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 1st July 2024.

Present: Dr A M Brady (*Chair*), Dr E Amirak, Dr E Bush, Dr K. L Chan, Mr C E Giartosio, Mrs H Hall (Lay member), Dr J Halliday, Dr V Jaitely, Mr S Jones, Dr O Kavanagh, Dr M Lane, Mr R Lowe (*Vice-Chair*), Dr P Marshall, Ms C Nicholson (Lay member), Professor Y Perrie (*absent for items discussed under minutes 685 to 700*), Mr J Rickard, Professor M Simmonds (*attended the meeting from minute 680.3*).

In Attendance: Mr S Hoare (Secretary and Scientific Director), Mr P Crowley, Dr C Swann, Mr K Rakowski.

Also present: Ms S Begum, Ms S Bowles, Ms H Corns, Dr M Dmitriieva, Ms G Li-Ship, Mr R Smith, Ms S Song, Dr D Tong, Mr O Waddington, Mr M Whaley, and Mr S Young.

680 **Introductory Remarks**

Welcome The Chair welcomed members to the meeting and extended her welcome to new Commission members. The appointments of three members had lapsed and were appointed as co-opted "Members for the Day".

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 specific interests at the start of relevant discussions. Any changes to interests throughout the year should be sent to committeeservicesteam@mhra.gov.uk.

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

681 The minutes of the meeting held on 4th March 2024 were accepted, subject to minor editorial comments.

II MATTERS ARISING FROM THE MINUTES

682 The following matters arising from the meeting held on 4th March 2024 were noted.

Minute 656 – Alkyl Sulfonate Ester Impurities The European Pharmacopeia Commission had considered the UK Delegation's request to treat alkyl sulfonate impurities in the same way as nitrosamine impurities, via the general monographs. This was not supported by other delegations and the production statements would remain in the individual monographs for mesilate salts.

Minute 656 – Branded vs Generic Products EAG PCN members at their September 2023 meeting had agreed that no further action would be taken. The outcome was pending from the Safety and Surveillance group investigation.

Minute 656 – Observer discussions The Secretariat would develop a policy on stakeholders observing Commission meetings, the outcome of which would be brought to a future meeting.

Minute 658 – BP Ways of Working The Secretariat was to set a suitable date for a workshop with the BP Commission on BP Ways of Working.

Minute 659 – Sustainability The sustainability information pack had been published on the BP website in March with the Secretariat to explore the interchangeability of carrier gases used in GC analysis.

Minute 662 – Microbiome and Bacteriophage content The Secretariat had relayed to the Commission's comments on the guidance to the Standards Research and Innovation group.

Minute 663 – Horizon Scanning The Secretariat considered members' comments and agreed to bring a horizon scanning process to a future meeting.

Minute 668 - Aide Memoire Secretariat to consider the draft wording to the policy document with input from Commission members.

Minute 669 – Falsified medicines proposal The Secretariat would consult within the Agency and report back to a future meeting.

Minute 670 – Bacterial Endotoxin Update The Secretariat had discussed the request for revision for high endotoxin limits with representatives from the Ph. Eur. BET expert group and Group 12 and had been invited to present on the issue at a future meeting of CHMs Chemistry, Pharmacy and Standards committee.

A member raised a query from a user about the European Pharmacopoeia method 2.6.14 on endotoxin testing, noting that the endotoxin tolerance standard be harmonised across these product types.

The request, along with input from representatives of the Ph. Eur. BET expert group and Group 12, as well as confirmation of the approach taken by MHRA assessors would be discussed further at a future BPC meeting.

III REPORTS AND CORRESPONDENCE

GOVERNANCE

683 **Update from the Secretary & Scientific Director**

Mr Hoare provided members with an update on key activities for the MHRA.

OPERATIONAL

684 **British Pharmacopoeia Commission: Membership** COM(24)18

BPC Appointments A review of the membership appointments had been conducted through the DHSC Public Appointments Unit. A total of seven new members (five technical experts and two lay members) were appointed to the British Pharmacopoeia Commission, effective from the 3rd June 2024, for a four year term.

