SUMMARY MINUTES

of the

BRITISH PHARMACOPOEIA COMMISSION

A meeting of the British Pharmacopoeia Commission was held via videoconference on Monday 30th June 2025.

Present: Dr A M Brady (*Chair*), Mr Rob Lowe (*Vice-Chair*), Dr E Amirak, Dr E Bush, Dr K L Chan, Mr C E Giartosio, Dr J Halliday, Ms H Hall (*Lay member, left early, Minute 756)*, Dr V Jaitely, Mr S Jones, Dr O Kavanagh *(joined late, Minute 755)*, Dr M Lane, Dr P Marshall, Ms C Nicholson (*Lay member)*, Prof Y Perrie, Mr J Rickard and Prof M Simmonds.

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

Also present: Dr B Bahsoun, Ms S Bowles, Dr M Dmitriieva, Ms R Feltham, Mr R Legg, Mr R Smith, Dr C Swann, Ms A Thomson, Dr D Tong, Mr M Whaley, and Mr S Young.

Apologies: Ms H Corns

752 **Introductory Remarks**

Welcome The Chair welcomed members to the meeting. The Chair also welcomed Ms Stephanie Elliott who had joined the BP&LS for 6 months as part of her 2nd year of the MHRA Graduate Scheme.

Confidentiality of Proceedings Members were reminded of the confidential nature of the meeting and that the papers and minutes should not be disclosed.

Declaration of Interests Members were reminded of the need to declare any relevant interests at the start of agenda items. Any changes to interests throughout the year should be notified to the BP Secretariat.

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.

Appraisals Appraisals for the year had been completed and the Chair thanked members for their comprehensive and timely contributions.

BP 2024 Annual Report The Chair reported that the BP 2024 Annual Report was now in the process of being finalised and thanked members for their comments.

Reappointments The Chair updated members that the reappointments of Dr E Bush, Mr C E Giartosi, Mr J Rickards and Mr S Jones had been approved by ministers.

If re-appointed for a third term, Dr E Amirak would require approval from the Commissioner for Public Appointments under DHSC governance. To prevent a membership gap, he was "co-opted" for this meeting.

The Chair reminded members that Prof M Simmonds term ends December 2025. An advert for her replacement was expected to have been publicised shortly after the meeting.

I MINUTES

753 The minutes of the meeting held on 3rd March 2025 were confirmed, subject to editorial corrections.

II MATTERS ARISING FROM THE MINUTES

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

Minute 448 – Laboratory Evaluation Risk Assessment Review A review of the laboratory evaluation risk assessment would be presented at a future meeting, which would include sustainability assessment.

Minute 729 – Alkyl Sulfonate Ester Impurities Following the previous meeting to share Dr Snodin's article for information at upcoming EAG meetings, the Secretariat had agreed to upload his article to the BP Forum with an explanatory context for any EAG experts interested in this issue.

Minute 729 - Ways of Working Workshop Members agreed a workshop was no longer required and instead requested that on an annual basis, a list of improvements to ways of working can be provided.

Minute 731 – BP Policies and Procedures A link to the Ph. Eur. Technical Guide and Ph. Eur. Style Guide had been included in the Policies and Procedures list.

Minute 732 – Patient Impact Metrics The Secretariat had begun collecting data and base-lining metrics demonstrating patient impact of the BP. A paper detailing the collated metrics will be presented at a future meeting.

Minute 734 – Sustainability Project The draft update to sustainability information pack had been completed as agreed and published to the BP website once in a suitable digital format. A draft section on sustainability for inclusion in the Aide Memoire would be presented at a future meeting.

Minute 739 – Finalised text The finalised texts for the BP 2026 and BAN 2026 had been sent to the publisher and both publications were in the final stages for publication online or in print.

Minute 745 – Dispense and Supply Statements This would be brought to a future Commission meeting for endorsement.

Minute 748 – Blunt-fill needles The Secretariat had contacted DMRC regarding any reported defects caused by the replacement of hypodermic needles with blunt-fill needles. DMRC had reported limited data and suggested that NHS QA or patient groups could be surveyed on the types of needles and extent of observed issues.

III REPORTS AND CORRESPONDENCE

GOVERNANCE

755 **Update from Secretary & Scientific Director**

Members were provided with an overview of changes in MHRA senior staff, new training initiatives, and ongoing recruitment. It was also noted that the Agency had opened a new digital hub in Leeds to boost digital capabilities and access talent.

The Agency's business plan had been published and its work on signals and Yellow Card schemes highlighted in the Patient Safety Commissioner's annual report.

756 **BP & LS Strategy** **COM(25)18**

Members were provided with an update on the various aspects of the BP&LS strategy

OPERATIONAL

757 **Policy Proposal for Hosting Observers in BP Meetings** **COM(25)19**

A draft policy was presented which would allow selected stakeholders to observe Commission meetings, aiming to boost transparency and attract diverse scientific input. Members discussed criteria for observers, agenda access, participation limits and confidentiality.

