SUMMARY MINUTES

of the

BRITISH PHARMACOPOEIA COMMISSION

A meeting of the British Pharmacopoeia Commission was held at 10 South Colonnade, Canary Wharf, London E14 4PU on Monday 3rd March 2025.

Present: Dr A M Brady (*Chair*), Mr R Lowe (*Vice Chair*), Dr. E Bush, Dr K A Chan, Mr C E Giartosio, Dr J Halliday, Mrs H Hall (*Lay member*), Dr V Jaitely *(left at 3 pm)*, Mr S Jones, Dr O Kavanagh, Dr M Lane, Dr P Marshall, Ms C Nicholson (*Lay member*), Prof V Perrie, Mr J Rickard, Prof M Simmonds (*via MS Teams at 12 pm*)

In attendance: Mr S Hoare (*Secretary & Scientific Director*), Mr P Crowley, Ms G Li-Ship, Mr K Rakowski, Dr C Swann.

Also present: Dr B Bahsoun, Ms S Bowles, Ms H Corns, Dr M Dmitriieva, Ms R Feltham, Ms A Peabody, Mr R Smith, Mr O Waddington, Mr M Whaley, and Mr S Young.

Apologies: Dr E Amirak.

727 **Introductory Remarks**

Welcome The Chair welcomed members to the meeting. She welcomed the return of Dr D Tong to the BP & LS team after special leave. As this was the annual in-person meeting, Mr Crowley had sent members a consent form for a group photo of the Commission and members were reminded to complete these if they wished to participate. Completed forms were to be returned by email or could be completed on the day.

Declaration of Interests; Confidentiality of Proceedings Members were reminded of the need to inform the Secretariat of any changes to their interests which are required for publication of the Annual report. Members were also reminded of the confidential nature of the meeting and that the papers and minutes should not be disclosed.

BPC Membership and Appraisals The Chair provided an update on reappointments. There were three members being reappointed, which were ongoing with DHSC and Professor Simmonds 10-year term was expiring and an advert had been prepared for her position on the HCM expert advisory group. Committee Services Team would be in contact with members for appraisals.

Fees and expenses Members were asked to submit any claims for fees and expenses to committeeservicesteam@mhra.gov.uk, clearly indicating the meeting to which they referred.

I MINUTES

728 The minutes and summary minutes of the meeting held on 4th November 2024 were confirmed, subject to a couple of editorial amendments.

II MATTERS ARISING FROM THE MINUTES

729 Members had been invited to provide any comments or corrections to the Minutes from the previous meeting.

The following matters arising from the meeting held on 3rd March 2025 were noted.

Minute 682.8 – Reconstituted Oral Liquids A policy concerning shelf-life testing of reconstituted Oral Liquids and on products for which dry ingredients can be administered directly as well as reconstituted would be brought to a future meeting.

Minute 705.1 – Alkyl Sulfonate Ester Impurities The Secretariat agreed to share a journal article link and EDQM's scientific discussion to EAGs for further consideration.

Minute 705.3 – Observer discussions The Secretariat would bring a policy paper on stakeholders observing Commission meetings to a future meeting.

Minute 705.4 – BP Ways of Working Following on from workshops with EAG Chairs, the Secretariat would set a suitable date for a workshop with the BPC on BP Ways of Working.

Minute 705.6 – Horizon Scanning The Secretariat considered members' comments and would bring a horizon scanning process to a future meeting.

Minute 705.7 – Falsified medicines proposal The MHRA Enforcement team had been consulted and did not endorse the Secretariat's proposal to develop a BP guidance on testing falsified medicines.

Minutes 712 and 713 – Aide memoire The Aide Memoire on the BP Forum had been updated to incorporate member feedback on the wording of the dissolution and chromatographic sections to reinforce reference to the Biopharmaceutics Classification System (BCS) and value of chromatographic system suitability tests.

Minutes 718 A member highlighted an example of a marketing licence which had been approved by assessors with limits outside the BP monograph.

III REPORTS AND CORRESPONDENCE

GOVERNANCE

730 **Update from Secretary & Scientific Director**

The Secretary and Scientific Director provided an update on the MHRA staff changes.

A new Chair, Professor Anthony Harnden, had recently been appointed 1st Jan.

The Chief Executive Officer role had been extended to the end of April to enable a handover to the incoming successful CEO, which was still unknown at the time of the verbal update.

SECRETARIAT NOTE: At the end of the meeting, news regarding the new CEO became available and was presented to members as Mr Lawrence Tallon.

Adverts for a new Chief Science Officer and a new Chief Operating Officer were being placed by the Department of Health.