Reappointments The reappointments for three BP Commissioners whose four-year terms ended on the 21st June were delayed due to the pre-election period and will be processed by the DHSC after the July election. The three Commissioners attended the BPC meeting as co-opted "Members for the Day", and fully participated in discussions and decisions.

Annual report The chair requested all members to check the record of their nominal titles and qualifications which were included in the Annual Report of the BP Commission.

685 **BP Strategy** COM(24)19

Mr Hoare provided an update on the development of the strategy for the British Pharmacopoeia and Laboratory Services.

686 **British Pharmacopoeia Laboratory** COM(24)20

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

British Pharmacopoeia Chemical Reference Substances Tables providing information on BPCRS up to the end of May 2024 were provided for information.

IV FUTURE PUBLICATIONS

687 **BP Website Redevelopment** COM(24)21

An update of the new functions such as a feedback button accessible on every page and a live webchat to assist users with website support purchasing queries, and handling complaints were highlighted to members.

Several functionalities, including a "Stay Connected" tool, BP Dashboard, and tiered access, were set for release by the end of July. Members were informed about the Accounts Per User (APU) system, which required individual accounts for all users, including those with multi-user licenses.. An invoice buying system for publications was scheduled for release by September, aimed at simplifying purchases without requiring card access.

The continuous improvement plans developed by TSO for the next year were under review. A customer survey was planned to gather user insights, and members were asked to participate in interviews and share the survey with their networks.

V ANALYTICAL ISSUES

688 **Use of Multi-Attribute Method (MAM) by Mass Spectrometry as a QC Release and Stability Tool** COM(24)22

An approach to Multi-Attribute Method (MAM) by LC-MS peptide mapping was discussed and members were briefed on the key advantages of the method, which included the capacity to identify new peaks in biologics - crucial for detecting deviations from expected profiles post-cell line expression, thus ensuring safety and efficacy.

689 **Revision of ICH Q1 family of guidelines and ICH Q6A/6B update** COM(24)23

Members were made aware of the initiatives undertaken to revise the existing ICH Q1A-F/Q5C and Q6A/Q6B. The guidelines were being streamlined for a harmonised interpretation with the aim to address potential gaps and add new areas like ATMPs and accelerated stability assessment protocols. The members discussed the potential impact of this revision on the work and elaboration of monographs by the British Pharmacopoeia. The guidelines were in the consensus-building stage among working groups. The final draft for revised Q1A-F and Q5C was planned to be completed by Q4 2025.

It was noted that the MHRA has not been directly involved in the revision of ICH Q1 guidelines but has in Q6. A Commission member, who is involved in the Q1 revision work, committed to keeping the BPC updated on the progress.

690 **WP ATMP Update: Initiating CRISPR Guidance** COM(24)24

Members were provided with an overview of a funded project being initiated by teams at the MHRA's Science Campus at South Mimms.

It was proposed that a new subgroup would be established through the ATMP Working Party to support development of the CRISPR guidance project, particularly the review and approval of guidance materials it generates, for which members were supportive.

VI EXPERT ADVISORY GROUPS / PANELS OF EXPERTS

691 **EAG BIO and WP ATMP: Membership appointment** COM(24)25

A notice had been posted on several platforms including social media and on the BP website inviting individuals with an interest in joining one or more of the WP ATMP subgroups to submit a written expression of interest and a CV.

Several expressions of interests were received and following a review by the Secretariat and working party Chair, six new members were proposed for the "Encapsidated DNA characterisation" subgroup, and four new members are proposed for the "Primary protein sequence modifications of encapsidated DNA" subgroup.

Additionally, since the November 2023 meeting, one individual was identified by the EAG BIO Chair as a suitable expert to the EAG.

All proposed appointments for EAG BIO and WP ATMP were confirmed by Commission members.

