

Human Medicines Regulations 2012

Advisory Bodies

British Pharmacopoeia Commission

Annual Report 2023

Published July 2024



**Human Medicines
Regulations 2012
Advisory Bodies**

British Pharmacopoeia Commission

Annual Report 2023

Medicines and Healthcare products Regulatory Agency

**HUMAN MEDICINES REGULATIONS 2012
ADVISORY BODIES**

British Pharmacopoeia Commission

**ANNUAL REPORT
2023**

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



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

Medicines and Healthcare products Regulatory Agency

Customer Services

10 South Colonnade

Canary Wharf

London E14 4PU

Tel: 020 3080 6000

E-mail: info@mhra.gov.uk

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Foreword by the Secretary Of State For Health and Social Care

It gives me great pleasure to present the annual reports for 2023 of the Human Medicines Regulations Advisory Bodies: The British Pharmacopoeia Commission. These reports include a record of members' interests in the relevant industry as per the Conflicts of Interest Code of Practice.

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

Wes Streeting MP

BRITISH PHARMACOPOEIA COMMISSION

BRITISH PHARMACOPOEIA COMMISSION

ANNUAL REPORT FOR 2023

Introduction

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

It is of paramount importance that the medicines received by patients are safe, effective and of a suitable quality. The BP and BP(Vet) 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 and beyond. The BP is used across the globe and referenced in the legislation of several countries.

The membership

A list of members of the BPC during 2023 is shown in this report.

The final term of office for two lay members of the BPC ended on 31st December 2023 and one member retired in Autumn 2023. A campaign to identify new members was carried out in collaboration with the Department of Health and Social Care Appointments Team during the year and the appointment of new members was finalised in early 2024.

A comprehensive review of membership of the Expert Advisory Groups (EAG), Panels of Experts and Working Parties (WP) was undertaken during the year. A significant number of expressions of interest were received from individuals keen to become involved in the work of the BP. The terms of office for all newly appointed and re-appointed members will run from 1st January 2024 to 31st December 2028.

A list of members of the supporting EAGs, Panels of Experts and WPs for 2023 is given in Appendix II.

Code of practice

1. Members of the BPC are required to comply with the Medicines and Healthcare products Regulatory Agency (MHRA) Code of Practice on Identifying, Declaring and Managing Interests. This new Code of Practice was launched on 8th September 2022 and replaced the former BPC Code of Practice. Members of the EAGs, Panels of Experts and WPs are also required to comply with the new Code of Practice, with the exception of the Chair and members of the BPC and its supporting EAGs, Panels of Experts and WPs are permitted to hold personal interests in the pharmaceutical industry. This allowance ensures that the BPC and its supporting groups benefit from the practical insights and up-to-date knowledge that these technical members bring from their active roles in the industry.

Meetings

2. The BPC met three times during 2023. Thirteen meetings of the EAGs, Panels of Experts and WPs were also held during the year, together with several meetings of the four sub-groups of the Working Party on Advanced Therapy Medicinal Products (ATMP WP). Of note, 2023 marked the return of in-person meetings at 10 South Colonnade, Canary Wharf, London E14 4PU, although the majority continued to be held virtually. It is expected that a hybrid model will be adopted in future.
3. Summary Minutes of the meetings of the BPC and its EAGs, Panels of Experts and WPs can be found on the BP website ([Meetings and minutes - British Pharmacopoeia](#)).

Secretariat

4. The BP is based at 10 South Colonnade, Canary Wharf, London E14 4PU.

Laboratory

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

Costs

6. For each meeting that they attend, members of the BPC are entitled to claim a taxable attendance fee of £325 (Chair's fee, £500). Members of the EAGs, Panels of Experts and WPs 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 2023

7. Following publication of the BP 2023, three online updates were issued providing users with the texts of the 11th Edition and of Supplements 11.1 and 11.2 of the European Pharmacopoeia.

British Pharmacopoeia 2024

8. The BP 2024 was published in August 2023. This new edition is available as a package containing the five volumes of the BP 2024, the one volume of the BP (Vet) 2024 and access to the electronic versions of both publications (online BP and offline download format).
9. This new edition contains approximately 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 BP 2024 is 1st January 2024.
10. All monographs published within the 11th Edition of the European Pharmacopoeia, as amended by Supplements 11.1 to 11.2, are included either in this edition of the BP or, where appropriate, in the associated edition of the BP (Vet). 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.
11. The BP 2024 contains 21 new monographs of national origin which were not published in previous editions, including two new monographs for unlicensed formulations. A significant number of national monographs were amended in respect of technical or editorial content (93 in total) and the titles of 8 national monographs were amended in this edition.
12. Three new Appendices: Appendix XIV Q. Assay of Bet v 1 Allergen; Appendix XIV R. Cell-based Assays for Potency Determination of TNF-alpha Antagonists; Appendix XVI I. Microbiological Examination of Human Tissues have been incorporated by means of this edition.

13. One new Supplementary Chapter was added by means of this edition, **SC IV V. Information on Implementation of Pharmacopoeial Procedures.**
14. Seventeen national monographs for products no longer marketed were omitted from the BP 2024 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) 2024

15. The BP (Vet) 2024 was published as a companion volume to the BP 2024 in August 2023. 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 BP (Vet) 2024 is 1st January 2024.
16. The BP (Vet) 2024 contains six new monographs of national origin which were not published in previous editions.

British Approved Names 2022

17. BANs 2022 (Supplement No.2) was published in August 2023. This Supplement defines 43 new chemical and biological entities that are used in medicines in the UK. The majority of the new names are for active substances used in medicinal products that have not previously been marketed in the UK.

Digital Publications

18. The BP 2024 publications can be accessed through the online version (pharmacopoeia.com) and the offline download edition. Both formats have been updated to include the European Pharmacopoeia supplements 11.3 to 11.4 in their entirety and will be updated in 2024 to include supplement 11.5.
19. The BP website was redesigned and updated to provide users with a better experience and was launched in December 2023. The redesigned website incorporates a range of updated features including new and improved site design and navigation, improved purchasing journeys, an updated timeline and improved tracked changes to better visualise changes to monographs.

20. The new BP website also incorporated the BAN publication which have been converted into a new format with the same look and feel of the BP digital publication.
21. Following the regular public consultation scheduled for new and revised monographs, four three-month consultation periods were held during 2023. This continued to provide users with the opportunity to contribute to the monograph development and revision process, helping to ensure that published monographs are relevant and robust.

Prices and Availability

22. Details of the prices and availability of the above-mentioned publications are shown in **Appendix I**.
23. 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

24. By the end of 2023 work was progressing on the preparation of the next editions of the BP and BP (Vet). These will be published during 2024 and will have an effective date of 1st January 2025.
25. A digital update to the BP 2024 was issued in November 2023, providing users with the text of the Supplement 11.3 of the 11th Edition of the European Pharmacopoeia which came into effect on 1st January 2024. A further update was issued in December providing users with the text of Supplement 11.4, which will come into effect on 1st April 2024. Supplement 11.5 will be available in advance of its implementation on 1st July 2024. These updates will only be available via the online BP and the offline download. The texts will subsequently be included in the BP 2025 publications as appropriate.

Other pharmacopoeial matters

Biological Medicines

26. While continuing to maintain quality standard monographs for biological products, the main focus during the year has been the continued development of non-mandatory guidance for the analysis of cell and gene therapy products.
27. The ATMP WP continued to develop non-mandatory guidance documents that support quality and innovation in these medicines. Work to draft guidance documents continued in new topic areas with new publications entitled “Characterisation of the capsid particle population in rAAV products” and “T cell and NK cell characterisation assays” scheduled to be published in January and March 2024 respectively. The BP also established two new subgroups to draft new guidance and protocol documents: “Replication-competent virus assays” and “Validation protocols and reports for digital and quantitative polymerase chain reaction for vector copy number and genomic titre”.
28. The importance of stakeholder contributions and systems-wide approaches is recognised, and the ATMP WP includes representatives from the NHS, academia, industry, and the UK Catapult network. In addition, a close working relationship between the MHRA and the Cell and Gene Therapy Catapult has been extended and continues to support the work and continued staff development in both organisations. The Working Party continues to focus on horizon scanning and identifying new topics and is working to produce further non-mandatory guidance documents for the ATMP community.
29. The BIO-DPS Working Party (Alternative Approaches for Documentary and Physical Standards for Biotechnological Products) has continued to explore the potential of performance and class-based standards for biotechnological products. The results from the international multi-laboratory monoclonal antibody analysis were used to assess the value of alternative standards with discussions held to re-establish concepts and outline future next step approaches for the study.
30. In addition to the work related to standards development, the BP works alongside the MHRA to support broader engagement across the biopharmaceutical and ATMP landscape. The BP, alongside the MHRA, remains active within the regulatory and pharmacopoeial community, for example through continued engagement with colleagues in the US Standards Coordinating Body for Regenerative Medicines (SCB), BioPhorum and the Centre for Process Innovation.

Unlicensed Medicines

31. Monographs that have been developed to cover unlicensed formulations are identified as such in the BP. 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.
32. A number of monographs for unlicensed formulations are being developed as part of a series of family monographs alongside those for licensed products containing the same active ingredient. This initiative will make the most efficient use of Laboratory resources and will provide assurance that the methods for the unlicensed formulations are suitable.

Herbal and Complementary Medicines

33. Laboratory assessment was completed on the first two candidate monographs (Juniper Tincture and Green Tea Extract) during the year, and it is intended that monographs for green tea extracts will be included in the BP 2025.
34. In parallel, work to maintain and update the existing monographs for herbal medicines which are still used and would benefit from modernisation continues and several updated monographs were published for public consultation and will be revised in BP 2025.

Nomenclature

35. 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 BANs when they are first included in licensed medicines. UK Experts provided input into two INN Consultations during the year and contributed to the evaluation of INN requests and the development of WHO policies on drug nomenclature. Two rINN Lists (89 and 90) were published by WHO during the year.

36. The BP Secretariat is also responsible for advising the MHRA on the acceptability of proposed invented names for medicines in the UK. BP staff also continue to provide advice to manufacturers on the acceptability of invented names and remain the experts on the acceptability of invented names within the MHRA.

Sustainability

37. The BP has prepared a Sustainability Information Pack which aims to address environmental impacts associated with quality control testing, primarily in laboratory settings. Published to the BP Website, this Sustainability Information Pack incorporates feedback and case studies from stakeholders to support the adoption of greener practices.
38. Efforts are also underway in the BP laboratory to reduce solvent usage during quality control testing through method adjustments. Trials include solvent recirculation and no solvent pre-mixing techniques, demonstrating significant reductions in solvent usage without compromising test results. Further trials are planned, with successful methods intended for publishing as part of the Sustainability Information Pack.
39. Proposals to integrate sustainability into monograph elaboration and revision processes have been introduced, including scaling down column sizes and utilising method greenness calculators. A method scaling trial has shown promise with broad support for including information on scaled methods on the BP website. However, the consensus remains that the official monograph method should remain based on validated method parameters and information on scaled methods published in the “more resources” tab.
40. A significant change has been implemented in the primary packaging used to ship British Pharmacopoeia Chemical Reference Substances (BPCRS) materials, transitioning from 3-vial capacity expanded polystyrene (EPS) to 9-vial capacity cardboard boxes. This change aims to reduce environmental impact through decreased carton usage and improved recyclability. A risk assessment ensured the robustness of the new cartons, with communications sent to customers informing them of the change. Feedback will be monitored closely, with a plan to switch entirely to the new packaging going forward.

Liaison with Other UK Organisations

41. The BP and Veterinary Medicines Directorate (VMD), an executive agency of the Department for Environment, Food and Rural Affairs, continue to collaborate closely on the development of monographs for veterinary medicines through representation from the VMD on Expert Advisory Groups.
42. The MHRA has joined a Pharmaceuticals in the Environment (PiE) collaboration of UK regulators including the VMD, Environment Agency, Health and Safety Executive, and devolved nations equivalents. This group aims to address the prevalence of certain animal and human medicines in the water tables of the UK through monitoring and regulatory action. This is also pertinent to addressing anti-microbial resistance (AMR). The BP is supporting the MHRA Partnerships group in this task.