Members were informed that Innovative Devices Group had now joined the Innovation and Compliance group under Mr Pound, where the BP & LS team also sits.

MHRA Activities Since the last meeting, the Agency together with the Office of Life Sciences (OLS) had launched UK Centres of Excellence in Regulatory Science and Innovation (CERSI).

There had also been a Sustainable Medicines Manufacturing Innovation Programme (SMMIP) launch, a joint MHRA project with Innovate UK, which had received expressions of interest. The objective was to bring forward and accelerate ideas that could help with sustainable manufacturing in the UK.

Members were informed that the MHRA had passed a British Standards Institute (BSI) ISO 9001 audit with only 1 minor non-conformance, which did not apply to the BP.

Mr Hoare had represented the MHRA and BP at a Pharma Sustainability Integrates (PSI) Conference at AstraZeneca's Discovery Centre in Cambridge.

Future Look Mr Hoare updated members that the BP Strategy would be presented to the Executive Committee on 4th March and then to the Agency Board on 18th March. This is a public meeting and members were invited to attend if they wished.

The World Health Organisation (WHO) had approached the BP for advice in their publication of the International Pharmacopoeia for feedback or assistance.

Mr Hoare had also accepted an invitation from the Royal Society of Chemistry to present the keynote on sustainability in analytical chemistry on 18th March.

731 **BP Policies and Procedures** **COM(25)01**

Members were presented with an updated version of the Policy and Guidance list. The Secretariat intended to update the document as necessary and provide it annually to the BPC for information purposes.

732 **Patient Impact** **COM(25)02**

In line with the BP & Labs Strategy 2024-2029, the Secretariat had been assigned the task of developing a clearer understanding of the patient impact of BP products and services. The Secretariat had sought volunteers amongst the BPC Members and held an online workshop to identify and shape such metrics.

OPERATIONAL

733 **British Pharmacopoeia Laboratory** **COM(25)03**

British Pharmacopoeia Laboratory Reports The list of new and revised monograph reports that had been prepared by the Laboratory since the November 2024 meeting was provided for information.

British Pharmacopoeia Chemical Reference Substances Tables providing information on BPCRS up to the end of January 2025 were provided for information.

LGC Laboratory Move Progress on the Laboratory move from Teddington to the Surrey Research Park in Guildford was reported to be on track for the beginning of April 2025.

Mr Young informed the group that communications had been prepared for users concerning CRS supply. He reassured members concerned with CRS supply that a greater stock of inventory had been built up to cope with the temporary shutdown. Further communications would follow to confirm last shipping dates to prewarn users over the laboratory shutdown during the move.

734 **Sustainability Project Update** **COM(25)04**

Sustainability Information Pack

Members were provided with an updated draft sustainability pack which included an additional seven case studies from external domestic and international contributors. One case study still awaited clearance for release from the contributing company's communications team.

Laboratory

Both solvent recirculation and separation of the aqueous and organic portions of mobile phase laboratory investigations alongside drafted monograph methods were still ongoing and members were provided with two additional monograph project examples.

The two additional monograph projects had successfully utilised mobile phase recirculation, which had led to a reduction in mobile phase of approximately 55%.

In addition, the Laboratory had successfully investigated the replacement of helium with nitrogen as a carrier gas in a recent test to verify a WHO draft method for Diethylene Glycol and Ethylene Glycol in in Liquid Preparations for Oral Use.

Sustainability in monographs Method scaling investigations alongside solvent recirculation and gas replacement projects had continued to be investigated. Successful method scaling projects (Assay and Dissolution methods for Solifenacin Oral Solution; Assay methods for Trimethoprim Oral Solution, Trimethoprim Tablets and Ibuprofen Injection; Related substances method for Trimethoprim Tablets) had been included in the updated sustainability information pack as case studies.

Future Work The Secretariat would continue to work with Laboratory colleagues and consider suitable case studies in taking the sustainability initiative forward.

Members were updated that in the January 2025 MC1 EAG meeting, members discussed how to incorporate sustainability as a fixed item on EAG meeting agendas. The Secretariat was developing a strategy to roll this out across all EAGs in future.

735 **BP Website Continuous Improvement** **COM(25)05**

Contracted Deliverables Members were provided with an update on the final contracted deliverable remaining to be delivered, Account Per User. APU obligates every user in multi-user subscriptions to set up an individual account for logging in and provides a personalised dashboard once the licence manager has agreed a migration date to the new model.

APU had now been deployed and the migration of multi-user licence customers was still ongoing.

Continuous Improvement Continuous improvement initiatives had been divided into a project plan for the next six months, the following year and the following two years. Initiatives based on insights or generated from research would be added to the project plan or be amended.

