SUMMARY MINUTES

of the

BRITISH PHARMACOPOEIA COMMISSION

A meeting of the British Pharmacopoeia Commission was held via videoconference on Monday 3rd November 2025.

Present: Dr A M Brady (*Chair*), Mr Rob Lowe (*Vice-Chair*), Dr E Amirak, Dr E Bush, Dr K L Chan, Dr J Halliday, Ms H Hall (*Lay member)*, Dr V Jaitely, Mr S Jones, Dr O Kavanagh *(joined, Minute 775)*, Prof M Lane, Dr P Marshall (*left, Minute 778*), Ms C Nicholson (*Lay member)*, Prof Y Perrie, Mr J Rickard and Prof M Simmonds.

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

Also present: Dr B Bahsoun, Ms S Bowles, Dr J Campbell (*observer*), Ms H Corns, Dr M Dmitriieva, Ms L Feather, Ms R Feltham, Mr R Smith, Dr C Swann, Mr M Whaley, and Mr S Young.

Apologies: Mr C E Giartosio.

770 **Introductory Remarks**

Welcome The Chair welcomed Dr Jonathan Campbell who was observing the meeting prior to joining the BP Secretariat, and Ms Laura Feather (a new GSE Fast Streamer).

Staff It was noted that Ms Alice Peabody (GSE fast streamer) and Ms Stephanie Elliot (MHRA Graduate) placements had ended with both rotating to new placements in September. Ms Amelia Thomson had also taken a temporary position in the Agency's Policy group. The Chair thanked them for their contributions to the BP.

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

It was noted that guidance on the handling of official sensitive committee papers had been revised to include electronic documents and the prohibition on screenshots and recordings.

Declaration of Interests The Chair reminded members that they are required 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.

BPC Membership The Chair paid tribute to Professor Simmonds whose final term of office was due to end on 31st December 2025 providing valuable herbal expertise throughout her tenure.

I MINUTES

771 The minutes and summary minutes of the meeting held on 30th June 2025 were confirmed.

II MATTERS ARISING FROM THE MINUTES

772 The following matters arising from the meeting held on 30th June 2025 were noted.

Minute 730 – Secretary and Scientific Director Update – Future Look The MHRA Chair, Prof Harnden would be attending the in-person March 2026 meeting between 3 and 4 pm.

Minute 754 – Alkyl Sulfonate Ester Impurities Following the previous meeting, the article on the alkyl sulfonate ester impurities had been uploaded to the BPC June 2025 forum for experts' information, as agreed.

Minute 759 – Membership Review Process A detailed plan for a staggered membership review process would be presented at a future meeting.

Minute 768 - Bacterial endotoxins The group was updated that due to staff availability, the BET working group meeting had been rescheduled and would be meeting in the New Year in time for the next BPC meeting.

III REPORTS AND CORRESPONDENCE

GOVERNANCE

773 **Update from Secretary & Scientific Director**

Mr Crowley provided an update, noting that Mr Hoare had taken a temporary position in Partnerships from August but was returning to his role as Secretariat & Scientific Director shortly.

OPERATIONAL

774 **Policy Proposal for Hosting Observers in BP Meetings** **COM(25)32**

The draft policy for observers had been updated following previous meeting comments.

775 **Digital Therapeutics** **COM(25)33**

MHRA Activities The Secretariat reported that Digital Therapeutics was a rapidly evolving field and now broadly referred to digital wellness tools, not only medical-grade software. The MHRA referenced two regulated categories: Software as a Medical Device (SaMD) and Artificial Intelligence as a Medical Device (AIaMD). Digital therapeutics resided outside of these more regulated areas, though overlaps existed. Members were updated on legislative updates and guidance being developed by the MHRA including major initiatives such as the AI Airlock and Centres of Excellence for Regulation (CERSIs) that improved the regulatory framework for SaMD / AIaMD and directly impact DTx products. Guidance documents that the MHRA had published to support legal changes to the regulations on digital therapies, were highlighted.

USP Activities The Commission was informed that the United States Pharmacopeia (USP) referenced digital tools for quality assurance in its 2030 strategy summary but did not specifically mention digital therapeutics. It was noted that the US FDA had operated an active pre-certification programme for digital therapeutics and had introduced additional relevant legislation.