Laboratory

43. The Laboratory has continued to support the work of the BPC and the wider MHRA remit relating to public health throughout 2023.
44. During the year laboratory work on 38 new and revised BP monographs was undertaken for inclusion in future publications. The Laboratory also provided data to support several regulatory investigations during the year.

BP Reference Materials

45. Fourteen new BPCRS were established to support the BP and BP (Vet) publications, fifty-two were replaced and two hundred and nineteen were re-tested to ascertain their continued stability.
46. All new BPCRS that were introduced into the BP 2024 and BP (Vet) 2024 were made available by July 2023 to coincide with publication in August 2023. Making the materials available as early as possible ensures that users are ready to comply with the new and revised monographs before they come into force.
47. The demand for these reference materials remained high throughout the year. A total of 36,372 vials were sold within the UK and to countries worldwide, representing an increase of approximately 1% compared to the previous year.

European Pharmacopoeia

48. The third and fourth Supplements to the 11th Edition of the European Pharmacopoeia (Supplements 11.3 and 11.4) were published in July 2023 and October 2023 respectively. Supplement 11.3 came into effect on 1st January 2024 and Supplement 11.4 will come into effect on 1st April 2024. The fifth Supplement (11.5) was published in January 2024 and will come into effect on 1st July 2024. The text of these publications was included in the online BP in advance of their effective date and will be published in the next editions of the BP and BP (Vet) as appropriate.
49. 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 BPC at meetings of the EPC, providing valuable input to the work of that Commission.
50. The Laboratory provides technical support for the work of the EPC, providing technical data to support the elaboration of new monographs and the revision of existing monographs.
51. 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 2023, is included in Appendix II.

International Liaison and Collaboration

52. 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 Indian Pharmacopoeia Commission (IPC) and the United States Pharmacopeia (USP).
53. BP Secretariat staff attended the fourteenth International Meeting of World Pharmacopoeias (IMWP) which was hosted by the Pharmacopoeia of the United Mexican States in November. 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. Four key issues were discussed: the requirement to ensure pharmacopoeial methods address patient safety in less developed regions (and thus the use of accessible technology); to further improve the administrative robustness of the IMWP; to consider pandemic preparedness through lessons learned during COVID; a collaboration towards reducing

the use of hazardous chemicals and wider climate-friendly pharmacopoeial practices. The UK delegation committed to lead a project to create a Terms of Reference document, and to support the India/US-led project on climate-friendly principles.

54. Throughout the year BP Secretariat staff provided feedback to WHO on draft monographs for the International Pharmacopoeia, which was greatly appreciated. Many of the standards included in the International Pharmacopoeia, and the policies employed, are consistent with those in the BP.
55. The BP attended the WHO Expert Committee meeting on Specifications for Pharmaceutical Preparations in April during which monographs and reference materials for the International Pharmacopoeia were discussed.
56. BP staff attended the 74th and 75th WHO Consultations on INN in April and October. The INN committee discussed a significant number of names for new chemical and biological substances at both meetings.
57. BP staff continued discussion with the Indian Pharmacopoeia on areas of mutual interest and candidate monographs were identified as part of a future work programme.
58. The BP was represented by Mr Hoare at the Annual Meeting of National Pharmacopoeia Secretariats in Helsinki in June. The UK was able to present its views on improved ways of working and offered its experience of workload prioritisation. The UK desire for public consultation on the recent European Pharmacopoeia work on monoclonal antibodies was discussed.
59. The Cooperation Agreement between the BP and the State Pharmacopoeia of Ukraine was further renewed in person in June. This agreement allows the publication of an agreed number of BP monographs in the Ukraine Pharmacopoeia, helping to increase the number of their national standards and ensuring the quality of medicines across the global supply chain.

Acknowledgements

60. The Commission wishes to express its gratitude to all EAG, Panel and WP members for the invaluable contribution they have made towards the continuing improvement of standards in the BP and to members of the United Kingdom delegation to the EPC 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. In particular, the BPC wishes to acknowledge the contribution of those members who have now retired from the EAGs, Panels of Experts and WPs of the BPC.

61. The BPC also wishes to record its immense gratitude to the staff of the BP and Laboratory Services Group of the MHRA. Significant input to the work of the BPC continued to be received from members of staff from the following Groups of the MHRA: Healthcare, Quality & Access; Scientific Research & Innovation; Communications and Engagement. Significant input has also been received from the BP and MHRA Laboratories, from the Department of Health and Social Care, from the Cell and Gene Therapy Catapult and from the Veterinary Medicines Directorate.
62. The BPC wishes to acknowledge the advice of the publishing team at The Stationery Office in the production of the BP 2024, the BP (Vet) 2024 and Supplement No.2 to BANs 2024.
63. Dr Fiona Swanson retired from the Secretariat during the year. The BPC wishes to place on record its gratitude to Dr Swanson for her long service to the BP, a member of the Secretariat for over 30 years.

Obituaries

64. It was with sadness and regret that the BPC learned of the death of Dr Andrew Barnes. Appointed to the BPC in 2020, Dr Andrew Barnes remained an active member until he stepped down from his position as a BPC member in 2023.

APPENDIX I

BRITISH PHARMACOPOEIA COMMISSION PUBLICATIONS DURING 2023

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

British Pharmacopoeia 2024 package

Consisting of: -

British Pharmacopoeia 2024

British Pharmacopoeia (Veterinary) 2024

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

BP Download Edition (single-user licence)

(Subscription price £1000; £875 for print, online or download edition only)

Individual BP Monograph (only supplied electronically)

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

British Approved Names

British Approved Names 2022: Supplement No.2

(Price £20)

Code of Practice for the British Pharmacopoeia Commission and other expert advisory committees

All chairs, members, co-opted members and invited and patient experts of all our scientific advisory committees are required to declare any personal and non-personal interest, or any significant interests held by close family or friends, which may be reasonably perceived to influence their judgement in performing their functions and obligations.

Furthermore, all chairs and members declare their interest in any items being discussed at meetings and will declare any new conflict of interest at the earliest opportunity in advance of the next meeting they attend and openly at that next meeting. These are recorded in the published meetings. Where a member declares a potential conflict at meetings, it is recorded in the minutes and the member takes no part in the meeting for the duration of that item of discussion.

The principles in the Code also apply to observers and invited experts who are asked to contribute written advice and do not attend committee meetings.

The Code of Practice is published on:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1103036/2022.09.07_The_Code.pdf

The list of declared interests for chairs and members of the BPC (and EAGs, Working Parties and Panels) is available below.

APPENDIX II

Membership of the British Pharmacopoeia Commission

Post	Name and title	Affiliations
Chair	Dr Anna-Maria Brady BSc PhD	Former Head of Biologicals and Administration, Veterinary Medicines Directorate
Vice Chair	Mr Robert Lowe BPharm FRPharmS	Director of Pharmacy Quality Assurance Specialist Services, NHS East of England & Northamptonshire
Lay Member	Dr Alison Gleadle BSc PhD ¹	Former Group Product Risk Director, Tesco Stores Ltd.
Lay Member	Ms Sharon Palser MSc ²	Former Director of Development, NHS Plymouth
Member	Dr Emre Amirak BSc MBBS MRCS	Country Medical Director, UK & Ireland, Orphazyme A/S; President & Chief Medical Director, Vionelix Therapeutics
Member	Dr Andrew Barnes ³ BSc PhD FRSC	Pharmaceutical aspects (NHS). Quality Assurance Pharmacist, East Suffolk and North Essex NHS Trust.
Member	Dr Edward Bush BSc PhD	Principal Scientist – Pharmacopoeial Specialist, Chemical Development, AstraZeneca
Member	Mr Carlo Emanuele Giartosio MSc	Former Regulatory Coordination & Scientific Support Manager, Merck Serono
Member	Dr Vikas Jaitely BPharm MPharm PhD MRPharmS GPhC MTOPRA	Director (EU Digital Healthcare & Devices), Global Regulatory Affairs, Merck
Member	Mr Sean Jones BSc MSc MRPharmS	Former Expert Quality Assessor, MHRA; former Trust Quality Controller, Guy's and St. Thomas' NHS Foundation Trust
Member	Dr Paul Marshall BPharm PhD MRPharmS MAPS FTOPRA	Director, Global Regulatory Affairs, Jazz Pharmaceuticals
Member	Mr James Rickard MPharm	Chief Scientific Officer, Richmond Research Institute; Visiting Senior Lecturer, Kings College, London
Member	Professor Monique Simmonds OBE JP BSc PhD FLS FBS FRES FWIF	Deputy Director of Science, Royal Botanic Gardens, Kew

¹ End of Appointment 31/12/2023

² End of Appointment 31/12/2023

³ Stepped down 15/09/2023

Membership of the Anti-Infective Medicines Expert Advisory Group (AIM EAG)

Post	Name and title	Affiliations
Chair	Dr Rodney Horder	Retired; former Vice President, Strategic Regulatory Affairs, Europe, Abbott Laboratories
Vice Chair	Dr Graham Cook	Consultant
Member	Mr Greg Blake MRSC, CChem	Site Director GSK Worthing
Member	Mr Eamon Flahive B.Sc, HDAS (Ap.Sci), PDRA	Former Director and Head of Regulatory Affairs, Elanco Animal Health
Member	Dr Vikas Jaitely BPharm MPharm PhD MRPharmS GPhC MTOPRA	Director (EU Digital Healthcare & Devices), Global Regulatory Affairs, Merck
Member	Mr Sean Jones	Former Expert Quality Assessor, MHRA; Former Trust Quality Controller, Guy's and St. Thomas' NHS Foundation Trust
Member	Professor John Miller	Visiting Professor, Strathclyde University
Member	Mr Ian Williams	Formerly Quality Director Sumitomo Pharmaceuticals Europe Ltd

Membership of the Biological and Biotechnological Products Expert Advisory Group (BIO EAG)

Post	Name and title	Affiliations (if applicable)
Chair	Dr Anna-Maria Brady BSc PhD	Former Head of Biologicals and Administration, Veterinary Medicines Directorate
Vice Chair	Dr Emre Amirak BSc MBBS MRCS	Country Medical Director, UK & Ireland, Orphazyme A/S; President & Chief Medical Director, Vionelix Therapeutics
Member	Dr Keith Chidwick ⁴	Vice President Regulatory, Accord Healthcare
Member	Dr Simeon Gill	Director, CMC Regulatory Affairs, AstraZeneca, Member of The General Pharmaceutical Council and Associate Member of the Institute of Chemical Engineers
Member	Alistair Kippen ⁵	Vice President, BioPharmaceutical Development
Member	Dr Vincent Loh ⁶ BPharm PhD CBiol CChem CSci	Senior Director Global Regulatory Affairs, CMC

⁴ End of Appointment 31/12/2023

⁵ End of Appointment 31/12/2023

⁶ End of Appointment 31/12/2023

	EurChem EurProBiol FRSB FRSC ATC	
Member	Dr Brij Patel	RegExcel Consulting Ltd.
Member	Mr Lionel Randon	Head of GRA CMC Regulatory Intelligence, Merck KGaA, Switzerland
Member	Dr Robin Thorpe PhD FRCPATH	Fellow of the Royal College of Pathologists Former Head of Biotherapeutics Group, National Institute for Biological Standards and Control
Member	Mr Paolo Tozzi MSc	Global QC Director Pharmacopoeia Affairs and External Engagement Moderna Inc
Member	Dr Lincoln Tsang	Partner and Head of Life Sciences Practice, Ropes & Gray's European
Member	Dr Paul Varley PhD	Senior Vice President Development, Alchemab Therapeutics
Member	Dr Wayne Zunic ⁷	Senior Director of QC Commercial Operations, Biogen

