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 6th March 2023.

Present: Dr A M Brady, (*Chair*), Dr E Amirak, Dr A Barnes, Mr C E Giartosio, Dr A Gleadle (*lay member*), Dr V Jaitely (*attended remotely*), Mr S Jones, Dr P Marshall, Ms S Palser (*lay member*), Mr J Rickard, Professor M Simmonds (*attended remotely*).

In attendance: Mr J Pound (*Secretary & Scientific Director*), Dr F J Swanson.

Also present: Ms S Begum, Ms H Corns, Mr P Crowley, Dr M Dmitriieva, Ms A Estlin, Mr A Evans, Ms G Li-Ship, Mr K Rakowski, Mr R Smith, Mr D Tong, Mr M Whaley and Mr S Young.

Mr S Hoare attended the meeting as an observer.

Apologies for absence were received from Mr R Lowe (*Vice-Chair*) and Dr E Bush.

583 **Introductory Remarks**

Welcome The Chair welcomed members to the first in-person meeting of the British Pharmacopoeia Commission since November 2019. She also welcomed Dr Dmitriieva and Mr Tong, who had recently joined the BP & Laboratory Services team, and Mr Hoare who was attending the meeting as an observer.

BP/MHRA Staff Mr Pound informed members that Mr Steve Hoare would be taking up the role of Head of Standards and Regulatory Governance (which incorporated the role of Secretary & Scientific Director of the British Pharmacopoeia Commission) on 21st March. Mr Crowley had recently been promoted to the position of Head of BP and Labs (which incorporated the role of Editor-in-Chief).

Dr Brady thanked Mr Pound on behalf of the Commission for all his work with the BP over the years and highlighted the good relationship he had built up with the EDQM and his efforts to modernise 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.

Declaration of Interests Members were **r**eminded of the need to declare any specific interests at the start of relevant discussions. The annual declaration form had been circulated and this should be completed and returned by 10th March 2023.

BPC Membership Members were pleased to note that the terms of office for Mr Robert Lowe and Professor Monique Simmonds had been extended until 31st December 2023. Mr Lowe had taken on the role of Vice-Chair of the BP Commission with effect from 1st January 2023. He had also been appointed as a member of the UK delegation to the European Pharmacopoeia Commission and would be attending the 175th EPC Session.

BPC Appraisals Members were reminded that they were required to participate in the annual appraisal process which was due to be completed by the end of May.

Obituaries Members were saddened to learn of the death of Professor Sir Michael Rawlins, former Chair of the MHRA (2014 to 2020). Sir Michael had a long association with the MHRA, having served as the Chair of the Committee on the Safety of Medicines between 1992 and 1998.

I MINUTES

584 The minutes of the meeting held on 7th November 2022 were confirmed, subject to the following editiorial correction.

Minute 566 – Alkylsulfonate Ester Impurities; Next steps Third paragraph. For "Option 2 proposed …" read "The second option proposed …".

II MATTERS ARISING FROM THE MINUTES

585 The following matters arising from the meeting held on 7th November 2022 were noted.

Minute 564 – Combined Code of Practice on Interests The previously prepared guidance notes and examples of interests relevant to the Chair and members of the British Pharmacopoeia Commission and the Expert Advisory Groups had been updated to refer to the new MHRA Code of Practice on Identifying, Declaring and Managing Interests.

Minute 566 – Alkylsulfonate Ester Impurities The Secretariat had approached named individuals to seek their views regarding the continued inclusion of the Production statements in BP monographs. Feedback would be provided at a future meeting.

Minute 567 – Pyrogen/Bacterial endotoxin Testing Policy Further comments had been considered by the Expert Advisory Group on Biological and Biotechnological Products and several options were being considered.

Minute 573 – Panel of Experts MIC: Microbiology Dr Miriam Guest had accepted the invitation to join Panel MIC.

Minute 576 – EAG ABS Minutes; Ciclosporin Eye Ointment As the formulation was only licensed for veterinary use, it had been agreed that the monograph should be included in a future edition of the British Pharmacopoeia (Veterinary).

III REPORTS AND CORRESPONDENCE

GOVERNANCE

586 **Updates from the Secretary & Scientific Director**

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

587 **BPC Policies and Procedures** COM(23)1

The Policy and Guidance list presented at the last meeting had been updated to reflect the feedback received from members. It was agreed that the Secretariat should update the list as required throughout the year and that an updated version should be provided to members once a year.

Dissolution limits A member had raised some concerns around dissolution limits, specifically relating to BCS Class I drugs, defined as “high solubility and high permeability” under the Biopharmaceutics Classification System.

It was acknowledged that there were instances where the BP limits were lower than registered limits, but this was due to the fact that BP monographs were applicable to all relevant formulations on the market whereas a registered specification only applied to a particular product.

It was agreed that clear guidelines for setting BP dissolution limits should be established and included in the Aide Memoire and/or Policy List as appropriate.

