRC Clinical Pharmacology Training Scheme which is jointly funded by the MRC and these 4 companies. It trains medically qualified individuals to PhD level on a variety of projects. I am Director of the scheme.		
			Pfizer, Janssen, and Sanofi	I am part of an EU-funded IMI consortium on gene therapy, and these companies are partners in the project. The University of Liverpool will get funding from the EU (but not from		

AGILE	the partners), this IMI project commenced on 3rd November 2020. this is a Liverpool early phase trial platform (between University of Liverpool and Liverpool School of Tropical Medicine). It is funded by the Wellcome Trust and UKRI/DHSC/NIHR. It is NOT evaluating vaccines, but only drugs to treat COVID-19. I was a co-applicant on the funding applications to the UKRI and Wellcome Trust. I have no involvement with any of the developers of the compounds to be studied (academic or industrial). I am a member of the UK COVID Therapeutics Advisory Panel (UK-CTAP), and Chair its Immune

				sub-group, which is advising the CMO on which compounds need to be prioritised for the COVID trial platforms including RECOVERY+, PRINCIPLE, AGILE, and HEAL (these trials are funded via NIHR/DHSC and UKRI)		
Professor Christopher Weir	None	None	Lothian NHS Board	I am a committee member of the DHSC Covid Immunology Group since April 2021 Other relevant interest arising from link to the Lothian NHS Board. NHS Lothian R&D has partially funded Professor Weir's post at University of Edinburgh, since 2010, so that he could provide methodological advice on health services research studies and clinical trials. I also have a non-	Yes	None

	personal, non-specific interest in Imperial College. Since 2018 my department has collaborated on clinical trials with Imperial College and receives grant income related to these collaborations. I am not involved in these collaborations.

AD HOC STAKEHOLDER GROUP TO CONSIDER A PRODUCT TO TREAT VAGINAL ATROPHY MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Professor Kevin M G Taylor	None	None	None	None	N/A	None
Dr Martin Duerden	None	None	None	None	N/A	None
Dr Rubin Minhas	None	None	None	None	N/A	None
Mr Haitham Hamoda	None	None	None	None	N/A	None
Tim Hillard	None	None	None	None	N/A	I am a Board member of the International Menopause Society and associate Editor of their journal, Climacteric. I am currently updating the International recommendations on the management of vulvovaginal atrophy (VVA)/genitourinary syndrome of the menopause (GSM). I am a Board member of the British Menopause Society. I have received honoraria for lectures from related companies: Theramex (DHEA) and Shionogi (Ospemifene)

Emma Anderson	None	None	None	None	N/A	I work for the Centre for Pharmacy Postgraduate Education (CPPE), updating and running courses on emergency contraception, contraception and sexual health. In the past year I have sat on the Specialist Pharmacy Services short-life working group for contraception and sexual health as part of my employment with CPPE.
Joanne Jenkins	None	None	None	None	N/A	None
Raymond Anderson	None	None	None	None	N/A	None
Dr Asha Kasliwal		I have received fees from Bayer to speak about a product which is not in either of these two categories i.e. not an oral contraceptive or HRT.	None	None	N/A	Completed a questionnaire regarding risks and benefits of reclassification of Progestogen only pill in July 2019, No payment was received.
Mrs Elia C Monteiro	None	None	None	None	N/A	None
Ms Ruth Bailey	None	None	None	None	N/A	None

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

	Personal Interest		Non-Personal Interest			
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	**Additional Information**
Sajjad Ahmad	Thea Pharmaceuticals	Honorarium for talk	None	None	No	None
Bruce Allan	Thea Pharmaceuticals	Honoraria for speaking two corneal surgical meetings sponsored	NIHR BRC in Ophthalmology at Moorfields and UCL Institute of Ophthalmology	Partial salary support for research sessions	No	None
Mr Ejaz Ansari	None	None	None	None	None	None
Professor Paul Bishop	None	None	None	None	No	None
Professor Baljean Dhillon						
Ms Cecelia Fenerty	None	None	None	None	No	none
Professor Sir Peng T Khaw	Radiance Therapeutics	Co-founder Radiation therapy for scarring	Santen Pharmaceuticals	Funding PhD Student Co supervised with UCL School of Pharmacy	Yes	None
	Optceutics	Co-founder developing a pharmacokinetic model of the eye				

	CMER Hospital Group Hong Kong	Research Advisory Group share options not taken up				
	Aerie Pharmaceuticals	Consultancy for Chairing symposium on future glaucoma treatments				
	Novartis	Consultancy for Chairing scientific advisory board				
	Thea	Consultancy for advising on specific product				
Professor David O'Brart	Rayner Ltd	Non-commercial research grant	None	None	Yes	None
Professor Sunil Shah	Presbyopia Treatment Ltd	Shares	None	None	No	None
	The Laser and Lens Network Ltd	Dormant	None	None	No	
	The Eye Doctors Ltd	Shares	None	None	No	
	SS Laser Consultancy Ltd	Shares	None	None	No	
	Visual Entrepeneurs Ltd	Dormant	None	None	No	
	Eye-Docs Ltd	Shares	None	None	No	
	Allergan	Consultancy occasional	None	None	No	

	Shire	Consultancy occasional	None	None	No	
	Max Biotech	Shares	None	None	No	
	Photon Therapeutics	Shares	None	None	No	
	GERSO	Educational Charity	None	None	No	
Miss Laura Steeples Mr Anthony J King Mr Martin McKibbin	Allergan	Consultancy fee Speaker fee Speaker fee	None	None	No	None

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

	Personal Interest		Non-Personal Interest			Additional Information
Member	**Company Name**	**Nature of Interest**	**Company Name**	**Nature of Interest**	**Current**	
Prof K Taylor	None		None		N/A	None
Dr E Amirak	Akcea Therapeutics	Salary	None		N/A	None
	Sanofi	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 Working Party	Member (unpaid)	Yes	
	Vernalis	Shares (immediate family member)	None		No	
Dr G D Cook	Pfizer	Salary, Shares	None		N/A	None
	Viatris/Upjohn	Shares				

Prof A G Davidson (Vice-Chair)	None		None		N/A	None
Dr A Gleadle	Tesco PLC	Shares	None		N/A	None
	AstraZeneca (Medimmune)	Salary (other person)				
Dr V Jaitely	Ares Trading (Merck)	Salary	None		N/A	None
Mr R Lowe	None		None		N/A	None
Dr P Marshall	Jazz Pharmaceuticals	Salary, Shares	None		N/A	None
	Reckitt Beckiser	Shares				
	Individior	Shares				
	Sims Marshall Consultancy	Consultancy (range of products)				
Prof J Miller	None		None		N/A	None
Ms S Palser	None		None		N/A	None
Prof M Simmonds	Pharmakos Ltd	Director	College of Medicine	Member	Yes	None
			DEFRA Darwin Initiative Advisory Committee	Member	Yes	

			Hong Kong Department of Health, Pharmacopoeia International Advisory Committee	Member	Yes	
Dr R Torano	GlaxoSmithKline	Salary, Shares	None		N/A	None
Dr P Varley	Kymab Ltd	Salary, Share options	None		N/A	None

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