Membership of the Herbal and Complementary Medicines Expert Advisory Group (HCM EAG)

Post	Name and title	Affiliations
Chair	Professor Monique Simmonds OBE JP BSc PhD FLS FBS FRES FWIF	Deputy Director of Science, Royal Botanic Gardens, Kew
Vice Chair	Dr Dick Middleton PhD, MPhC	Director, British Herbal Medicine Association
Member	Mr Paul Anderson	Head of Compliance, G R Lane Health Products Ltd.
Member	Dr Anthony Brooker MSc, PhD, MRSC, FLS	Senior Lecturer in Ethnopharmacology and Medicinal Plant Science Honorary Lecturer UCL School of Pharmacy Associate Editor, Frontiers in Ethnopharmacology Fellow of The Linnaean Society
Member	Dr Chris Etheridge PhD MRSC MCPD CChem DoIC ARCS BSc (Hons) Chem BSc (Hons) Phyto	Integrated Cancer Specialist
Member	Professor Sukhdev Swami Handa ⁸	
Member	Dr Christine Leon PhD	Honorary Research Associate (Chinese Medicinal Plants), Royal Botanic Gardens, Kew

⁷ End of Appointment 31/12/2023

⁸ End of Appointment 31/12/2023

Member	Mr Barry Moore BSc MSc	Regulatory Affairs Consultant – Herbals, Bath
Member	Dr Eike Reich	Retired. Head of Laboratory and Chief Scientific Officer at CAMAG, Muttenz, Switzerland.
Member	Dr Michael Rowan	
Member	Professor Adrian Slater BSc MSc PhD	Emeritus Professor, Faculty of Health and Life Sciences, De Montfort University
Member	Dr Katja Strohfeldt PhD, PGCAP, MRSC, PFHEA	Professor in Pharmaceutical Chemistry and Education Dean (Teaching and Learning), Vice-Chancellor's Office, University of Reading
Member	Dr Ruben Thanacoody PGCertEd MD FRCP FRCP(Edin)	Consultant Physician, Royal Victoria Infirmary, Newcastle upon Tyne Hospitals NHS Foundation Trust Honorary Clinical Senior Lecturer in Clinical Pharmacology, Newcastle University Honorary Consultant Clinical Toxicologist, UK Health Security Agency Director National Poisons Information Service (Newcastle unit)
Member	Mr Clive Welham MRSC	Technical Manager, Ransom Naturals Ltd.
Member	Dr Elizabeth Williamson	Emeritus Professor of Pharmacy, The School of Pharmacy, University of Reading
Member	Dr Kaicun Zhao	Programme leader in Chinese Herbal Medicine Department of Mental Health, Social Work and Integrative Medicine School of Health, Social Care & Education, Middlesex University London

Membership of the Medicinal Chemicals Expert Advisory Group (MC1 EAG)

Post	Name and title	Affiliations
Chair	Dr Paul Marshall BPharm PhD MRPharmS MAPS FTOPRA	Director, Global Regulatory Affairs, Jazz Pharmaceuticals
Vice Chair	Dr Edward Bush BSc PhD	Principal Scientist – Pharmacopoeial Specialist, Chemical Development, AstraZeneca
Member	Dr Varada Bapat B Pharm, M Pharm, PhD	Vice President R&D, RV Lifesciences Ltd, India
Member	Dr John Berridge	Independent Pharmaceutical Consultant
Member	Mr Seamus Boland BSc	Analytical Science & Technology Specialist. SGS International Service Laboratories

Member	Professor Donald Cairns BSc (Hons), PhD, FRPharmS, FRSC.	Professor Emeritus, School of Pharmacy and Life Sciences, Robert Gordon University
Member	Mr Adrian Caws	Member of the Royal Society of Chemistry
Member	Mr Paul Fleming	Technical Director for the British Generic Manufacturers Association (BGMA)
Member	Dr John Lough	Programme Leader, MSc Drug Discovery and Development, University of Sunderland
Member	Mr Dave Malpas BSc, MRSC, CChem.	Pharmaceutical Consultant
Member	Mr Steven Nolan	QP Consultant/Director, United QP Consulting Ltd

Membership of the Medicinal Chemicals Expert Advisory Group (MC2 EAG)

Post	Name and title	Affiliations
Chair	Dr Graham Cook	Consultant
Vice Chair	Mr Chris Goddard BSc DIS CSci CChem FRSC	Analytical Consultant
Vice Chair	Mr James Rickard MPharm	Chief Scientific Officer, Richmond Research Institute; Visiting Senior Lecturer, Kings College, London
Member	Mr Mohamed Abdelhamid Ali BPharm TQM	QC/R&D Head, Sunny Pharmaceutical
Member	Professor James Birchall B.Pharm.(Hons), Ph.D., FHEA	Deputy Head of School School of Pharmacy and Pharmaceutical Sciences College of Biomedical and Life Sciences
Member	Mr James Cowie BSc	Formerly Regulatory Facilitator and lead of Analytical Science and Technology Team at Novartis Grimsby Ltd
Member	Dr Karen Foster	Group Scientist Quality Expert PHC Global Product Stewardship
Member	Mr Elliot Hook MChem	Analytical Leader, GSK
Member	Professor John Miller	Visiting Professor, Strathclyde University
Member	Mr Shekhar Natarajan BSc MSc FRSC FTOPRA	Vice President- Regulatory Affairs Dyne Therapeutics
Member	Dr Andrea Ruggiero PhD	Director - GRA CMC Regulatory Intelligence working for Merck KGaA
Member	Dr Zena Smith BSc, PhD	Senior Director, Regulatory CMC Jazz Pharmaceuticals
Corresponding Member	Dr Marius Brits B.Pharm, M.Sc Pharmaceuticals, PhD Pharmaceutics	Associate Professor: Pharmaceutics North West University, School of Pharmacy, Potchefstroom - South Africa

Membership of the Medicinal Chemicals Expert Advisory Group (MC3 EAG)

Post	Name and title	Affiliations
Interim Chair	Mr Ian Williams ⁹	Former Quality Director Sumitomo Pharmaceuticals Europe Ltd.
Co-vice Chair	Mr Carlo Emanuele Giartosio MSc	Former Regulatory Coordination & Scientific Support Manager, Merck Serono
Co-vice Chair	Mr Chris Goddard BSc DIS CSci CChem FRSC	Analytical Consultant
Member	Mr Martin Coxon MChem ARCS	Analytical Development Manager, Custom Pharma Services
Member	Ms Karen Foster	Group Scientist Quality Expert, PHC Global Product Stewardship. Procter & Gamble Technical Centres
Member	Mr Phil Hampshire BSc Hons	QC Analytical Support Senior Team Leader, Accord Healthcare.
Member	Mr Jigar P. Mehta M.Sc.	Deputy General Manager, (Subject Matter Expert Analytical/Quality), Zydus Lifesciences Ltd Member of SEPC (Stakeholder Engagement Planning Committee) in US Pharmacopoeia. Reviewer for monograph and guidance in International Pharmacopoeia (WHO).
Member	Ms Desireen Nader Obaid MPharm	Scientific Affairs Manager, Joswe Medical Pharmaceuticals
Member	Mr Ron Torano BSc PhD, MRSC	Former Process Owner, Quality Regulatory Intelligence for GlaxoSmithKline
Member	Mr Chris Turville MSci MRSC MRQA	Raw Materials Team Leader, Wrafton Laboratories Ltd (trading as Perrigo)

⁹ Appointed interim Chair 31/12/2023

Membership of the Pharmacy and Nomenclature Expert Advisory Group (PCN EAG)

Post	Name and title	Affiliations
Chair	Dr Jeff Aronson MA, DPhil, MBChB, FRCP, HonFFPM, HonFBPhS	Hon Consultant Physician and Clinical Pharmacologist, Centre for Evidence Based Medicine
Vice Chair	Mr Robert Lowe BPharm FRPharmS	Director of Pharmacy Quality Assurance Specialist Services, NHS East of England & Northamptonshire
Member	Dr Adam Brelsford MPharm PhD	Clinical Writer – Pharmaceutical Press, Royal Pharmaceutical Society
Member	Dr David Elder PhD, FRSC, CChem	Independent CMC consultant
Member	Dr Rodney Horder	Former Vice President, Strategic Regulatory Affairs, Europe, Abbott Laboratories
Member	Angela McFarlane ¹⁰ BSc, DipClinPharm	Content Manager (BNF Publications)
Member	Dr Oisin Kavanagh MPharm PhD MRPharmS SFHEA	Lecturer – School of Pharmacy, Newcastle University
Member	Mr John McGuire BSc MSc	Regulatory Affairs Director
Member	Dr Gerry Moss	Former Senior Lecturer in Organic Chemistry, Queen Mary University of London
Member	Professor Kevin Taylor BPharm, PhD, FRPharmS	Emeritus Professor, University College London
Member	Dr Robin Thorpe PhD FRCPPath	Fellow of the Royal College of Pathologists Former Head of Biotherapeutics Group, National Institute for Biological Standards and Control
Corresponding Member	Dr Raffaella Balocco Mattavelli ¹¹	Group Lead, International Nonproprietary Names (INN) Programme, WHO, Switzerland

¹⁰ End of Appointment 31/12/2023

¹¹ End of Appointment 31/12/2023

Membership of the Unlicensed Medicines Expert Advisory Group (ULM EAG)

Post	Name and title	Affiliations
Chair	Mr Robert Lowe ¹² BPharm FRPharmS	Director of Pharmacy Quality Assurance Specialist Services, NHS East of England & Northamptonshire
Chair	Dr Gerard Lee ¹³	Retired
Vice Chair	Mr V'lain Fenton-May ¹⁴	Retired
Member	Dr Andrew Barnes ¹⁵ BSc PhD FRSC	Pharmaceutical aspects (NHS). Quality Assurance Pharmacist, East Suffolk and North Essex NHS Trust.
Member	Mr Alex Bosley	Lead Qualified Person & Pharmacist, Torbay Pharmaceuticals Ltd
Member	Dr David Caulfield ¹⁶	NHS
Member	Mr Wayne Goddard	Education & Training Lead – Pharmacy & QC Care Group 1 – Healthy Lives North Tees & Hartlepool NHS Foundation Trust, University Hospital of North Tees
Member	Ms Sarah Hartley BSc (Hons)	Manager Analytical R&D Rosemont Pharmaceuticals Ltd
Member	Mr Joaquim Ramada-Magalhes BSc, MSc, CChem, CSci, MRSC	Associate Director, Global Quality Compliance, Lonza Senior QA Manager (Consultant), St Barts NHS Trust – Nuclear Medicine & Radiopharmacy
Member	Mr Mark Santillo ¹⁷	Regional Quality Assurance Officer, Torbay & South Devon NHS Foundation Trust
Member	Dr Julian Smith PhD MRPharmS	Director at JCS Pharma Consulting Ltd
Member	Mr Andrew Sully	Principal Pharmacist Quality Control & Qualified Person, Cardiff and Vale University Health Board
Member	Mr Philip Weir ¹⁸	Principal Scientist, Head of Quality Control North West at Quality Control North West, Stepping Hill Hospital

¹² Appointed Chair 6/11/2023

¹³ End of Appointment 31/12/2023

¹⁴ End of Appointment 31/12/2023

¹⁵ Stepped down 15/09/2023

¹⁶ End of Appointment 31/12/2023

¹⁷ End of Appointment 31/12/2023

¹⁸ End of Appointment 31/12/2023

Membership of the Panel Of Experts For Blood Products (BLP Panel)

Post	Name and title	Affiliations
Chair	Dr Paul Varley PhD	Senior Vice President Development, Alchemab Therapeutics
Member	Mr James Rickard ¹⁹ MPharm	Chief Scientific Officer, Richmond Research Institute; Visiting Senior Lecturer, Kings College, London
Member	Dr Keith Chidwick ²⁰	Vice President Regulatory, Accord Healthcare
Member	John More ²¹	Director of Research & Development, BPL