758 **BP Publications Update** **COM(25)20**

Account Per User Access Members were given an update on the transition of multi-user licences to individual email access. A request for an additional tool to the Shibboleth software was being investigated for cost-effectiveness.

Continuous Improvement An update on the BP2026 price and format changes was presented. Progress on other projects including two-factor authentication and a Favourites page tool was also provided.

BP 2026 Format and Price User Acceptance Testing for self-serve on the new simplified packages had been successfully completed and would be rolled out for the BP2026. No significant concerns had been raised.

759 **Membership Review Process** **COM(25)21**

The current membership recruitment process, membership terms and review cycles for EAGs, Panels and Working Parties were presented to Commission.

Various options to modernise the process were considered with members endorsing a staggered review model and with the introduction of structured performance monitoring system while retaining no maximum term limit.

760 **British Pharmacopoeia Laboratory** **COM(25)22**

British Pharmacopoeia Laboratory Reports The list of new and revised monograph reports that had been prepared by the Laboratory since the March 2025 meeting was provided for information.

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

New BPCRS for BP2026 An update on the progress to establish reference standards for BP2026 was provided for information.

LGC Laboratory Move

The BP laboratory had successfully relocated to its new site in Guildford and the laboratory had regained its accreditation and resumed BPCRS delivery operations.

There had been an incident over the weekend of the 21st June where a freezer had tripped out and affected several catalogue items stored in vials. The laboratory team was working to assess the impact and initiate reactive analysis to restock the items, based on stability data and demand. An investigation into the freezer incident was ongoing with weekly progress reports from the laboratory.

761 **EAG HCM Update** **COM(25)23**

An update on the status of the EAG HCM work programme was provided., including a summary of the challenges, opportunities, future strategy and direction.

The group was focusing on several fronts including developing standards for widely used herbal extracts and updating older monographs for licensed herbal medicines.

Challenges identified included a limited pool of expertise and leadership changes when Prof Simmonds steps down as BPC member at end of her term.

Opportunities were seen in developing impactful extract monographs overlapping areas of interest between the MHRA and the Food Standards Agency.

With the increased use of herbals and potential for drug-herb interactions, the importance of improving the quality of herbal products was emphasised. HCM was also considering revisiting the use of DNA analysis for identification and quality control as the costs for such analysis had decreased significantly.

IV Future Publications

762 **Adding Restricted Herbs Statements to Relevant Monographs** **COM(25)24**

During the 11.6 update for a Ph.Eur. herbal monograph, the EAG Herbal and Complementary Medicines group discovered several herbal drugs which have safety restrictions in the UK.

The Commission endorsed a proposal to add statements to selected BP monographs to indicate that specific herbal materials were subject to restrictions in the UK to enhance transparency and ensure compliance with UK regulations. The added

statements would be based on the relevant statutory instruments and a government-issued list of banned or restricted ingredients.

V Analytical Issues

None.

VI Expert Advisory Groups / Working Parties / Panels of Experts

763 Membership Update (ATMP; HCM) COM(25)25

Capsid Protein Characterisation Working Party The working party for Capsid Protein Characterisation had identified the need for an additional expert with specialised knowledge of techniques.

Members endorsed Professor Michael Themis, who had extensive experience in this area, and had the support of the EAG ATMP Chair.

CRISPR Cas9 Off-target analysis Working Party At the November ATMP meeting, the scope and expertise needed for CRISPR Cas9 guidance were discussed and refined with EAG ATMP experts. A call for members had been posted across multiple platforms, resulting in several applications. After review, five candidates were proposed; however, one applicant, had not submitted the required documentation.

Members, therefore, endorsed the appointment of the four remaining members.

Expert Advisory Group HCM; Herbal and Complementary Medicines The appointment of Ms Claire Nicholson as a member for EAG HCM was endorsed by members based on her background in food safety and novel foods.

764 Expert Advisory Group MC1: Medicinal Chemicals 1 COM(25)26

The report and summary report of the EAG MC1 meeting (29:01:25) were endorsed and the following points were raised.

Diltiazem Prolonged Release Capsules It was noted that one of the MAHs had a release and shelf-life limit of 85.5% to 94.5%, which was relatively low. This had raised concerns about the product's efficacy. The Secretariat would be contacting the MAH about their low content limit.

Felodipine Prolonged Release Capsules There had been a discussion about setting Assay limits to ensure they cover a reasonable number of products. It had been noted that some licensed products had been authorised outside the BP published limits, which has been followed up with the MHRA.

It was emphasised that assessors should routinely apply BP standards.

Warfarin Tablets In response to a customer query highlighting issues with the Related Substances method, the Laboratory had rapidly investigated a revised procedure and confirmed it was fit for purpose. A Letter of Intent had been proposed to be published in advance of the proposed revision in BP 2027.

New BP paper format The MC1 group had provided positive feedback on a new format for BP papers, where individual papers were provided separately rather than as single compiled document.

