SUMMARY MINUTES

of the

BRITISH PHARMACOPOEIA COMMISSION

A meeting of the British Pharmacopoeia Commission was held via videoconference on Monday 4th March 2024.

Members Present: Dr A M Brady (*Chair*), Dr E Amirak, Mr C E Giartosio, Dr V Jaitely (*absent for items discussed under minutes 661 to 662*), Mr S Jones, Mr R Lowe (*Vice-Chair*), Dr P Marshall, and Mr J Rickard.

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

Also present: Dr B Bahsoun, 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.

Ms M Guler and Mr J Alam (Committee Services, MHRA) also attended the meeting.

An apology for absences were received from Dr E Bush and Professor M Simmonds.

654 **Introductory Remarks**

Welcome The Chair welcomed members to the meeting. She also welcomed Mr Oliver Waddington who had recently joined the BP & Laboratory Services team.

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.

BPC Membership The Chair informed members that there had been a delay with the onboarding of new Commission members due to ongoing security checks. The full complement of BPC members would be achieved at the July in-person meeting.

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

655 The minutes and summary minutes of the meeting held on 6th November 2023 were reviewed and approved.

II MATTERS ARISING FROM THE MINUTES

656 The following matters arising from the meeting held on 6th November 2023 were noted.

Minute 631.3 – Extractable Volume of Parenteral Preparations A proposal for developing pharmacopeial comparison documents raised at the International Meeting of World Pharmacopoeias in November was not supported.

Minute 631.4 – Branded vs Generic Products Data was shared with the Safety and Surveillance group for investigation, the outcome of which would be considered by EAG PCN at a future meeting.

Minute 631.5 – Alkyl Sulfonate Ester Impurities The Secretariat had replied to a further request for information relating to the BP review of production statements for mesilate-salt products.

Minute 649 – Observer discussions The Secretariat was to consider developing a policy on stakeholders observing Commission meetings, the outcome of which would be brought to a future meeting.

III REPORTS AND CORRESPONDENCE

GOVERNANCE

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

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

658 **BP Ways of Working update** COM(24)1

Mr Hoare provided an update on the BP ways of working since the last meeting in November.

OPERATIONAL

659 **Sustainability Project: Update** COM(24)2

A progress report on the BP sustainability project since the last update at the November 2023 meeting (minute 636 refers) was presented.

Sustainability Guidance The BP had developed an environmental sustainability information pack aimed at promoting more sustainable practices among users. The completed pack would be available for download from the

"Environmental hub" on the BP website, scheduled for publication later in March.

Sustainability in Monographs The BP laboratory was continuing to find ways to bring in sustainability to the monograph elaboration and revision process by scaling down column sizes leading to a reduction in solvent use through adjustments of chromatographic conditions specified in Appendix III, Chromatographic Separation Techniques.

Monographs for Solifenacin Oral Solution and Oral Suspension would be published in BP 2025 using original validated parameters. The scaled Assay procedure would be available online under the monographs more resources tab.

660 **BP Laboratory** COM(24)3

British Pharmacopoeia Laboratory Reports The list of reports concerning new and revised monographs that had been prepared by the Laboratory since the November 2023 meeting was provided for information.

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

661 **Working Party ATMP: Progress Report** COM(24)4

Since the last update in November, the Characterisation of Capsid Particle Population for rAAV Products guidance had been published on the new BP website and the T Cell and NK Cell Characterisation Assay guidance would be released in March 2024.

The WP-ATMP subgroups for both RCV and PCR had prepared draft guidance documents for consultation by June 2024. The guidance would be available for review by the Commission after public feedback.

In February 2024, a new subgroup focusing on encapsidated DNA characterisation and post-translational modifications had been established.

662 **Microbiome and Bacteriophage content** COM(24)5

Members were presented with two non-mandatory guidance documents for microbe based medicinal products and non-binding bacteriophages which had been developed by staff from the Agency Standards Research and Innovation (SRI).

663 **Horizon Scanning** COM(24)6

Ms Corns outlined the intention to build a horizon scanning process for the BP & Labs group, aimed at informing strategic decisions and prioritisation. Members were invited to contribute ideas and experience to shape the

development of the process. Members discussed the importance of alignment with the Agency's established Horizon Scanning Working Group. It was noted that a horizon scanning process needed to be well resourced and documented to be an effective tool. Suggestions included a regular agenda item in BPC and EAG meetings, investigating horizon scanning processes of other Agency committees and in the wider health system and creating a model to prioritise initiatives.

IV FUTURE PUBLICATIONS

664 **British Pharmacopeia 2025 Publications** COM(24)7

BP 2025 The Secretariat was currently preparing text for inclusion in the British Pharmacopoeia 2025 and British Pharmacopoeia (Veterinary) 2025. All items from the 11th edition of the European Pharmacopoeia, along with those from Supplements 11.1 to 11.5, would be incorporated into either the BP 2025 or the BP (Vet) 2025 as appropriate. The 2025 publication would be published in August 2024 and would come into effect on 1st January 2025.

Electronic updates The text from Supplements 11.3 and 11.4 of the European Pharmacopoeia had been added to the online BP 2024 in November and December 2023 respectively. Text from Supplement 11.5 would be added in advance of its implementation on 1st July 2024.

Text for approval The first batch of new and revised text for inclusion in the BP 2025 and BP (Vet) 2025 publications had been reviewed by members in February. The second and final batch of text for Commission approval would be available for comment on the Document Review Tool (DRT) between 22nd March and 7th April.