Membership of the Panel Of Experts For Excipients (CX Panel)

Post	Name and title	Affiliations
Chair	Dr Paul Marshall ²² BPharm PhD MRPharmS MAPS FTOPRA	Director, Global Regulatory Affairs, Jazz Pharmaceuticals
Member	Professor Hannah Batchelor BSc PhD	Professor of Pharmaceutics and Biopharmaceutics, Strathclyde Institute of Pharmaceutical and Biomedical Sciences, University of Strathclyde
Member	Dr Richard Cawthorne BSc PhD CChem MRSC	Research and Technology Fellow, Croda Europe
Member	Mr C Mroz ²³	Supplier Quality Director, Colorcon

Membership of the Panel Of Experts For Inorganic and General Chemicals (IGC Panel)

Post	Name and title	Affiliations
Chair	Mr Chris Goddard BSc DIS CSci CChem FRSC	Analytical Consultant
Member	Mr Seamus Boland BSc	Analytical Science & Technology Specialist. SGS International Service Laboratories.
Member	Mr Peter Henrys BSc	IGC Panel Member QRA Technical Manager, BOC Healthcare

¹⁹ Appointed 6/11/2023

²⁰ End of Appointment 31/12/2023

²¹ End of Appointment 31/12/2023

²² Appointed Chair 6/11/2023

²³ End of Appointment 31/12/2023

Membership of the Panel Of Experts For Microbiology (MIC Panel)

Post	Name and title	Affiliations
Chair	Dr Vikas Jaitely ²⁴ BPharm MPharm PhD MRPharmS GPhC MTOPRA	Director (EU Digital Healthcare & Devices), Global Regulatory Affairs, Merck
Chair	Mr V'lain Fenton May ²⁵	Retired
Member	Brian Alexander ²⁶	
Member	Mrs Miriam Guest	Senior Principal Scientific Advisor, Charles River Labs, Microbial Solutions
Member	Dr Joao Inacio Silva PhD FHEA	Principal Lecturer Pharmaceutical Microbiology, School of Applied Sciences, University of Brighton
Member	Dr Vikas Jaitely BPharm MPharm PhD MRPharmS GPhC MTOPRA	Director (EU Digital Healthcare & Devices), Global Regulatory Affairs, Merck

Membership of the Panel Of Experts For Radioactive Materials (RAD Panel)

Post	Name and title	Affiliations
Chair	Dr Paul Marshall BPharm PhD MRPharmS MAPS FTOPRA	Director, Global Regulatory Affairs, Jazz Pharmaceuticals
Member	Dr Istvan Boros ²⁷ PhD	
Member	Dr Roger Pickett	Retired

Membership of the Panel Of Experts For Veterinary Medicines (VET Panel)

Post	Name and title	Affiliations
Chair	Professor Elizabeth Williamson	Emeritus Professor of Pharmacy, The School of Pharmacy, University of Reading
Member	Mr Andrew Cairns	Murray Farmcare Ltd. Industry liaison
Member	Dr Sarah Cockbill PhD, BPharm, MPharm, LL.M, DAgVetPharm, FRPharmS, FVPA	Honorary Lecturer Cardiff School of Pharmacy and Pharmaceutical Services

²⁴ Appointed Chair 6/11/2023

²⁵ End of Appointment 31/12/2023

²⁶ End of Appointment 31/12/2023

²⁷ End of Appointment 31/12/2023

		Cardiff University
Member	Mr David Evans	Pharmacist
Member	Mr Eamon Flahive	Former Director and Head of Regulatory Affairs, Elanco Animal Health

Membership of the Panel Of Experts For Veterinary Immunological Products (VIP Panel)

Post	Name and title	Affiliations
Chair	Dr Anna-Maria Brady BSc PhD	Former Head of Biologicals and Administration, Veterinary Medicines Directorate
Member	Dr Rhona Banks²⁸ PhD	Veterinary Biologicals Consultant at RA-ELECT
Member	Dr Martin Illott	Efficacy and Safety Director, Australian Pesticides and Veterinary Medicines Authority
Member	Dr Catrina Stirling	Manager/Associate Director at Zoetis
Member	Dr Ralph Woodland BSc PhD	Former Senior Assessor in Biologicals Assessment Team, Veterinary Medicines Directorate

²⁸ End of Appointment 31/12/2023

Membership of the Analytical Quality by Design Working Party (AQbD WP)

Post	Name and title	Affiliations
Chair	Dr Graham Cook	Consultant
Member	Dr Phil Borman DSc, CChem, FRSC	Director & Senior Fellow, QbD Platforms & Acceleration, GlaxoSmithKline
Member	Marion Chatfield ²⁹	Statistician, GSK
Member	Dr Stephen L R Ellison	Science Fellow, National Measurement Laboratory, LGC Ltd, Teddington
Member	Dr Peter Hamilton	Head of Product and Process Control, AstraZeneca, UK
Member	Professor Melissa Hanna-Brown	Professor of Analytical Chemistry (Futures Pharmaceuticals), University College Cork
Member	Mr Sean Jones	Former Expert Quality Assessor, MHRA; former Trust Quality Controller, Guy's and St. Thomas' NHS Foundation Trust
Member	Mr Alec Kettle	Director of Global Strategic Account Management, Waters Ltd.
Member	Dr Rosario LoBrutto PhD, MBA, MS	Principal at Pharma Vision Consulting LLC
Member	Dr John Lough	Programme Leader, MSc Drug Discovery and Development, University of Sunderland
Member	Dr Tina Morris Ph.D.	Executive Director, American Association of Pharmaceutical Scientists (AAPS)
Member	Dr Phil Nethercote BSc PhD	Retired
Member	Dr Mustafa Zaman BPharm (Hons) PhD MRPharmS	Senior Consultant, Granzer Regulatory Consulting and Services GmbH; Visiting Senior Lecturer, King's College, London
Corresponding Member	Dr Kimber Barnett PhD	Former Research Fellow, Pfizer, Groton, USA
Corresponding Member	Mr Brent Harrington MSc	Senior Director and Drug Product Statistics Lead, Pfizer Research and Development, PSSM Data Sciences, Groton, CT

²⁹ End of Appointment 31/12/2023

Membership of Advanced Therapy Medicinal Products Working Party (ATMP WP)

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

Post	Name and title	Affiliations
Chair	Dr Jacqueline Barry	Cell and Gene Therapy Catapult
Member	Dr Ian Anderson PhD	Senior Global Principal Scientist, Lonza
Member	Dr Clare Blue Ph.D	Senior CMC Translation Consultant, eXmoor Pharma Concepts Ltd.
Member	Dr George Bou-Assaf ³⁰	Biogen
Member	Dr John Campbell PhD FRSB	Chemokine Research Group, School of Infection and Immunity College of Medical, Veterinary and Life Sciences University of Glasgow
Member	Dr Paul Carter BSc	Senior Director MSAT, Quell Therapeutics
Member	Dr David Caulfield	NHS
Member	Matthew Collis ³¹	Spark Therapeutics
Member	Dr Sabine Domning	King's College London
Member	Dr Peter Emery-Billcliff PhD, BSc	Senior Scientist, Analytical Development, Complement Therapeutics
Member	Dr Alicja Fiedorowicz MSc	Senior Consultant, Dark Horse Consulting
Member	Dr Paul Getty	Senior Technical Specialist, Pharmaron Biologics (UK) Ltd.
Member	Dr Kimberly Gilmour Ph.D., FRCPATH	Consultant Clinical Scientist, Clinical Lead Immunology and Director of Cell Therapy Camelia Botnar Laboratories Great Ormond Street Hospital for Children NHS Foundation Trust
Member	Dr Davide Grandolfo ³²	Merck Italia
Member	Dr Zara Hannoun	Senior Scientist at Zelluna Therapeutics, Oslo Norway
Member	Dr Tishwant Kanwarjit	Director, Autolus
Member	Dr Lily Li PhD	Lead Scientist, AviadoBio
Member	Dr Archie Lovatt BSc(Hons) PhD	Health & Nutrition Health Sciences - Scientific Operations Director, Biosafety & Characterisation Services - Cell Banks, Biologics, Vectors & Vaccines

³⁰ End of Appointment 31/12/2023

³¹ End of Appointment 31/12/2023

³² End of Appointment 31/12/2023

Member	Dr Mark Lowdell PhD FRCPATH FRSB	Professor of Cell & Tissue Therapy, UCL
Member	Dr Jenny McIntosh ³³	University College London
Member	Dr Juan Miguel-Sánchez-Nieto ³⁴	Orchard Therapeutics
Member	Dr Keith McLuckie	Head of Non-Clinical Cell and Gene Therapy Catapult
Member	Dr Josefina Nilsson PhD	CEO of Qutem, Sweden
Member	Dr Rickard Nordstrom	Vironova
Member	Dr Leonard Pattenden PhD	CEO, CMC Biopharma Ltd, UK
Member	Dr Stuart Paul-Adams FRCPATH	Consultant Clinical Scientist (SIHMDS-Haematology), Joint Trust Lead Healthcare Scientist, Honorary Associate Professor (Infect, Imm, Infla. & Physio Med, UCL), Level 2 Camelia Botnar Laboratory, Great Ormond Street Hospital
Member	Dr Jasbir Rattu MPharm PhD MRSC MRPharmS MCQI CQP	Consultant Industrial Pharmacist ATMP Qualified Person (QP), CeutiQus
Member	Mr Ian Rees	Regulatory Affairs Consultant, D.I., Rees Ltd
Member	Dr Rita Rego PhD MRSB QP	Senior Vice President (SVP), Quality at ViroCell Biologics, Ltd
Member	Dr Chaminda Salgado	Head of Analytics at eXmoor Pharma
Member	Dr Franz Schnetzinger	CMC Technology Lead, CEPI UK Ltd Independent Consultant
Member	Dr Isobel Searing	Director Analytical Development Group (ADG) Oxford Biomedica
Member	Dr Beata Surmacz-Cord MSc, PhD, CMgr CMIFellow	Study Delivery Leader, GlaxoSmithKline
Member	Dr Huimin Tao	Associate Director ADO Molecular Biology, Novartis Gene Therapies, USA
Member	Dr Victoria Vanhoutte ³⁵	Scottish National Blood Transfusion Service
Member	Dr Wei Wang BSc MSc PhD	Principal Scientist, Analytical Development, Autolus Therapeutics
Member	Dr Peng Wang	Lonza Houston Inc.
Member	Dr Caroline Weydert PharmD PhD	EMEA Sales Specialist Genomics - Biopharma Bio-Rad Laboratories N.V

³³ End of Appointment 31/12/2023

³⁴ End of Appointment 31/12/2023

³⁵ End of Appointment 31/12/2023

Membership of Alternative Approaches for Documentary and Physical Standards for Biotechnological Products Working Party (BIO-DPS WP)

Post	Name and title	Affiliations
Chair	Dr Paul Varley PhD	Senior Vice President Development, Alchemab Therapeutics
Vice Chair	Dr Anna-Maria Brady BSc PhD	Former Head of Biologicals and Administration, Veterinary Medicines Directorate
Member	Dr Laurent Duhau	Sanofi R&D, Global CMC Development, Global Head of BioAnalytics
Member	Mr Carlo Emanuele Giartosio MSc	Former Regulatory Coordination & Scientific Support Manager, Merck Serono
Member	Dr Frederike Plath	
Member	Dr Alla Polozova PhD	Director, Attribute Sciences, Process Development, Amgen
Member	Dr Ash Ramzan PhD, FTOPRA	Principal Consultant, Woodley Bioreg Ltd.
Member	Barbara Rellahan ³⁶	Executive Director, Quality, Product Quality at Amgen

EUROPEAN PHARMACOPOEIA COMMISSION – Members of the United Kingdom Delegation During 2023

Name	
Main	A-M Brady
Main	R Lowe
Main	S Hoare
Alternates	P Crowley
Alternates	S Young