European Activities The Commission was advised that the European Pharmacopoeia and related European activities did not currently have specific legal regulation on digital therapeutics. Germany had implemented a Digital Healthcare Act and France was moving towards similar implementation. The EU has a regulation on clinical investigation and sale of medical devices for human use, but this does not specifically address digital therapeutics. The British Standards Institution and the FDA had published relevant standards and guidance, but these were not specific to digital therapeutics.

Due to the vast amounts of guidance and wider initiatives being progressed in this area, the Secretariat recommended there was no current demand for BP involvement. The Commission agreed with the recommendation not to introduce BP standards for digital therapeutics at this time.

The Commission acknowledged the complexity of standardising software and confirmed that digital therapeutics and related AI topics could be included in the BP's regular horizon scanning updates, as appropriate new developments arose, or if BP involvement became necessary.

776 **EAG ATMP: Progress Report** **COM(25)34**

Conversion of Working Party to Expert Advisory Group The Commission was reminded that Working Party ATMP had been converted into an Expert Advisory Group following confirmation at the March 2025 meeting of Commission, with working parties established underneath this to progress specific guidance. The EAG ATMP membership included original working party members as well as representatives from each active working party.

Upcoming publications The Replication Competent Virus (RCV) Testing Guidance had been published alongside the BP 12.1 update. Further guidance documents were expected to be published.

CRISPR A new Working Party on CRISPR Cas9 Off-target Analysis had been established following earlier discussions in 2024 together with a review of its scope. Recruitment of industry experts had strengthened the group's capability and development work was ongoing.

Encapsidated DNA Characterisation and Capsid Protein Characterisation Further guidance documents for public consultation were expected to be published.

Concluding remarks The Commission was presented with a project plan and horizon scanning activities specific to ATMPs.

The Commission was informed that the published ATMP guidance had been downloaded by users in 68 countries, with over 1,500 unique downloads recorded, and that usage data would continue to be monitored. ATMP guidance was currently available to download for free.

777 **Publication Update** **COM(25)35**

BP 2026 Webinar
A webinar marking the publication of the BP 2026 had been held in July. The event attracted 700 registrants, 305 attendees and over 134 questions, which represented a significant increase in engagement from the previous year.

A second webinar was held in September for non-users with presentations on pricing and product availability. Recordings of both webinars were made available on the BP website.

OKO Survey Results 2025 The Commission was updated on the OKO survey, which had achieved its highest response rate to date.

778 **British Pharmacopoeia Laboratory** **COM(25)36**

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

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

LGC Laboratory Move The laboratory had successfully relocated to the new Surrey Research Park in Guildford, which had been marked with an official opening event.

IV Future Publications

779 **BP Work Programme Scoring Framework** **COM(25)37**

At the March 2025 meeting, members approved the scoring framework proposals, and 2024 usage data had been used received and applied to ~2500 drug substances and drug substance combinations to provide a criticality score.

The scoring framework had been introduced to modernise how the BP identified, prioritized and managed the work programme. Historically, new monographs have been initiated using usage data. Ms Corns explained that the new framework was structured so that individual expert advisory groups can prioritise review or revision order. There were three areas of activity that this would support: 1) identifying and prioritizing a need for new drug substance monograph development; 2) identifying and prioritizing a need for new drug product monographs and 3) identifying and prioritizing a need for the revision of existing monographs and additional new monographs. The scoring framework also aligned with patient importance and UK usage data which ensured public health relevance.

Scoring Framework rollout
The framework would guide three main activities: to prioritise new drug substance monographs, new drug product monographs and revisions to existing monographs. Scores would inform submission of drug substances to the EDQM work programme and decisions on BP monograph development especially for biological medicines.

Expert advisory groups would begin working through the lists in priority order, subject to work already in progress. There is flexibility for lower-priority items to be taken forward, providing a more nuanced approach to monograph development.

Reporting and re-scoring
The new scoring system replaces usage volume as the main driver for initiating monographs. The BP would update internal processes, procedures and Supplementary Chapter 3B which outlined the BP's criteria on monographs.

Members endorsed the rollout of the scoring framework.

V Analytical Issues

780 **Aide-Memoire, Style Guide and Policy List: Development of a BP Technical Guide** **COM(25)38**

The Commission was informed about the development of a BP Technical Guide, which would consolidate the Aide-Memoire, Style Guide, and Policy List into a single resource.

VI Expert Advisory Groups / Working Parties / Panels of Experts

781 **Expert Advisory Group AIM: Anti Infective Medicines** **COM(25)39**

The report and summary report of the EAG AIM meeting (24:09:25) were endorsed and the following points were raised.