Preliminaries Members recommended that the British Pharmacopoeia 2025 and the British Pharmacopoeia (Veterinary) 2025 should be published and confirmed that the draft Prefaces to both publications were acceptable.

Ph. Eur. 11th Edition and Supplements 11.3, 11.4, and 11.5 The Commission reviewed a list of monographs documented in the European Pharmacopoeia for the first time in Supplements 11.3, 11.4, and 11.5, along with title changes implemented in these supplements. Eleven items required approved synonyms and were approved.

665 **Monographs for Omission from the BP 2025 and BP (Vet) 2025** COM(24)8

Since the publication of the BP 2024, several monographs had been identified as candidates for omission from the BP 2025 as the items were no longer subject of UK Marketing Authorisations. The Secretariat had contacted countries that included the BP in their legislation and/or where the BP was widely used to ascertain if there was any international usage of these items. The list was also sent to the EAG on Unlicensed Medicines (ULM) to check if any of the items were available as unlicensed formulations.

In view of the continues use of Meglumine Iodipamide Injection and Oxetacaine, it was agreed that these monographs should be retained in the BP 2024.

The list of proposed omissions from the BP 2025 was endorsed, subject to the removal of the two monographs noted above.

666 **British Approved Names 2025** COM(24)9

New BAN The new Supplement to British Approved Names 2022 containing 23 new names had been prepared with an effective date of 1st January 2025. The text had been agreed by the EAG Pharmacy and Nomenclature and sent to manufacturers for comments.

Hardcopy format The Secretariat reported the successful launch of the new online format for the British Approved Name (BAN) publication. Due to declining use of the hardcopy and positive feedback on the online version, the Commission approved discontinuing hardcopy BAN publications and endorsed publishing the draft Supplement content alongside BP 2024.

667 **BP Website Redevelopment** COM(24)10

As part of the new publication contract the current BP website was being redeveloped by The Stationery Office (TSO).

668 **Aide Memoire Update** COM(24)11

The aide memoire had been updated to reflect changes and issues that had been discussed since the last version had been issued in December 2021, together with several additional changes for clarity. A copy of the draft revised document was provided, and the major changes had been highlighted for the benefit of members. The updated text was accepted, subject to minor editorial points.

669 **Proposal to Develop Guidance on Practical Aspects of Detecting Falsified Medicines** COM(24)12

Members discussed the dangers of falsified medicines noting the lack of practical guidance available for end users to handle these counterfeit drugs.

670 **Bacterial Endotoxin Update** COM(24)13

An update related to Bacterial Endotoxin limits was presented.

V ANALYTICAL ISSUES

None.

VI EXPERT ADVISORY GROUPS / PANELS OF EXPERTS

671 **Expert Advisory Group MC2: Medicinal Chemicals** COM(24)14

The report and summary report of the EAG MC2 meeting (held in two parts on 16:11:23 and 21:11:26) was endorsed and the following points were raised.

Solifenacin preparations Members were reminded that a sustainable Assay with reduced mobile phase consumption and run time had shown acceptable results (minute 659 refers). This method would be made available as an example for monograph users in the "more resources" area on the BP website.

Donepezil preparations It was brought to the Commission that a review of approved dissolution rate specifications for several tablet and members agreed that a revised limit of not less than 75% (Q) in 30 minutes was acceptable, pending stakeholder comments.

672 **Working Party BIO-DPS: Alternative Approaches for Documentary and Physical Standards for Biotechnological Products.** COM(24)15

The report and summary report of the WP DPS meeting (27:11:23) was endorsed and the following points was raised.

The Chair noted that the meeting was a review of progress to date including the statistics from the round-robin study. Next steps were to investigate linking to other related data sets as well as options to publicise the work prior to WP DPS making recommendations to a future BPC meeting.

673 **Working Party ATMP: Advanced Therapy Medicinal Products 6th Meeting** COM(24)16

The report and summary report of the WP ATMP meeting (07:12:23) was endorsed and the following points were raised.

Characterisation of the capsid particle population for rAAV products Members were briefed on the restructuring of the guidance, which involved restructuring the main body of the text by virus type.

dPCR and qPCR validation protocols and reports for VCN Members were updated on the PCR guidance, highlighting ongoing revisions that included adjustments to the effective copy number guidance. Furthermore, the subgroup was in the process of revising the published VCN guidance to expand and improve PCR-related sections.

VII EUROPEAN PHARMACOPOEIA

674 **European Pharmacopoeia Update** COM(24)17

European Pharmacopoeia Commission Members discussed items from the 177th Session of the EP Commission.

UK Membership of expert groups of the European Pharmacopoeia Commission Members were informed of several experts who had been nominated to represent the UK on five expert groups of the European Pharmacopoeia 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

675 **International Update**

Members were provided with an oral update on international activities.

International Meeting of the World Pharmacopoeias At the November 2023 meeting in Mexico City, the BP had committed to leading the creation of a charter or terms of reference for the International Meeting of World Pharmacopeia (IMWP) to clarify the scope, output, and framework. The BP also committed to supporting the development a set of environmental sustainability principles.

IX ANY OTHER BUSINESS

676 **Annual Appraisal Reminder**

The Chair reminded members that the annual appraisal period was approaching.

677 **Date of next meeting**

1st July 2024 in person at Canary Wharf.

FOR INFORMATION:

678 **Actions Log**

Previous list of actions was provided to Commission for information.

679 **Items for Future Meetings**

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