³⁶ End of Appointment 31/12/2023

DECLARATION OF INTERESTS

British Pharmacopoeia Commission, Commission's Expert Advisory Groups members, Working Parties and Panels of Experts have declared current personal and non-personal interests in the pharmaceutical industry as follows:

Member	Committee	Interest Type	Company / Organisation / Sponsor	Nature of Interest	Current	Additional Information
Adrian Caws	MC1 EAG	Personal	GSK	Shares	No	
Adrian Caws	MC1 EAG	Personal	Haleon	Shares	No	
Adrian Caws	MC1 EAG	Non-Personal	NIL	N/A	N/A	
Adrian Caws	MC1 EAG	Additional				Immediate family member holds shares in GSK and Haleon.
Adrian Slater	HCM EAG	Personal	Mycorrhizial Systems	Consultancy on DNA barcoding and metagenomics	No	
Adrian Slater	HCM EAG	Non-Personal	PhytoGenomics	Grant from Stanley Smith Trust for DNA barcoding of ornamental plants	No	
Alec Kettle	WP AQbD	Personal	Waters Corporation	Shares, salary	Yes	
Alec Kettle	WP AQbD	Non-Personal	NIL	N/A	N/A	
Alex Bosley	ULM EAG	Personal	Torbay Pharmaceuticals	Salary	Yes	
Alex Bosley	ULM EAG	Personal	Torbay Pharmaceuticals (Torbay and South Devon	Salary	No	

			NHS Foundation Trust)			
Alex Bosley	ULM EAG	Non-Personal	NIL	N/A	N/A	
Alicja Fiedorowicz	WP ATMP	Personal	Pfizer	Shares	Yes	
Alicja Fiedorowicz	WP ATMP	Non-Personal	NIL	N/A	N/A	
Alison Gleadle	BPC	Personal	Tesco plc	Shares	Yes	
Alison Gleadle	BPC	Non-Personal	NIL	N/A	N/A	
Alison Gleadle	BPC	Additional				Family member is currently employed by Astra Zeneca
Alistair Kippen	BIO EAG	Personal	Ipsen Biopharm Ltd	Salary	Yes	
Alistair Kippen	BIO EAG	Non-Personal	NIL	N/A	N/A	
Alistair Kippen	BIO EAG	Additional				Also Committee Member of EFPIA-MQEG, CASSS CMC Strategy Forum, Bioindustry Association (BIA)
Andrea Ruggiero	MC2 EAG	Personal	Merck KGaA	Consultancy	Yes	
Andrea Ruggiero	MC2 EAG	Non-Personal	NIL	N/A	N/A	
Andrew Barnes	BPC, ULM EAG	Personal	East Suffolk and North Essex NHS Foundation Trust	Occasional employment	Yes	
Andrew Barnes	BPC, ULM EAG	Personal	Tristel plc	Shareholding	Yes	

Andrew Barnes	BPC, ULM EAG	Non-Personal	NIL		N/A	N/A
Andrew Cairns	Panel VET	Personal	NIL		N/A	N/A
Andrew Cairns	Panel VET	Non-Personal	NIL		N/A	N/A
Andrew Sully	ULM EAG	Personal	NIL		N/A	N/A
Andrew Sully	ULM EAG	Non-Personal	NIL		N/A	N/A
Angela McFarlane	PCN EAG	Personal	NIL		N/A	N/A
Angela McFarlane	PCN EAG	Non-Personal	NIL		N/A	N/A
Anna-Maria Brady	BPC, BIO EAG, WP BIO-DPS, Panel VIP	Personal	GlaxoSmithKline	Immediate family member holds shares		Yes
Anna-Maria Brady	BPC, BIO EAG, WP BIO-DPS, Panel VIP	Personal	Astra Zeneca	Immediate family member holds shares		Yes
Anna-Maria Brady	BPC, BIO EAG, WP BIO-DPS, Panel VIP	Non-Personal	NIL		N/A	N/A
Anna-Maria Brady	BPC, BIO EAG, WP BIO-DPS, Panel VIP	Additional				I act as a section editor and reviewer for the journal Biologicals. This is an unpaid position.
Anna-Maria Brady	BPC, BIO EAG, WP BIO-DPS, Panel VIP	Additional				I am a panel member for the HS2 "need to sell scheme." I receive a fee for panel attendance.

Anthony Booker	HCM EAG	Personal	Herbprime UK	Consultancy	Yes
Anthony Booker	HCM EAG	Personal	Shizhen TCM	Auditing fee	Yes
Anthony Booker	HCM EAG	Personal	Phoenix medical	Consultancy	Yes
Anthony Booker	HCM EAG	Personal	Herbprime UK	Auditing fee	Yes
Anthony Booker	HCM EAG	Personal	Ransoms Naturals	Consultancy	Yes
Anthony Booker	HCM EAG	Personal	Ransoms Naturals	Consultancy	Yes
Anthony Booker	HCM EAG	Non-Personal	British Herbal Medicine Association	Charitable donation to research fund at employment (University of Westminster)	Yes
Anthony Booker	HCM EAG	Non-Personal	European Herbal and Traditional Practitioners Association	Charitable donation to research fund at employment (University of Westminster)	Yes
Anthony Booker	HCM EAG	Non-Personal	DePlantis UK	Charitable donation to research fund at employment (University of Westminster)	Yes
Archie Lovatt	WP ATMP	Personal	SGS	Salary	Yes
Archie Lovatt	WP ATMP	Non-Personal	NIL	N/A	N/A
Ash Ramzan	WP BIO-DPS	Personal	NIL	N/A	N/A
Ash Ramzan	WP BIO-DPS	Non-Personal	NIL	N/A	N/A

Barbara Rellahan	WP BIO-DPS	Personal	Amgen	Shares	Yes
Barbara Rellahan	WP BIO-DPS	Non-Personal	NIL	N/A	N/A
Barry Moore	HCM EAG	Personal	Pukka Herbs	Salary	No
Barry Moore	HCM EAG	Personal	Sebastian Pole	Consultancy	Yes
Barry Moore	HCM EAG	Non-Personal	NIL	N/A	N/A
Beata Surmacz-Cordle	WP ATMP	Personal	GSK	Salary, shares	Yes
Beata Surmacz-Cordle	WP ATMP	Non-Personal	NIL	N/A	N/A
Brent Harrington	WP AQbD				
Brian Alexander	Panel MIC				
Brij Patel	BIO EAG	Personal	Variety of pharmaceutical companies - list provided	Consultancy	Yes
Brij Patel	BIO EAG	Personal	Pfizer	Immediate family employment and shares	Yes
Brij Patel	BIO EAG	Non-Personal	NIL	N/A	N/A
Brian Ward	Panel VET	Personal	NIL	N/A	N/A
Brian Ward	Panel VET	Non-Personal	NIL	N/A	N/A
Carl Mroz	CX Panel				
Carlo Emanuele Giartosio	BPC, WP BIO-DPS	Personal	NIL	N/A	N/A

Carlo Emanuele Giartosio	BPC, WP BIO-DPS	Non-Personal	NIL	N/A	N/A
Carol Iverson	Panel MIC	Personal	Merck KGaA	Salary	Yes
Carol Iverson	Panel MIC	Non-Personal	NIL	N/A	N/A
Caroline Weydert	WP ATMP	Personal	Bio-Rad Laboratories	Salary	Yes
Caroline Weydert	WP ATMP	Non-Personal	NIL	N/A	N/A
Chaminda Salgado	WP ATMP	Personal	Phacillitate	Consultancy	Yes
Chaminda Salgado	WP ATMP	Personal	CS CMC Consulting	Committee member of decentralised funding	Yes
Chaminda Salgado	WP ATMP	Personal	T-Cypher Bio	Employee	No
Chaminda Salgado	WP ATMP	Personal	eXmoor Pharma	Employee	Yes
Chaminda Salgado	WP ATMP	Non-Personal	NIL	N/A	N/A
Chris Etheridge	HCM EAG	Personal	BHMA	Chair of the BHMA – receive monthly honorarium.	Yes
Chris Etheridge	HCM EAG	Personal	UK TIA	Independent consultancy.	Yes
Chris Etheridge	HCM EAG	Non-Personal	NIL	N/A	N/A
Chris Goddard	MC2 EAG, MC3 EAG, Panel IGC	Personal	NIL	N/A	N/A
Chris Goddard	MC2 EAG, MC3 EAG, Panel IGC	Non-Personal	NIL	N/A	N/A

Christine Leon	HCM EAG	Personal	NIL	N/A	N/A
Christine Leon	HCM EAG	Non-Personal	NIL	N/A	N/A
Clare Blue	WP ATMP	Personal	eXmoor Pharma	Employee in role of CMC consultant. As a consultant to external CGT Companies some of the content defined within the ATMP working group (analytical guidance) may apply to these companies. Additionally as eXmoor also serves as a CDMO and supporting Clients through process development projects some of the content discussed within the ATMP working group may also apply to these activities.	Yes
Clare Blue	WP ATMP	Non-Personal	NIL	N/A	N/A
Clive Welham	HCM EAG	Personal	Ransom Naturals Ltd	Salary	Yes
Clive Welham	HCM EAG	Non-Personal	NIL	N/A	N/A
Dave Malpas	MC1 EAG	Personal	GSK	Shareholder	Yes
Dave Malpas	MC1 EAG	Personal	Sanofi	Shareholder	Yes

Dave Malpas	MC1 EAG	Non-Personal	NIL	N/A	N/A
David Caulfield	ULM EAG, WP ATMP	Personal	Caulfield Pharma Consulting	Owner, director, shareholder and employee	Yes
David Caulfield	ULM EAG, WP ATMP	Personal	Autolus	Shareholder	Yes
David Caulfield	ULM EAG, WP ATMP	Personal	Autolus	Consultancy	Yes
David Caulfield	ULM EAG, WP ATMP	Personal	Pfizer	Consultancy	Yes
David Caulfield	ULM EAG, WP ATMP	Personal	Kings University Vector manufacturing facility	Consultancy	Yes
David Caulfield	ULM EAG, WP ATMP	Personal	Kings College Hospital	Consultancy	Yes
David Caulfield	ULM EAG, WP ATMP	Personal	Newcastle Advanced Therapies	Employment	Yes
David Caulfield	ULM EAG, WP ATMP	Non-Personal	NIL	N/A	N/A
David Elder	PCN EAG	Personal	David P Elder Consultancy – list provided	Providing paid consultancy for CMC (Chemistry, Manufacturing & Controls) issues	Yes
David Elder	PCN EAG	Personal	GlaxoSmithKline	Shares	Yes
David Elder	PCN EAG	Personal	Astra Zeneca	Shares	Yes
David Elder	PCN EAG	Personal	AbbVie	Shares	Yes
David Elder	PCN EAG	Non-Personal	NIL	N/A	N/A
David Evans	Panel VET				

Davide Grandolfo	WP ATMP	Personal	NIL	N/A	N/A
Davide Grandolfo	WP ATMP	Non-Personal	NIL	N/A	N/A
Donald Cairns	MC1 EAG	Personal	NIL	N/A	N/A
Donald Cairns	MC1 EAG	Non-Personal	NIL	N/A	N/A
Eamon Flahive	AIM EAG, Panel VET	Personal	Eli Lilly & Co	Shares	Yes
Eamon Flahive	AIM EAG, Panel VET	Personal	Elanco Animal Health	Shares	Yes
Eamon Flahive	AIM EAG, Panel VET	Personal	Aenorasis S.A.	Consultancy	Yes
Eamon Flahive	AIM EAG, Panel VET	Non-Personal	NIL	N/A	N/A
Edward Bush	BPC, MC1 EAG	Personal	AstraZeneca Pharmaceuticals	Salary	Yes
Edward Bush	BPC, MC1 EAG	Personal	AstraZeneca Pharmaceuticals	Shares	Yes
Edward Bush	BPC, MC1 EAG	Non-Personal	NIL	N/A	N/A
Eike Reich	HCM EAG	Personal	NIL	N/A	N/A
Eike Reich	HCM EAG	Non-Personal	NIL	N/A	N/A
Elizabeth Williamson	HCM EAG, Panel VET	Personal	NIL	N/A	N/A
Elizabeth Williamson	HCM EAG, Panel VET	Non-Personal	NIL	N/A	N/A
Elliot Hook	MC2 EAG	Personal	GlaxoSmithKline	Salary, shares	Yes
Elliot Hook	MC2 EAG	Personal	Haleon	Shares	Yes
Elliot Hook	MC2 EAG	Non-Personal	NIL	N/A	N/A