Members were provided with a list of potential improvements from the 2024 survey, including the initiatives planned for the next six months.

Next steps The BP would be consulting registered users on the proposed BP2026 prices changes. After this publication, the BP would continue to review prices on an annual basis.

736 **MHRA Corporate Plan 2023-2026** **COM(25)06**

The MHRA corporate plan for 2023-2026 included a strategic goal of enabling healthcare access to safe and effective medical products.

The Secretariat provided an update on the feasibility of initiatives to support the approval of new generic marketing authorisations.

737 **Priority Work Programme Scoring Framework** **COM(25)07**

Following the November 2024 BPC meeting, the Secretariat considered the members' feedback for the scoring system for the priority work programme and a draft scoring framework was presented.

Members endorsed the scoring system in principle.

738 **WP ATMP Update** **COM(25)08**

An update on the recent activities of the Working Party on Advanced Therapy Medicinal Products was provided for information.

7th Meeting At their November 2024 meeting the Working Party had reviewed two subgroups that were nearing their public consultation stages, confirmed the scopes of two new subgroups, and carried out a workshop to brainstorm ideas for additional subgroups.

Public consultations Two guidance documents had been released for public consultation: a new “Replication Competent Virus Assays” guidance and a revision of the “Vector Copy Number” guidance with the addition of “Polymerase Chain Reaction validation” annexes.

New Subgroups The "Encapsulated DNA Characterisation" and "Capsid Protein Characterisation" subgroups, which were agreed to be taken forward by the WP ATMP during their 6th meeting, have been established, assigned a Scientific Lead, and had commenced drafting their respective guidance documents.

Next steps Following a workshop with the WP ATMP, significant progress had been made towards establishing new subgroups for topics identified within the MHRA and agreed upon during the 7th WP ATMP meeting. The subgroups "CRISPR Cas 9 Off-Target Effects" and "Considerations for the Cryopreservation of Cells" have been prioritised.

Working Party to Expert Advisory Group Members endorsed the Secretariat proposal to convert the Working Party to an EAG as the ATMP work had demonstrated it was a viable content stream instead of having defined start and end of a project as a Working Party.

IV Future Publications

739 British Pharmacopoeia 2026 Publications COM(25)09

BP 2026 The Secretariat was currently preparing text for inclusion in the British Pharmacopoeia 2026 and the British Pharmacopoeia (Veterinary) 2026.

Members were thanked for their comments on the DRT batch one and reminded of the upcoming DRT batch two.

Preliminaries Members recommended that the British Pharmacopoeia 2026 and the British Pharmacopoeia (Veterinary) 2026 should be published and confirmed that the draft Prefaces to both publications were acceptable.

Approved Synonyms; Ph. Eur. Supplements 11.6, 11.7 and 11.8 All new approved synonyms relating to the new monographs in supplements 11.6 - 11.8 were endorsed by the members.

740 Monographs for Omission from the 2026 and BP (Vet) 2026 COM(25)10

Since publication of the BP 2025 publications, several monographs had been identified as candidates for omission from the BP 2026 and the BP (Vet) 2026. The Secretariat had contacted countries which included the BP in their legislation and/or in which the BP was

widely used to ascertain if there was any international usage of these items, and a news item had been posted on the BP website. The list had also been sent to the Expert Advisory Group on Unlicensed Medicines to check if any of the items were available as unlicensed formulations.

Comments had been received back from the World Health Organization highlighting that Bumetanide Injection was on the current 23rd WHO Model List of Essential Medicines and thus should also be included in national lists of essential medicines. The Secretariat confirmed that this product was not on the UK or EMA list of critical medicines with potential supply issues, however, members agreed that the Bumetanide Injection monograph should be retained in the BP 2026 publication.

Two other monographs proposed for omission, Senna Liquid Extract and Standardised Senna Granules, were endorsed by the members.

BAN 2026 **COM(25)11**

A list of new BAN entries was provided for members for publication in August 2025, with an effective date of 1st January 2026. The text had been agreed by the Expert Advisory Group on Pharmacy and Nomenclature and had been sent to manufacturers for comment. There were 39 new BAN entries which related to new medicines now available on the UK market; this yearly BAN update would be named BAN 2026.

Subject to any comments received, the Commission approved the content of the draft BAN 2026 and recommended that it should be published. The BAN 2026 would be published at the same time as the BP 2026 publications.

V Analytical Issues

None.

VI Expert Advisory Groups / Working Parties / Panels of Experts

742 EAG Membership COM(25)12

Since the November, meeting several BP Commission members had agreed to EAGs.