The resignation of a long-standing member, Professor John Miller, was acknowledged, with appreciation expressed for his contributions.

Matters Arising – Minute 634 - Oxytetracycline Calcium There were compliance challenges with the monograph for oxytetracycline calcium, which was used in one UK marketed product only. It was reported that batch-specific variations were being used to manage the issue, and that further action would depend on discussions with the marketing authorisation holder.

782 **Expert Advisory Group ULM: Unlicensed Medicines** **COM(25)40**

The report and summary report of the EAG ULM meeting (28:05:25) were endorsed and the following points were raised.

Minute 694 - Work programme It had been difficult to complete items on the work programme for various reasons and it had been agreed trying to prioritise the 56 items was difficult and the group would be looking at how to prioritise these, especially for vulnerable populations where usage was not high but the need for a monograph was high. Members would be liaising with other expert groups to support prioritisation.

Minute 694 - Excipient Labelling The practical difficulties of excipient labelling on small containers was discussed and potential exemptions. There are exemptions for certain presentations with discussions with inspectors who would be consulting further to clarify expectations to balance regulatory requirements with practicalities.

Minute 694 - 3D Printed Tablets The group explored this topic as a potential alternative to oral solutions, particularly for paediatric and geriatric populations. A draft Supplementary Chapter in the BP had been proposed.

Minute 696 – Paediatric Formulary Working Party The group discussed the benefits of reviewing and commenting on paediatric monographs from the EDQM Paediatric Formulary WP.

783 **Panel RAD: Radiopharmaceuticals** **COM(25)41**

The report and summary report of the Panel RAD meeting (01:05:25) were endorsed.

VII European Pharmacopoeia

784 **European Pharmacopoeia Update** **COM(25)42**

European Pharmacopoeia Commission The 182nd session of the EPC was held on 17th and 18th June 2025 and was attended in-person by the Chair, Vice-Chair and Mr Hoare.

European Pharmacopoeia Membership Review – 2025 As part of the 2025 European Pharmacopoeia membership review, an evaluation of UK expert representation across EDQM working groups had been undertaken.

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

VIII International Collaboration

785 **International Update** **COM(25)43**

Members were provided with an update on international activities.

United States Pharmacopoeia Prospective Harmonisation Meeting, 11 September
The USP and BP held an online meeting to discuss the harmonization of a potential monograph candidate.

International Laboratory Forum on Falsified Medicines, 23rd – 26th September
This meeting, hosted by the UN International Narcotics Control Board in Vienna, was attended by Mr Young and other regulatory authorities. Key topics discussed included the growing prevalence of GLP-1 products, new risks from vaping products, and adulterated herbal food supplements.

BP and USP Joint Environmental Sustainability Summit, 7th October
The summit was attended by members of the BP and the USP and focused on sharing insights into environmental sustainability.

Midwest Compendial Discussion Group User Forum, 14th-15th October

At this meeting, BP and USP sustainability activities were discussed including the BP's sustainability pack, initiatives by an instrument manufacturer and the importance of emphasising this topic to future scientists.

BP webinar World Standards Day, 16th October The BP and Merck/Sigma-Aldrich co-hosted a short webinar which Mr Young and Dr Swann attended. An overview of the BP and development of reference standards was given including how compendial standards added value to pharmaceutical testing.

World Health Organisation INN Consultation, 13-17 October 2025 Mr Evans chaired the hybrid meeting on small molecule chemical applications, which included progressing applications covering five new therapeutic areas.

World Health Organisation Expert Committee on Specifications for Pharmaceutical Preparations, 20-23 October 2025
Ms Corns attended the meeting virtually. The meeting reviewed guidelines for pharmaceutical preparations and discussed WHO initiatives on high-risk excipients, paediatric formulations, and continuous manufacturing.

Future Look - World Health Organisation 16th International Meeting of the World Pharmacopoeias, Brazillia, 15 – 17th June 2026 The meeting dates of 15 – 17th June were provisional and still in the early planning stages. The meeting would review progress of ongoing projects and identify new areas for collaboration.

IX Any Other Business

786 **BP 2027 – DRT Review Dates 2026** **COM(25)44**

The dates for reviewing the BP 2027 and BP (Vet) 2027 text using the document review tool (DRT) were provided for information.

Date of next meeting

2nd March 2026