Emre Amirak	BPC, BIO EAG	Personal	Orphazyme A/S	Salary	No
Emre Amirak	BPC, BIO EAG	Personal	Vionelix Pharmaceuticals	Shares	No
Emre Amirak	BPC, BIO EAG	Personal	Sanofi	Shares	No
Emre Amirak	BPC, BIO EAG	Non-Personal	NIL	N/A	N/A
Franz Schnetzinger	WP ATMP	Personal	Gyroscope Therapeutics Ltd (a Novartis company)	Salary - Shares - Pension entitlement	No
Franz Schnetzinger	WP ATMP	Personal	Independent Consultant for Cell Gene Therapy Products	Consultancy	Yes
Franz Schnetzinger	WP ATMP	Personal	CEPI UK Ltd	Salary - Pension entitlement	Yes
Franz Schnetzinger	WP ATMP	Non-Personal	NIL	N/A	N/A
Friederike Plath	WP BIO-DPS	Personal	F Hoffmann-La Roche Ltd., Basel/Switzerland	Salary	Yes
Friederike Plath	WP BIO-DPS	Non-Personal	NIL	N/A	N/A
George Bou-Assaf	WP ATMP	Personal	Biogen	Shares and Salary	Yes
George Bou-Assaf	WP ATMP	Non-Personal	NIL	N/A	N/A
Gerard Lee	ULM EAG				
Gerry Moss	PCN EAG	Personal	NIL	N/A	N/A
Gerry Moss	PCN EAG	Non-Personal	NIL	N/A	N/A

Gillian Clarke	AIM EAG	Personal	NIL	N/A	N/A
Gillian Clarke	AIM EAG	Non-Personal	NIL	N/A	N/A
Graham Cook	AIM EAG, MC2 EAG, WP AQbD	Personal	Pfizer	Shares, Salary	Yes
Graham Cook	AIM EAG, MC2 EAG, WP AQbD	Personal	Viatrix	Shares	Yes
Graham Cook	AIM EAG, MC2 EAG, WP AQbD	Non-Personal	NIL	N/A	N/A
Greg Blake	AIM EAG	Personal	GSK	Salary and Shareholder	Yes
Greg Blake	AIM EAG	Non-Personal	NIL	N/A	N/A
Hannah Batchelor	CX Panel, MC1 EAG	Personal	NIL	N/A	N/A
Hannah Batchelor	CX Panel, MC1 EAG	Non-Personal	UCB	Grant awarded to support a PhD student under my supervision	Yes
Hannah Batchelor	CX Panel, MC1 EAG	Non-Personal	GSK	Grant awarded to support a PhD student under my supervision	Yes
Huimin (Helen) Tao	WP ATMP	Personal	Novartis	Salary, shares	Yes
Huimin (Helen) Tao	WP ATMP	Personal	Fate Therapeutics	Shares	Yes
Huimin (Helen) Tao	WP ATMP	Personal	Sandoz group	Shares	Yes
Huimin (Helen) Tao	WP ATMP	Non-Personal	NIL	N/A	N/A

Ian Anderson	WP ATMP	Personal	Lonza	Salary	Yes
Ian Anderson	WP ATMP	Non-Personal	NIL	N/A	N/A
Ian Williams	AIM EAG, MC3 EAG	Personal	Pfizer	Shares	Yes
Ian Williams	AIM EAG, MC3 EAG	Personal	Viatrix	Shares	Yes
Ian Williams	AIM EAG, MC3 EAG	Non-Personal	NIL	N/A	N/A
Isobel Searing	WP ATMP	Personal	Oxford Biomedica	Salary, share options	Yes
Isobel Searing	WP ATMP	Non-Personal	NIL	N/A	N/A
Istvan Boros	Panel RAD	Personal	NIL	N/A	N/A
Istvan Boros	Panel RAD	Non-Personal	NIL	N/A	N/A
Jacqueline Barry	WP ATMP	Personal	NIL	N/A	N/A
Jacqueline Barry	WP ATMP	Non-Personal	NIL	N/A	N/A
James Birchall	MC2 EAG	Personal	AstraZeneca	Small shareholding	No
James Birchall	MC2 EAG	Personal	Avaxzipen	Member advisory board	Yes
James Birchall	MC2 EAG	Personal	Latch Medical	Consultancy	No
James Birchall	MC2 EAG	Non-Personal	NIL	N/A	N/A
James Cowie	MC2 EAG	Personal	Novartis Pharma AG	Consultancy	Yes
James Cowie	MC2 EAG	Non-Personal	NIL	N/A	N/A
James Cowie	MC2 EAG	Conferences/	Gene Therapy Analytical	Gave talk on gene therapy. Free admission.	No

		Scientific Meetings	Development Conference		
James Norton	WP ATMP	Personal	Meiragtx	Salary, bonus, shares, pension, private medical insurance, travel insurance, expenses for conference and business travel.	Yes
James Norton	WP ATMP	Non-Personal	NIL	N/A	N/A
James Rickard	BPC, MC2 EAG	Personal	Biotherapy Services Ltd	Shares, Share Options & Salary	Yes
James Rickard	BPC, MC2 EAG	Personal	Richmond Pharmacology Ltd	Salary	Yes
James Rickard	BPC, MC2 EAG	Personal	Amylyx	Shares	Yes
James Rickard	BPC, MC2 EAG	Personal	King's College London	Visiting Snr Lectureship	Yes
James Rickard	BPC, MC2 EAG	Personal	Manchester University	Fees	Yes
James Rickard	BPC, MC2 EAG	Non-Personal	NIL	N/A	N/A
Jasbir Rattu	WP ATMP	Personal	Galapagos	Consultant and GMP auditor for ATMPs	Yes
Jasbir Rattu	WP ATMP	Personal	Roslin Cell Therapy	Consultant and educator for ATMPs	Yes
Jasbir Rattu	WP ATMP	Personal	PCI Pharma Services	Consultant and educator for ATMPs	Yes
Jasbir Rattu	WP ATMP	Non-Personal	NIL	N/A	N/A

Jeff Aronson	PCN EAG	Personal	NIL	N/A	N/A
Jeff Aronson	PCN EAG	Non-Personal	NIL	N/A	N/A
Jenny McIntosh	WP ATMP	Personal	Freeline	Shares, consultancy	Yes
Jenny McIntosh	WP ATMP	Personal	BioMarin	Royalties	Yes
Jenny McIntosh	WP ATMP	Non-Personal	NIL	N/A	N/A
Jenny McIntosh	WP ATMP	Conference /Scientific Meetings	Qiagen User Day - Sponsor: Qiagen	Travel and Accommodation Expenses	No
Joao Inacio Silva	Panel MIC	Personal	NIL	N/A	N/A
Joao Inacio Silva	Panel MIC	Non-Personal	NIL	N/A	N/A
Joaquim Ramada-Magalhaes	ULM EAG	Personal	Ascend Gene & Cell Therapies	Salary, shares	Yes
Joaquim Ramada-Magalhaes	ULM EAG	Personal	GSK	Shares	Yes
Joaquim Ramada-Magalhaes	ULM EAG	Non-Personal	NIL	N/A	N/A
John Berridge	MC1 EAG	Personal	NIL	N/A	N/A
John Berridge	MC1 EAG	Non-Personal	NIL	N/A	N/A
John Campbell	WP ATMP	Personal	Resolution Therapeutics Ltd.	Shares, consultancy	Yes
John Campbell	WP ATMP	Personal	Adthera Bio Ltd	Shareholding, Consultancy	Yes
John Campbell	WP ATMP	Personal	Swarm Oncology Ltd	Shareholding, Consultancy	Yes

John Campbell	WP ATMP	Personal	Lift Biosciences Ltd	Consultancy	Yes	
John Campbell	WP ATMP	Personal	Cellular Origins Ltd	Consultancy	Yes	
John Campbell	WP ATMP	Non-Personal	NIL	N/A	N/A	
John Campbell	WP ATMP	Conference /Scientific Meetings	Miltenyi Biotec Ltd	Cell Therapy Meeting IX: Expenses, accommodation	No	
John Lough	MC1 EAG, WP AQbD	Personal	NIL	N/A	N/A	
John Lough	MC1 EAG, WP AQbD	Non-Personal	NIL	N/A	N/A	
John Lough	MC1 EAG, WP AQbD	Additional				Elsevier: payment for preparation of book chapter on "British Pharmacopoeia"
John Lough	MC1 EAG, WP AQbD	Additional				Interest in academic research into "modernised" pharmaceutical quality control methods.
John McGuire	PCN EAG	Personal	AstraZeneca	Salary, Shares	Yes	
John McGuire	PCN EAG	Non-Personal	NIL	N/A	N/A	
John Miller	AIM EAG, MC2 EAG	Personal	NIL	N/A	N/A	
John Miller	AIM EAG, MC2 EAG	Non-Personal	NIL	N/A	N/A	
John More	BLP Panel	Personal	NIL	N/A	N/A	
John More	BLP Panel	Non-Personal	NIL	N/A	N/A	

Josefina Nilsson	WP ATMP	Personal	QuTEM AB	Shares and Salary	Yes
Josefina Nilsson	WP ATMP	Personal	Vironova AB	Salary	No
Josefina Nilsson	WP ATMP	Personal	Vironova Bioanalytics ABN?A	Shares and Salary	No
Josefina Nilsson	WP ATMP	Non-Personal	NIL	N/A	N/A
Juan Miguel Sánchez Nieto	WP ATMP	Personal	Orchard Therapeutics	Salary and Shares	Yes
Juan Miguel Sánchez Nieto	WP ATMP	Personal	Moderna	Salary and Shares	No
Juan Miguel Sánchez Nieto	WP ATMP	Non-Personal	NIL	N/A	N/A
Julian Smith	ULM EAG	Personal	JCS Pharma Consulting Ltd	Director, Consultant and Shareholder	Yes
Julian Smith	ULM EAG	Personal	AstraZeneca UK	Shares	Yes
Julian Smith	ULM EAG	Personal	Reckitt Benckiser Group Plc	Shares	Yes
Julian Smith	ULM EAG	Non-Personal	NIL	N/A	N/A
Kaicun Zhao	HCM EAG	Personal	NIL	N/A	N/A
Kaicun Zhao	HCM EAG	Non-Personal	NIL	N/A	N/A
Karen Foster	MC2 EAG, MC3 EAG	Personal	Procter & Gamble	Salary	Yes
Karen Foster	MC2 EAG, MC3 EAG	Non-Personal	NIL	N/A	N/A
Katja Strohfeltd	HCM EAG	Personal	NIL	NIL	N/A

Katja Strohfeltd	HCM EAG	Non-Personal	NIL	NIL	N/A
Keith Chidwick	BIO EAG, BLP Panel				
Kevin Taylor	BPC, PCN EAG	Personal	NIL	N/A	N/A
Kevin Taylor	BPC, PCN EAG	Non-Personal	NIL	N/A	N/A
Kimber Barnett	WP AQbD	Personal	Pfizer	Salary, shares	Yes
Kimber Barnett	WP AQbD	Non-Personal	NIL	N/A	N/A
Kimber Barnett	WP AQbD	Conference Scientific Meetings	USP Measurement and Data Quality Expert Committee meeting	Expert Committee Member and Volunteer; reimbursement of travel expenses for in person meeting	No
Kimber Barnett	WP AQbD	Conference Scientific Meetings	USP Expert Committee on Measurement and Data Quality	Volunteer and member	Yes
Kimberly Gilmour	WP ATMP	Personal	NIL	N/A	N/A
Kimberly Gilmour	WP ATMP	Conference /Scientific Meetings	Miltenyi	Donation of pens and pads for Science4U Schools Day of which KG is chair of the organising committee	No
Kimberly Gilmour	WP ATMP	Non-Personal	NIL	N/A	N/A
Kimberly Gilmour	WP ATMP	Additional			Involved in trials of gene therapy for primary

immunodeficiency and CAR T cell trials based at Great Ormond Street Hospital.