OPERATIONAL

588 **Analytical Quality by Design** COM(23)2

Atorvastatin Tablets The Assay for Atorvastatin Tablets had been developed using Analytical Quality by Design (AQbD) concepts. Additional information relating to the ranges for sample preparation, chromatographic parameters and method performance had been included on the “More Resources” tab on the website which provided users with information that would help them to understand the sensitivities of the procedure.

ICH Guidelines In collaboration with MHRA pharmaceutical assessors and inspectors the BP had reviewed, and provided comments on, recent ICH guidance documents.

589 **Sustainability Project** COM(23)3

Ms Estlin provided an update on the work carried out to date as part of the fast stream project on reducing the environmental impact of the British Pharmacopoeia. This work supported the wider goals of the MHRA as it moved towards embedding sustainability and reducing carbon emissions throughout its work. The two main aims of the project were (1) to reduce the environmental impacts associated with the BP operations and products in line with MHRA net zero ambitions and (2) to consider how to use the position of the BP to enable the sector to become more sustainable.

Workshop Recommendations A workshop had been held on 2nd March with attendees including members of industry bodies and analytical chemistry and sustainability experts. The aims of the workshop had been to seek views on whether there would be value in the BP developing guidance on sustainability, what any such guidance should cover and how best the BP could work with industry to develop the guidance.

While there had been strong support for the BP to develop guidance on sustainability the need to consider current national and international green initiatives had been highlighted, together with the need to address both chemical and biological medicines. The attendees had indicated their willingness to help in the development of any future guidance and members would be kept informed of developments.

590 **Extractable Volume of Parenteral Preparations** COM(23)4

A member had prepared a paper on Extractable Volume of Parenteral Preparations. The document had been prepared to provide a comparison of the requirements for Extractable Volume included in several international pharmacopoeias and was intended to assist users in ensuring that they complied with the relevant requirements in different regions.

The purpose of the paper was to seek members views on whether they supported the development of this and potentially other comparison documents for users of the BP. Preliminary discussions with the Secretariat in advance of the meeting had indicated that such documents might be more suited to discussions in forums such as the WHO International Meeting of World Pharmacopoeias.

Several members agreed that the development of such documents would be helpful to users.

The matter would be considered carefully by the BP management before further discussion by the BP Commission.

591 **British Pharmacopoeia Laboratory** COM(23)5

British Pharmacopoeia Laboratory Reports The list of reports concerning new and revised monographs that had been prepared by the Laboratory since the November 2022 meeting was provided for information.

British Pharmacopoeia Chemical Reference Substances Tables providing information on BPCRS up to the end of January 2023 were provided for information.

IV FUTURE PUBLICATIONS

592 **British Pharmacopoeia 2024 Publications** COM(23)6

BP 2024 The Secretariat was currently preparing text for inclusion in the British Pharmacopoeia 2024 and the British Pharmacopoeia (Veterinary) 2024. All items included in the 11th Edition of the European Pharmacopoeia, together with those from Supplements 11.1 and 11.2, would be incorporated in either the BP 2024 or the BP (Vet) 2024, as appropriate. The 2024 publications would be published in August and would come into effect on 1st January 2024.

Electronic updates The text from the 11th Edition of the European Pharmacopoeia and from Supplement 11.1 had been added to the online BP in November and December 2022 respectively. The text from Supplement 11.2 would be available in advance of its implementation on 1st July 2023.

Text for approval The first batch of new and technically-revised monographs for the BP 2024 publications had been reviewed by members during February. The second and final batch of text would be available for review between 24th March and 9th April.

Preliminaries Members recommended that the British Pharmacopoeia 2024 and the British Pharmacopoeia (Veterinary) 2024 should be published and confirmed that the draft Prefaces to both publications were acceptable.

Ph. Eur. 11th Edition and Supplements 11.1 and 11.2 No new approved synonyms were required relating to the new monographs included in these publications. The titles of several Ph. Eur. monographs had been changed and this would be reflected in the BP 2024 appropriately.

593 **Monographs for Omission from the BP 2024 and BP (Vet) 2024** COM(23)7

Since publication of the BP 2023 publications, several monographs had been identified as candidates for omission from the BP 2024 (no items had been identified for omission from the BP (Vet) 2024). 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.

In view of the continued use of Aspirin Effervescent Soluble Tablets and Colistin Tablets outside the UK it was agreed that these monographs should be retained in the BP 2024.

The list of proposed omissions from the BP 2024 was endorsed, subject to the removal of the two monographs noted above.

594 **British Approved Names 2022: Supplement No. 2** COM(23)8

Supplement No. 2 to British Approved Names 2022, containing 43 new names, had been prepared and a copy was provided for confirmation. The text had been agreed by the Expert Advisory Group on Pharmacy and Nomenclature and had been sent to manufacturers for comment. With the exception of Imidacloprid, the entries were all International Non-proprietary Names (rINN) (or rINN Modified) relating to medicines that were available on the UK market.