765 **Expert Advisory Group MC3: Medicinal Chemicals 3** **COM(25)27**

The report and summary report of the EAG MC3 meeting (26:03:25) were endorsed and the following points were raised.

Isosorbide Preparations Two BPCRS used in Isosorbide preparations (classified as explosive substances), had been intended to be replaced by EPCRS due to shipping restrictions. However, with the procurement of alternative material, these two BPCRs would not now be withdrawn.

Naloxone Injection A critical safety issue had been identified in the monograph, which incorrectly indicated a concentration of 20 mg/mL instead of 20 µg/mL. The dosage was updated for the BP 2026 publication.

766 **Expert Advisory Group HCM: Herbal and Complementary Medicines** **COM(25)28**

The report and summary report of the EAG HCM meeting (06:02:25) were endorsed and the following points were raised.

Sustainability of Solvents The group discussed the importance of using more green solvents in the preparation of herbal materials, recognising it as a significant issue for future work.

Member Contributions The significant contributions of group members, including their laboratory expertise, were acknowledged, highlighting their commitment to supporting the Commission's work.

767 **Expert Advisory Group AIM: Anti Infective Medicines** **COM(25)29**

The report and summary report of the EAG AIM meeting (15:04:25) were endorsed and the following points were raised.

Subgroups The EAG Chair suggested using subgroups to handle complex monographs, who would report back to the main EAG. The subgroups would meet outside of the main meeting to clarify details and report back to the full EAG for approval.

Oxytetracycline Calcium A request from an MAH to broaden limits had not been accepted; batch-specific variations had been suggested instead.

VII European Pharmacopoeia

768 **European Pharmacopoeia Update** **COM(25)30**

European Pharmacopoeia Commission The 181st and 182nd session of the EP Commission had taken place in February and June, respectively. The European Pharmacopoeia had also celebrated the launch of the 12th Edition, which would be a digital-only version.

Bacterial Endotoxin Limits The proposal to change upper limits for small volume injections been rejected by the BET working party and Group 12.

Recombinant Cascade Reagents A proposal from an MAH to include recombinant cascade reagents in the endotoxin testing methodology had been positively received by the European Pharmacopoeia.

UK Work Programme Priorities The UK had shared a list of important medicines, including biologics, for consideration in future European Pharmacopoeia work.

New Leadership A new chair and two new vice chairs had been appointed to the European Pharmacopoeia Commission.

Excipient Strategy The European Pharmacopoeia had conducted a comprehensive survey to develop an excipient strategy.

The MHRA had provided a detailed response to the survey, which would influence the development of the excipient strategy.

Photos for Microscopic Identification of Dried Herbal Drugs A survey had been received by the UK NPA regarding adding photographs for microscopic identification in the digital edition (issue 12.1). The UK NPA had responded that while illustrations are generally preferred, photos would be a useful but non-essential addition.

Environmental Sustainability A new working group had been proposed and approved to support the EP Commission, with a focus on sustainability and the 3Rs (Replacement, Reduction, and Refinement of animal testing).

Potential UK Industry experts had shown interest in taking part in this kind of work before, and the BP intended to encourage that involvement.

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

VIII International Collaboration

769 **International Update** **COM(25)31**

Members were provided with an update on international activities.

World Health Organisation 80th WHO INN Consultation, 18 – 21 March Mr Evans attended the hybrid meeting of the WHO Expert Group, where over 260 INNs for new chemical and biological entities were selected. Key topics included proposals for naming combined peptides and reviewing cell and gene therapy policies.

World Health Organisation Consultation on Quality Control and Pharmacopoeial Specifications of Medicines, 8-10th April Ms Corns and Mr Waddington had participated virtually in this meeting, which focused on the development of monographs and general texts for the International Pharmacopoeia. Discussions included several monographs for anti-infective medicines. The BP

Laboratory had contributed a verification report supporting nitrogen as a carrier gas in GC tests for diethylene glycol and ethylene glycol in oral liquids.

2025 USP Convention Meeting, 5-8th May Mr Hoare had attended the USP Convention virtually. During the meeting, members voted on resolutions shaping USP's strategic direction and confirmed appointments to the board of trustees and council.

Saudi Food and Drug Authority (SFDA), 22nd May Mr Hoare and Mr Crowley had participated in a virtual meeting with representatives from the Saudi Food and Drug Authority (SFDA) to discuss the launch of a new national Saudi Pharmacopoeia.

The SFDA expressed interest in pursuing collaborative agreements to reproduce BP monographs, align work programme priorities and jointly develop content.

Future look: BP/USP Sustainability Summit, 2nd week October The BP and USP planned to co-host a sustainability-focused summit in London. The event would provide a platform for open dialogue among stakeholders representing diverse viewpoints and ideas to explore challenges, concerns, and priorities related to environmental and sustainability issues across the drug product lifecycle.

IX Any Other Business

770 **Date of next meeting**

3rd November 2025