Laurent Duhau	WP BIO-DPS	Personal	Sanofi	Salary and shares	Yes
Laurent Duhau	WP BIO-DPS	Non-Personal	NIL	N/A	N/A
Leonard Pattenden	WP ATMP	Personal	CMC Biopharma Ltd	Provide training at BioNTech in CMC Project Management. Paid Consultancy and expenses	No
Leonard Pattenden	WP ATMP	Personal	CMC Biopharma Ltd	Provide Online training in CMC Biologics. Paid Consultancy.	No
Leonard Pattenden	WP ATMP	Personal	CMC Biopharma Ltd	Provide online training in CMC ATMPs. Paid Consultancy	No
Leonard Pattenden	WP ATMP	Personal	CMC Biopharma Ltd	Provide online training in CMC & Formulation Nucleic Acids. Paid Consultancy.	No
Leonard Pattenden	WP ATMP	Personal	CMC Biopharma Ltd	Owner of this Manufacturing, Consulting and training private company. Salary and dividends.	Yes
Leonard Pattenden	WP ATMP	Non-Personal	NIL	N/A	N/A
Lily Li	WP ATMP	Personal	AviadoBio	Salary	Yes

Lily Li	WP ATMP	Personal	Catapult	Salary	No	
Lily Li	WP ATMP	Non-Personal	NIL	N/A	N/A	
Lincoln Tsang	BIO EAG	Personal	Ropes & Gray LLP	Equity partner of an international law firm headquartered Boston, practising laws related to the life sciences sector	Yes	
Lincoln Tsang	BIO EAG	Non-Personal	NIL	N/A	N/A	
Lincoln Tsang	BIO EAG	Conference /Scientific Meetings				Public conferences attended not related to a specific product and no fees or gifts were given for attendance
Lincoln Tsang	BIO EAG	Additional				BiIndustry Association: Member of Advisory Committee. Non-remunerated.
Lincoln Tsang	BIO EAG	Additional				Association for the British Healthcare Industry: Member of advisory Committee. Auditor. Non-remunerated.
Lionel Randon	BIO EAG	Personal	Merck KGaA	Salary	Yes	
Lionel Randon	BIO EAG	Non-Personal	NIL	N/A	N/A	

Lionel Randon	BIO EAG	Additional				EDQM Expert in the MAB Working Party since 2016 and General Method Working Party since 2018.
Lionel Randon	BIO EAG	Additional				Member of EFPIA since 2009 involved in the Manufacturing & Quality, Biomanufacturing and Pharmacopoeia's expert groups.
Marius Brits	MC2 EAG	Personal	NIL		N/A	N/A
Marius Brits	MC2 EAG	Non-Personal	WHO		Financial support to provide technical assistance (laboratory work and monograph development) for the development of pharmacopoeial monographs for publication in The International Pharmacopoeia of the WHO.	Yes
Marius Brits	MC2 EAG	Conference /Scientific Meetings	AUDA-NEAPD and WHO		Travel, accommodation and per diem to attend 3rd Meeting of the Regulatory Capacity Development Technical Committee (RCDTC) in Dar	No

				es Salaam, Tanzania.	
Marius Brits	MC2 EAG	Conference /Scientific Meetings	WHO	Travel, accommodation and per diem to attend WHO Expert Committee meetings in Geneva, Switzerland, as I am a member of the WHO Expert Committee on Specifications Meetings and Consultations.	Yes
Mark Lowdell	WP ATMP	Personal	Virocell Ltd	Consultant	No
Mark Lowdell	WP ATMP	Personal	BitBio Ltd	Consultant	No
Mark Lowdell	WP ATMP	Personal	Cytoseek Ltd	Consultant, Member of SAB	No
Mark Lowdell	WP ATMP	Personal	Autolomous Ltd	Co-founder, co-director, shareholder	No
Mark Lowdell	WP ATMP	Personal	INmune Bio Inc	Co-founder, co-director, CSO, Shareholder, Consultant	Yes
Mark Lowdell	WP ATMP	Personal	Autolus Ltd	Consultant	Yes
Mark Lowdell	WP ATMP	Personal	Achilles Tx Ltd	Co-founder, Shareholder, Consultant	Yes
Mark Lowdell	WP ATMP	Personal	Avectas Ltd	Chair of SAB, Consultant	Yes
Mark Lowdell	WP ATMP	Personal	BioRecell Ltd	Member of SAB, Consultant	Yes

Mark Lowdell	WP ATMP	Personal	NWBiotherapeutics Inc	Consultant	Yes
Mark Lowdell	WP ATMP	Personal	Quell Therapeutics Ltd	Consultant	Yes
Mark Lowdell	WP ATMP	Personal	Sartorius GmbH	Member of SAB	Yes
Mark Lowdell	WP ATMP	Personal	Virocell Ltd	Shareholder	Yes
Mark Lowdell	WP ATMP	Non-Personal	INmune Bio Inc	"Grant to support PhD student under my supervision at University College London	Yes
Mark Santillo	UM EAG	Personal	NIL	N/A	N/A
Mark Santillo	UM EAG	Non-Personal	NIL	N/A	N/A
Martin Ilott	Panel VIP	Personal	NIL	N/A	N/A
Martin Ilott	Panel VIP	Non-Personal	NIL	N/A	N/A
Matthew Collis	WP ATMP				
Mellisa Hanna-Brown	WP AQbD				
Michael Rowan	HCM EAG	Personal	NIL	N/A	N/A
Michael Rowan	HCM EAG	Non-Personal	NIL	N/A	N/A
Miriam Guest	Panel MIC				
Monique Simmonds	BPC, HCM EAG	Personal	NIL	N/A	N/A

Monique Simmonds	BPC, HCM EAG	Non-Personal	DEFRA Darwin initiative advisory committee	Member no financial etc interest	Yes
Monique Simmonds	BPC, HCM EAG	Non-Personal	DEFRA group evidence science and analysis committee (GESAC)	Member no financial etc interest	Yes
Monique Simmonds	BPC, HCM EAG	Non-Personal	College of Medicine	Member no financial etc interest	Yes
Monique Simmonds	BPC, HCM EAG	Non-Personal	Grantham Centre for Sustainable Futures	Member no financial etc interest	Yes
Monique Simmonds	BPC, HCM EAG	Non-Personal	Good Practice Traditional Chinese Medicine Research Association	Chair no financial etc interest	Yes
Monique Simmonds	BPC, HCM EAG	Non-Personal	Hilliers Gardens Trust Advisory Board	Chair no financial etc interest	Yes
Monique Simmonds	BPC, HCM EAG	Non-Personal	Hong Kong Dept of Health, Pharmacopoeia International Advisory Committee	Member no financial etc interest	Yes
Monique Simmonds	BPC, HCM EAG	Non-Personal	Polypharmakos Limited	Director no financial etc interest	Yes
Monique Simmonds	BPC, HCM EAG	Non-Personal	Responsible Beauty Advisory Council (P&G)	Member no financial etc interest	Yes
Monique Simmonds	BPC, HCM EAG	Non-Personal	Royal Holloway University of LONDON	Member no financial etc interest	Yes

			Department of Health Advisory Board		
Monique Simmonds	BPC, HCM EAG	Non-Personal	P&G	Master collaboration agreement grant (no personal consultancy)	Yes
Monique Simmonds	BPC, HCM EAG	Conference /Scientific Meetings	Bayer	Costs for travel covered	No
Mustafa Zaman	WP AQbD	Personal	Granzer Regulatory Consulting and Services GmbH, Germany	Salary	Yes
Mustafa Zaman	WP AQbD	Non-Personal	NIL	N/A	N/A
Mustafa Zaman	WP AQbD	Conference /Scientific Meetings	European Centre for Clinical Research Training (ECCRT) workshop	The presentation was delivered on-line. Paid a fee to employer	No
Mustafa Zaman	WP AQbD	Conference /Scientific Meetings	Centre of Pharmaceutical Medicine Research (CPMR) Scientific Advisory Board meeting	No expenses, no fees, no gifts etc were received for attending this meeting	No
Mustafa Zaman	WP AQbD	Conference /Scientific Meetings	Kingston University	No expenses, no fees, no gifts etc were received for giving this lecture	No

Mustafa Zaman	WP AQbD	Conference /Scientific Meetings	King's College London	MPharm undergraduate (3rd year) lecture. No expenses, no fees, no gifts etc were received for giving this lecture	No
Mustafa Zaman	WP AQbD	Conference /Scientific Meetings	King's College London	Pharmaceutical Sciences MSc course lecture: No expenses, no fees, no gifts etc were received for giving this lecture	No
Neil Wynne	MC2 EAG	Personal	CP Pharmaceuticals	Salary	Yes
Neil Wynne	MC2 EAG	Non-Personal	NIL	N/A	N/A
Paul Anderson	HCM EAG	Personal	GR Lane Health Products Ltd	Salary	Yes
Paul Anderson	HCM EAG	Non-Personal	NIL	N/A	N/A
Paul Carter	WP ATMP	Personal	Quell Therapeutics	Salary and shares	Yes
Paul Carter	WP ATMP	Personal	GlaxoSmithKline	Shares and pension	Yes
Paul Carter	WP ATMP	Personal	AstraZeneca	Shares	Yes
Paul Carter	WP ATMP	Personal	Haelon	Shares	Yes
Paul Carter	WP ATMP	Non-Personal	NIL	N/A	N/A
Paul Fleming	MC1 EAG	Personal	British Generic Manufacturers Association (BGMA)	Fees - Technical Director, industry trade association	Yes

Paul Fleming	MC1 EAG	Personal	British Biosimilars Association	Fees - Technical Director, industry trade association	Yes
Paul Fleming	MC1 EAG	Non-Personal	NIL	N/A	N/A
Paul Getty	WP ATMP	Personal	Pharmon Biologics	Salary	Yes
Paul Getty	WP ATMP	Non-Personal	NIL	N/A	N/A
Paul Marshall	BPC, MC1 EAG	Personal	Jazz Pharmaceuticals	Salary & shares	Yes
Paul Marshall	BPC, MC1 EAG	Personal	Reckitt Benckiser Plc	Shares	Yes
Paul Marshall	BPC, MC1 EAG	Personal	Individior Plc	Shares	Yes
Paul Marshall	BPC, MC1 EAG	Personal	Sims Marshall Consultancy Ltd	Shares	Yes
Paul Marshall	BPC, MC1 EAG	Conference /Scientific Meetings	TOPRA	Presenter Expenses	No
Paul Marshall	BPC, MC1 EAG	Conference /Scientific Meetings	JPAG	Presenter Expenses	No
Paul Marshall	BPC, MC1 EAG	Non-Personal	NIL	N/A	N/A
Paul Varley	BIO EAG, BLP Panel, WP BIO-DPS	Personal	Alchemab Therapeutics	Salary and Share options	Yes
Paul Varley	BIO EAG, BLP Panel, WP BIO-DPS	Personal	Sanofi	Shares	Yes
Paul Varley	BIO EAG, BLP Panel, WP BIO-DPS	Personal	Various research stage biotechs	Consulting fees	Yes