Subject to any comments received, the Commission approved the content of the draft Supplement and recommended that it should be published. The Supplement would be published at the same time as the BP 2024 publications.

595 **BP Website Redevelopment** COM(23)9

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

V ANALYTICAL ISSUES

None.

VI EXPERT ADVISORY GROUPS / PANELS OF EXPERTS

596 **Expert Advisory Group MC1: Medicinal Chemicals** COM(23)10

The report of the EAG MC1 meeting (19:07:22) was endorsed and the following points were raised. This had been the last meeting for Professor Alastair Davidson, the outgoing Chair. Mr Pound had attended for part of the meeting and had paid tribute to Professor Davidson.

Topiramate Oral Suspension As the active ingredient was “slightly soluble in water”, the EAG would be seeking advice as to whether the dissolution test for the Tablets and Capsules formulations should be included in the monograph for the Oral Suspension.

597 **Expert Advisory Group BIO: Biological and Biotechnological Products** COM(23)11

The report of the EAG BIO meeting (22:09:22) was endorsed and the following points were raised. In addition to the main business, progress reports relating to the Working Parties on Advanced Therapy Medicinal Products and Alternative Approaches for Documentary and Physical Standards for Biotechnological Products had been provided.

Bacterial Endotoxin Testing The updated Supplementary Chapter had been discussed and further discussions had taken place after the meeting.

598 **Expert Advisory Group MC3: Medicinal Chemicals** COM(23)12

The report of the EAG MC3 meeting (28:09:22) was endorsed.

599 **Expert Advisory Group ULM: Unlicensed Medicines** COM(23)13

The report of the EAG ULM meeting (19:10:22) was endorsed and the following points were raised.

Gliclazide Oral Suspension Laboratory work was currently being undertaken on the unlicensed Oral Suspension alongside work on the licensed products.

Ciclosporin Eye Ointment It had been agreed that information should be sought on the extent of unlicensed usage of the veterinary formulation in human medicine.

Parenteral Nutrition Solutions; Aluminium In light of data received, it had been agreed that the limit for Aluminium should be increased to 50 µg per litre in the BP 2024. The matter would be kept under review with the intention of reducing the limit in a future publication if possible.

600 **Expert Advisory Group MC2: Medicinal Chemicals** COM(23)14

The report of the EAG MC2 meeting (9:11:22 & 10:11:22) was endorsed and the following points were raised.

Adrenaline Injection Preparations; Labelling Progress was being made regarding amendments to the product Labelling statements and Commission would be kept informed of developments.

Atenolol Preparations; Identification It had been agreed that guidance on what should be considered as “characteristic” for a UV spectrum in LC/UV-DAD Identification tests should be developed and the Secretariat had held some preliminary discussions internally.

601 **Working Party ATMP: Advanced Therapy Medicinal Products** COM(23)15

The report of the WP ATMP meeting (25:11:22) was endorsed and the following points were raised. The group had received progress reports from the sub-groups on Empty Capsids for AAV Products and on T Cell and NK Cell Characterisation Assays.

Consultations Two consultations had recently been published on the BP website for comment (Guidance on the Characterisation of the Particle Population in AAV Products and Guidance on T Cell and NK Cell Characterisation Assays).

VII EUROPEAN PHARMACOPOEIA

602 **European Pharmacopoeia Update** COM(23)16

European Pharmacopoeia Commission Members discussed items from the 174th Session of the EP Commission and advised the UK Delegation accordingly.

Chromatographic Separation Techniques The text on Chromatographic Separation Techniques had been updated in the 11th Edition of the European Pharmacopoeia. As a

result of recent data obtained by the EDQM the change to the signal-to-noise ratio introduced by means of the 11th Edition would revert to the previous value in Supplement 11.3 which would be published in July and implemented on 1st January 2024.

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

603 **International Update** COM(23)17

United States Pharmacopeia Monthly teleconferences between the BP and the USP were being held to continue discussions on areas of mutual interest.

Chinese Pharmacopoeia Further consideration was being given to the joint development of standards by the BP and the Chinese Pharmacopoeia.

Indian Pharmacopoeia Consideration was being given to holding a meeting between the BP and the Indian Pharmacopoeia to discuss the proposed work programme for the joint development of monographs and standards, together with other collaboration opportunities.

Ukraine Pharmacopoeia The renewed Memorandum of Understanding between the BP and the State Pharmacopoeia of Ukraine had been signed and returned to Ukraine. This initiative enabled standards to be developed more quickly and supported the MHRA policy of improving the global supply chain of medicines.

IX ANY OTHER BUSINESS

604 **Branded vs Generic Products**

Attention was drawn to a recent article published in the Pharmaceutical Journal regarding certain branded and generic products. Further information would be sent to the Secretariat.

605 **Date of next meeting**

Monday 10th July 2023.

FOR INFORMATION:

606 **Items for Future Meetings**

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