692 **Expert Advisory Group AIM Anti infective Medicines** COM(24)26

The report and summary report of the EAG AIM meeting (15:04:24) was endorsed and the following point was raised.

Testing of Reconstituted Antibiotics A paper was planned to be prepared by the Secretariat for the BPC November 2024 meeting.

693 **Expert Advisory Group HCM: Herbal and Complementary Medicines** COM (24)27

The report and summary report of the EAG HCM meeting (29:11:23) was endorsed.

694 **Expert Advisory Group MC1: Medicinal Chemicals 1** COM (24)28

The report and summary report of the EAG MC1 meeting (31:01:24) was endorsed.

695 **Expert Advisory Group MC3: Medicinal Chemicals 3** COM (24)29

The report and summary report of the EAG MC3 meeting (29:02:24) was endorsed.

696 **Expert Advisory Group PCN: Pharmacy and Nomenclature** COM(24)30

The report and summary report of the EAG PCN meeting (12:03:24) was endorsed.

VII EUROPEAN PHARMACOPOEIA

697 **European Pharmacopoeia Update** COM(24)31

European Pharmacopoeia Commission The 178th and 179th session of the EP Commission had taken place in March and June respectively. The European Pharmacopoeia had also celebrated its 60th anniversary with an event in June and was attended by BP Commission Chair.

UK Membership of expert groups of the European Pharmacopoeia Commission A list of new experts and their corresponding groups of the EPC was presented to the BP Commission.

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

698 **International Update** COM(24)32

Members were provided with an update on international activities.

United States Pharmacopeia There was ongoing dialogue between the BP and the USP on several areas of mutual interest, including: Collaborative Monograph Development, International Meeting of World Pharmacopoeias, and ICH Developments.

In addition to regular monthly calls, a face to face bilateral between the BP and USP management was planned for early October in London. Further to collaborative projects

and updates, the meeting would also serve as an opportunity to discuss a new Memorandum of Understanding between the BP and USP.

World Health Organisation 78th WHO INN Consultation, 19 – 22 March Mr Evans had attended the hybrid meeting of the WHO Expert Group in person. The meeting named over 260 new chemical/biological entities, including many new ATMP drugs that showed the increasing research in this area.

World Health Organisation Consultation on Quality Control and Pharmacopoeial Specifications of Medicines, 2 – 3 May Ms Dmitriieva attended the meeting virtually which was focussed on the development of monograph and general text for the International Pharmacopoeia. Of note was the initiation of a project to develop screening procedures for falsified products. Also, a general chapter for diethylene glycol and ethylene glycol testing in liquid preparations for oral use to include in the Int. Ph., consisting of the screening procedure for non-compliance by TLC method as well as the confirmation procedure by GC method, was presented, discussed, and recommended for inclusion.

World Health Organisation 15th International Meeting of the World Pharmacopoeias Mr Hoare and Mr Crowley had virtually attended a preparatory meeting for the 15th International Meeting of the World Pharmacopoeia, to be hosted by the Indian Pharmacopoeia Commission in New Delhi in February. In addition to a regular update from PDG, this meeting would seek agreement of a Charter for the IMWP as well as a set of sustainability principles. A discussion of ICH Q6 and its implications for setting specifications for pharmacopoeial monographs was also expected.

EDQM 60th Anniversary Symposium and events 11-12th June, Strasbourg The UK delegation was represented by the Chair of the BP Commission. The EDQM President was presented with a congratulatory card from the Agency.

IX ANY OTHER BUSINESS

699 A member informed everyone that Group 12 was developing a monograph for water activity and seeking volunteers with the right expertise. It was noted that the USP already contains such a monograph and members asked for access to the USP, if possible. Another member expressed their interest to support and contact colleagues at the Food Standards Agency to aid with the monograph development.

700 **Date of next meeting**

Monday 4th November 2024.

FOR INFORMATION:

701 **Actions Log**
A list of actions from previous meetings of the Commission was provided for information.

702 **Items for Future Meetings**

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