Paul Varley	BIO EAG, BLP Panel, WP BIO-DPS	Non-Personal	NIL	N/A	N/A
Peng Wang	WP ATMP	Personal	Lonza Houston	Salary	Yes
Peng Wang	WP ATMP	Non-Personal	NIL	N/A	N/A
Peter Emery-Billcliff	WP ATMP	Personal	GSK	Salary	No
Peter Emery-Billcliff	WP ATMP	Personal	Haleon	Shares	Yes
Peter Emery-Billcliff	WP ATMP	Personal	Complement Therapeutics	Salary	Yes
Peter Emery-Billcliff	WP ATMP	Conference /Scientific Meetings	Charles River	Cell & Gene therapy summit tour: Expenses paid by employer	No
Peter Emery-Billcliff	WP ATMP	Conference /Scientific Meetings	Alexion, Apellis, Biogen, Complement Technology, Exsera Biolabs, National Jewish Health, Quidel, Svar, Omeros, Hycult Biotech, Q32 Bio, Bio Cryst	29th International Complement Workshop: Expenses paid by employer	No
Peter Emery-Billcliff	WP ATMP	Conference /Scientific Meetings	Benchling	Benchtalk Europe: Expenses paid by employer	No
Peter Emery-Billcliff	WP ATMP	Conference /Scientific Meetings	Merck	Emerging Biotech Cell & Gene Therapy Symposium:	No

				Expenses paid by employer	
Peter Emery-Billcliff	WP ATMP	Conference /Scientific Meetings	Life Science Integrates	Advanced Therapies Integrates 2023	No
Peter Emery-Billcliff	WP ATMP	Non-Personal	NIL	N/A	N/A
Peter Hamilton	WP AQbD	Personal	AstraZeneca	Salary, Shares	Yes
Peter Hamilton	WP AQbD	Non-Personal	NIL	N/A	N/A
Peter Henrys	Panel IGC	Personal	BOC Ltd.	Salary	Yes
Peter Henrys	Panel IGC	Non-Personal	NIL	N/A	N/A
Peter Henrys	Panel IGC	Additional			Chairman of British Compressed Gas Association (BCGA) Medical Gas Committee (TSC7)
Peter Henrys	Panel IGC	Additional			Member of European Industrial Gas Association (EIGA) Medical Gas Committee (WG7) and Medical Gas Equipment Committee (WG15)
Peter Henrys	Panel IGC	Additional			Chairman of BSI CH 121 / SC6 Standards Committee (Medical Gas Supply Systems)

Peter Henrys	Panel IGC	Additional				Member of ISO TC 121 / SC6 Standards Committee (Medical Gas Supply Systems)
Peter Henrys	Panel IGC	Additional				Member of the Association of Anaesthetists Safety Committee
Peter Henrys	Panel IGC	Additional				Financial Director (Non-Paid) of BAREMA (British Anaesthetic and Respiratory Equipment Manufacturing Association)
Phil Borman	WP AQbD	Personal	GSK	Salary and Shares	Yes	
Phil Borman	WP AQbD	Non-Personal	NIL	N/A	N/A	
Phil Hampshire	MC3 EAG	Personal	Accord Healthcare	Salary	Yes	
Phil Hampshire	MC3 EAG	Non-Personal	NIL	N/A	N/A	
Phil Nethercote	WP AQbD	Personal	NIL	N/A	N/A	
Phil Nethercote	WP AQbD	Non-Personal	NIL	N/A	N/A	
Philip Weir	ULM EAG	Personal	NIL	N/A	N/A	
Philip Weir	ULM EAG	Non-Personal	NIL	N/A	N/A	
Raffaella Balocco	PCN EAG	Personal	NIL	N/A	N/A	
Raffaella Balocco	PCN EAG	Non-Personal	NIL	N/A	N/A	

Ralph Woodland	Panel VIP	Personal	NIL	N/A	N/A
Ralph Woodland	Panel VIP	Non-Personal	NIL	N/A	N/A
Rhona Banks	Panel VIP	Personal	Zoetis	Consultancy (including fees)	Yes
Rhona Banks	Panel VIP	Personal	LETI Laboratories	Consultancy (including fees)	Yes
Rhona Banks	Panel VIP	Personal	Ceva Phylaxia	Consultancy (including fees)	Yes
Rhona Banks	Panel VIP	Personal	Intervacc	Consultancy (including fees)	Yes
Rhona Banks	Panel VIP	Personal	ABIC (PHIBRO)	Consultancy (including fees)	Yes
Rhona Banks	Panel VIP	Personal	Galvmed	Consultancy (including fees)	Yes
Rhona Banks	Panel VIP	Personal	ECO Animal Health	Consultancy (including fees)	Yes
Rhona Banks	Panel VIP	Personal	GlaxoSmithKline	Shares	Yes
Rhona Banks	Panel VIP	Non-Personal	NIL	N/A	N/A
Richard Cawthorne	Panel CX	Personal	Croda International	Shares and salary	Yes
Richard Cawthorne	Panel CX	Non-Personal	NIL	N/A	N/A
Richard Middleton	HCM EAG	Personal	Herbal Medicines Regulatory Services Ltd	Director/Company dividends	Yes
Richard Middleton	HCM EAG	Non-Personal	NIL	N/A	N/A
Richard Middleton	HCM EAG	Additional			British Herbal Medicine Association: Director of Trade Association representing herbal

medicine
manufacturers. Nil
payments

Rickard Nordstrom	WP ATMP	Personal	Vironova Bioanalytics AB	Shares and Salary	Yes
Rickard Nordstrom	WP ATMP	Personal	QuTEM AB	Shares and Salary	Yes
Rickard Nordstrom	WP ATMP	Non-Personal	NIL	N/A	N/A
Rita Rego	WP ATMP	Personal	Virocell Biologics Ltd	Salary and Shares	Yes
Rita Rego	WP ATMP	Personal	Qualis Pharma Solutions Ltd	Director of the Company	Yes
Rita Rego	WP ATMP	Non-Personal	NIL	N/A	N/A
Robert Lowe	BPC, PCN EAG	Personal	NIL	N/A	N/A
Robert Lowe	BPC, PCN EAG	Non-Personal	NIL	N/A	N/A
Robin Thorpe	BIO EAG, PCN EAG	Personal	NIL	N/A	N/A
Robin Thorpe	BIO EAG, PCN EAG	Non-Personal	NIL	N/A	N/A
Rodney Horder	AIM EAG, PCN EAG	Personal	BioMaps	Consultancy	No
Rodney Horder	AIM EAG, PCN EAG	Personal	Blackrock Pharmaceuticals	Consultancy	Yes
Rodney Horder	AIM EAG, PCN EAG	Non-Personal	NIL	N/A	N/A
Roger Pickett	Panel RAD	Personal	GE Healthcare	Shares through prior employment	Yes
Roger Pickett	Panel RAD	Personal	GE Healthcare	Immediate family member held shares through prior employment	Yes

Roger Pickett	Panel RAD	Non-Personal	NIL	N/A	N/A
Ronald Torano	MC3 EAG	Personal	GSK	Salary and Shares	No
Ronald Torano	MC3 EAG	Personal	GSK	Pension and shares	Yes
Ronald Torano	MC3 EAG	Non-Personal	NIL	N/A	N/A
Rory Cooney	Panel VIP	Personal	NIL	N/A	N/A
Rory Cooney	Panel VIP	Non-Personal	NIL	N/A	N/A
Rosario LoBrutto	WP AQbD	Personal	Pharma Vision LLC	Consultancy	Yes
Rosario LoBrutto	WP AQbD	Personal	BIOTECH	Non-profit Organisation	Yes
Rosario LoBrutto	WP AQbD	Non-Personal	NIL	N/A	N/A
Ryan McCoy	WP ATMP	Personal	NIL	N/A	N/A
Ryan McCoy	WP ATMP	Non-Personal	NIL	N/A	N/A
Sarah Cockbill	Panel VET	Non-Personal	NIL	N/A	N/A
Sarah Cockbill	Panel VET	Personal	NIL	N/A	N/A
Sarah Hartley	ULM EAG	Personal	Rosemont Pharmaceuticals	Salary	Yes
Sarah Hartley	ULM EAG	Non-Personal	NIL	N/A	N/A
Seamus Boland	Panel IGC	Personal	Novartis International Pharmaceuticals	Shares	No
Seamus Boland	Panel IGC	Personal	SGS International	Shares	Yes

Seamus Boland	Panel IGC	Personal	SGS International	Salary	Yes	
Seamus Boland	Panel IGC	Personal	Janssen	Shares (immediate family member)	Yes	
Seamus Boland	Panel IGC	Personal	Janssen	Salary (immediate family member)	Yes	
Seamus Boland	Panel IGC	Non-Personal	NIL	N/A	N/A	
Sean Jones	BPC, AIM EAG, WP AQbD	Personal	NIL	N/A	N/A	
Sean Jones	BPC, AIM EAG, WP AQbD	Non-Personal	NIL	N/A	N/A	
Sean Jones	BPC, AIM EAG, WP AQbD	Additional				Immediate family member is a QC analyst working for Catalent in Swindon. The site manufactures Zydis fast dissolving tablets.
Sharon Palser	BPC	Personal	NIL	N/A	N/A	
Sharon Palser	BPC	Non-Personal	NIL	N/A	N/A	
Simeon Gill	BIO EAG	Personal	AstraZeneca	Salary and AZ shares	Yes	
Simeon Gill	BIO EAG	Non-Personal	NIL	N/A	N/A	
Simeon Gill	BIO EAG	Additional	AstraZeneca			AstraZeneca is a contract giver to contract research and contract manufacturing organisations

Stephen Ellison	WP AQbD	Personal	LGC (Teddington) Limited	Salary and some shares in LGC group	Yes
Stephen Ellison	WP AQbD	Non-Personal	NIL	N/A	N/A
Steven Nolan	MC1 EAG	Personal	Wockhardt UK Ltd	Acting as Contract Qualified Person and QA Consultant	Yes
Steven Nolan	MC1 EAG	Non-Personal	NIL	N/A	N/A
Stuart Paul-Adams	WP ATMP	Personal	NIL	N/A	N/A
Stuart Paul-Adams	WP ATMP	Non-Personal	NIL	N/A	N/A
Tina Morris	WP AQbD				
Tishwant Kanwarjit	WP ATMP	Personal	NIL	N/A	N/A
Tishwant Kanwarjit	WP ATMP	Non-Personal	NIL	N/A	N/A
V'Iain Fenton-May	ULM EAG, Panel MIC	Personal	NIL	N/A	N/A
V'Iain Fenton-May	ULM EAG, Panel MIC	Non-Personal	NIL	N/A	N/A
Vicky Smith	WP ATMP	Personal	NIL	N/A	N/A
Vicky Smith	WP ATMP	Non-Personal	NIL	N/A	N/A
Victoria Vanhoutte	WP ATMP	Personal	Scottish National Blood Transfusion Service	Salary	No
Victoria Vanhoutte	WP ATMP	Personal	British Standards Institution	Salary	No

Victoria Vanhoutte	WP ATMP	Personal	Quotient Biodiagnostics (AliveDx)	Salary	Yes
Victoria Vanhoutte	WP ATMP	Non-Personal	NIL	N/A	N/A
Vikas Jaitely	BPC, AIM EAG, Panel MIC	Personal	Merck Group (Merck KgAa) Germany	Salary	Yes
Vikas Jaitely	BPC, AIM EAG, Panel MIC	Non-Personal	NIL	N/A	N/A
Vincent Loh	BIO EAG	Personal	NIL	N/A	N/A
Vincent Loh	BIO EAG	Non-Personal	NIL	N/A	N/A
Wayne Goddard	ULM EAG	Personal	NIL	N/A	N/A
Wayne Goddard	ULM EAG	Non-Personal	NIL	N/A	N/A
Wayne Zunic	BIO EAG				
Zara Hannoun	WP ATMP	Personal	Oxford Biomedica	Share options	Yes
Zara Hannoun	WP ATMP	Personal	Zelluna Therapeutics	Salary	Yes
Zara Hannoun	WP ATMP	Non-Personal	NIL	N/A	N/A
Zheng-Tao Wang	HCM EAG				

Contact information about these reports:

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

Tel: 020 3080 6000

E-mail: info@mhra.gov.uk

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