Following the retirement of two members from the Working Party Analytical Quality by Design (AQbD), two candidates had been endorsed as new members.

Members approved all the proposed appointments.

743 Working Party ATMP COM(25)13

The report and summary report of the WP ATMP meeting (11:11:24) were endorsed.

744 **Expert Advisory Group MC2: Medicinal Chemicals** **COM(25)14**

The report and summary report of the EAG MC2 (12:11:24) was endorsed. The following points were raised.

Ibuprofen Preparations – Following an MAH report on the formation of esters in alcohols, an updated method had been drafted for the Gel monograph which could detect the three potential ester impurities. Members were updated on a successful implementation of a scaled assay method for the Ibuprofen Injection, which would be provided under the "More Resources" tab on the BP website.

Olmesartan Tablets – A request from an assessor to increase the impurity A limit based on stability data and justification provided by an MAH had been endorsed by the EAG. The Secretariat would revise the monograph with the increased limit following a full technical review of the monograph.

745 **Expert Advisory Group PCN: Pharmacy and Nomenclature** **COM(25)15**

The report and summary report of the EAG PCN meeting (07:02:25) were endorsed and the following points were raised.

Dispense and Supply Statements A review of the appropriateness of these statements was being carried out. PCN experts concluded that all dispense and supply statements should be removed from the BP as the BP is not an information source used by clinicians.

Aide Memoire: Consistency in Powders for Oral Liquid Monographs It was noted that not all licensed oral solution products contain flavourings, and it was recommended that the template for Oral Solution monographs would be updated from "suitable flavoured vehicle" to "suitable vehicle".

VII European Pharmacopoeia

746 **European Pharmacopoeia Update** **COM(25)16**

European Pharmacopoeia Commission The 180th Session of the EP Commission had taken place on 19th and 20th November, which had been attended by the UK Delegation virtually.

The 181st Session of the EPC will be held on 25th and 26th March 2025 and members were informed that the UKD would be attending virtually.

Election of Chairs The election schedule for Chairs, Vice-Chairs and Chairs of Groups had been announced at the 180th session. Election of the EPC Chair would be in March at 181st session, with Vice-Chairs and Chairs of Groups following at the 192nd and 183rd sessions, in June and November, respectively.

The Secretariat had received five expressions of interest for Chairs of Groups. If elected, this would represent a substantial increase compared to the previous round, during which we had only one UK Chair.

Critical Medicines At the 180th session of the EPC, members had been surveyed on a new potential process for incorporating medicines from the critical medicines for the EU into EDQM's work programme.

UK Membership of expert groups in the European Pharmacopoeia Commission

A list of experts who had been identified for corresponding groups of the EPC was presented for information. Three of the four experts had been endorsed at the 180th Session with the last application being reviewed internally.

Questionnaires sent to the UK National Authority A list of recent questionnaires relating to proposals to add or remove items from the Ph Eur work programme was presented for information.

VIII International Collaboration

747 International Update COM(25)17

Members were provided with an update on international activities.

United States Pharmacopoeia Regular monthly teleconferences between the BP and the USP had been held between November to January to continue discussions on mutual interest.

World Health Organisation 15th International Meeting of the World Pharmacopoeias, 5 – 7th February This meeting had been hosted by the Indian Pharmacopoeia Commission in New Delhi. The first open day had included industry and regulator delegates followed by tours of facilities for IMWP members.

The following two closed sessions included topics such as impurity control approaches and terms of reference for IMWP in addition to sustainability principles.

The next meeting would be hosted in May or June 20206 in Brazil, celebrating 100 years of Anvisa, the Brazilian Health Regulatory Agency.

2025 USP Convention Meeting, 5 – 8th May This meeting would be held at the USP headquarters in Rockville, to vote on the resolutions which comprise the USP 5-year strategy and confirm membership of its board of trustees and council.

IX Any Other Business

748 Blunt Filling Needles

A member informed the group that the 2014 Sharps Directive aimed to reduce needle stick injuries in healthcare. Blunt-fill needles (thicker, non-hypodermic) were therefore being used instead of ordinary needles when reconstituting vials but this had led to complaints of contamination with rubber bung particles in containers.

Appendix XIX E of the BP (rubber closure penetration tests, functional tests) currently specifies the use of hypodermic needles that does not reflect real-world use of blunt-fill needles and the European Pharmacopoeia (EP) was reviewing this Appendix.

749 **Date of next meeting**

30th June 2025

FOR INFORMATION:

750 **1. Items for future meetings**

A list of items for discussion at future meetings was provided for information.

751 **2. List of acronyms**

A list of actions from previous meetings of the Commission was provided for information.