SUMMARY MINUTES

of the

BRITISH PHARMACOPOEIA COMMISSION

A meeting of the British Pharmacopoeia Commission was held via videoconference on Monday 11th July 2022.

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

In attendance: Mr S Young, Dr F J Swanson.

Also present: Ms H Corns, Mr P Crowley, Mr A Evans, Dr G Kemp, Ms G Li-Ship, Ms C Swann, Ms A Thomson and Mr M Whaley.

Ms E Agca and Ms M Guler attended the meeting as observers.

Apologies for absence were received from Mr R Lowe and Mr J Pound* (*Secretary & Scientific Director*). [**Mr Pound attended the meeting for the items recorded under minutes 537 and 557.*]

534 **Introductory Remarks**

Welcome The Chair welcomed members to the meeting. He particularly welcomed Dr Bush, Mr Giartosio, Mr Jones and Mr Rickard, new members of the BP Commission who were attending their first meeting. The new members introduced themselves to the Commission. The Chair also welcomed Ms C Swann, who had recently transferred from NIBSC to the BP & Laboratory Services team, and also Ms Agca and Ms Guler from Committee Services (MHRA Governance) who were observing the meeting.

Declaration of Interests; Confidentiality of Proceedings Members were reminded of the need to inform the Secretariat of any changes to their interests throughout the year and of the need to declare any specific interests at the start of relevant discussions.

BPC Chair This was the last meeting for Professor Taylor who would be retiring from the Commission at the end of September.

I MINUTES

535 The minutes of the meeting held on 7th March 2022 were confirmed, subject to the following correction:

Minute 515 – Digital Therapeutics Final paragraph. For "...should maintain a watching brief..." read "...should maintain an active watching brief...".

II MATTERS ARISING FROM THE MINUTES

536 The following matters arising from the meeting held on 7th March 2022 were noted.

Minute 512 – Alkyl Sulfonate Ester Impurities A short "call for feedback" document had been prepared in order to seek the views of interested parties on the current Production statement approach towards controlling mesilate impurities in BP monographs. The text had been added to the BP website as part of a news item and had also been included as

part of the new and revised text that had been posted for comment in the July to September consultation window (Alkylsulfonates-call-for-feedback).

Minute 519 – Monographs for Omission from the BP 2023 and the BP (Vet) 2023 Erythromycin Estolate Capsules had been added to the list of monographs to be omitted from the BP 2023.

III REPORTS AND CORRESPONDENCE

GOVERNANCE

537 Updates from the Secretary & Scientific Director

Mr Pound provided members with an update on the transformation of the MHRA and other key activities.

538 Combined Code of Practice on Interests; Governance Activities COM(22)17

Combined Code of Practice on Interests A public consultation on the new MHRA-wide Code of Practice on Managing Conflicts of Interests for the Expert Advisory Committees had been undertaken between 12th April and 24th May 2022. Members would be kept informed of any developments.

Governance Activities Members had previously been informed that some of the governance activities relating to the work of the BP Commission and Expert Advisory Groups would be transferred to the Committee Services team within the new Governance group. The Secretariat was working with colleagues in Committee Services to ensure a smooth transition of responsibilities.

OPERATIONAL

539 British Pharmacopoeia Commission: Membership COM(22)18

A review of the membership of the British Pharmacopoeia Commission had been undertaken during 2021, in collaboration with the Department of Health and Social Care (DHSC) Public Appointments Unit. There had been some delays during the appointments process, but four new members had been appointed with effect from 1st May 2022 for a period of four years (Dr Edward Bush, Mr Carlo Emanuele Giartosio, Mr Sean Jones and Mr James Rickard).

BP Website A list of BPC members was included on the BP website (and also in the British Pharmacopoeia publications and in the Annual Report). An updated list including the details for the new members was provided and members were asked to inform the Secretariat if any changes to their details were required.

Expert Advisory Groups, Panels of Experts and Working Parties The new members would be invited to join at least one of the EAGs/Panels/Working Parties.

540 Working Party ATMP: Progress Report COM(22)19

An update on the recent activities of the Working Party on Advanced Therapy Medicinal Products was provided for information.

Background Members were reminded that the Working Party had been established as a consequence of implementing the MHRA Strategy for Pharmacopoeial Public Quality Standards for Biological Medicines and that the remit of the group was to develop non-mandatory best practice guidelines for Advanced Therapy Medicinal Products.

Guidance documents The current guidance documents on Flow Cytometry and Vector Copy Number, which were available as part of the online publication only, had recently been made available as a free download option.

Sub-group updates

Flow Cytometry A marketing campaign had been planned to raise awareness of the published guidance document.

Vector Copy Number A response to the public consultation undertaken in 2021 had been issued in March and the guidance had been added to the BP website as part of the online updates to the BP 2022 publication.

Empty Capsids for AAV Products The sub-group had held seven meetings to date and had made good progress with developing the draft guidance document.

T Cell and NK Cell Potency Assay The sub-group had held five meetings to date. A draft guidance document was being developed.

Dr Brady congratulated the Working Party and the sub-groups for developing these guidance documents, which covered difficult areas, so quickly.

541 **Pyrogen/Bacterial Endotoxin Testing Policy** COM(22)20

Current Policy Following discussions in 2014 and 2015, EAG BIO had reviewed the policy on bacterial endotoxin and pyrogen testing and this had been endorsed by the BP Commission. Significant progress with the replacement of tests for Pyrogens by tests for Bacterial endotoxins had occurred and there were now no BP monographs containing a test for Pyrogens.

Review Since the above policy had been agreed an additional test for Bacterial endotoxins using Recombinant factor C had been published and the Ph Eur had committed to removing all remaining pyrogen tests by 2026. EAG BIO would be reviewing the current policy at their meeting scheduled for September 2022, which would include an update of Supplementary Chapter I C: Bacterial Endotoxin Testing to ensure that it reflected the current position. The updated text would be presented to Commission at a future meeting.

Discussion Members welcomed the forthcoming review by EAG BIO and several points were raised for further consideration by EAG BIO.

542 **EAG PCN: Pharmacy and Nomenclature Review** COM(22)21

Expert Advisory Groups NOM: Nomenclature and PCY: Pharmacy had been merged to form EAG PCN in 2020 and it had been agreed that a review should be undertaken after one year to ensure that the new group was working effectively.

The following four areas were the main focus for the group:

MHRA Patient Safety Alerts The Secretariat reviewed all safety alerts and brought those that were relevant to the BP to the attention of the group. The PCN experts considered this to be a valuable part of their role.

New and Revised BP Monographs This included reviewing monograph titles and action and use statements for new and revised monographs in each publication.

British Approved Names This included identifying new items for inclusion in the BAN publication and reviewing the entries in the annual supplements and new editions.

Issues arising through EAGs and Regulatory Problems (*as required*) In the past some issues had been discussed separately by EAGs PCY and NOM. It had been agreed that discussion by a single group of experts with a wider area of expertise was more efficient.

Two successful meetings had been held in 2021, with all members invited to attend the whole meeting.

Members agreed that the merged EAG PCN was working successfully and endorsed the recommendation that it should remain as a single group.

543 **New Laboratory Services Contract** COM(22)22

Following an invitation to tender, a new contract for laboratory services had been awarded to the Laboratory of the Government Chemist (LGC) from 1st April 2022.

544 **British Pharmacopoeia Laboratory** COM(22)23

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

British Pharmacopoeia Chemical Reference Substances Tables providing information on BPCRS up to the end of May 2022 were provided for information.

IV FUTURE PUBLICATIONS

545 **How to use the BP Guide: Performance and Future Improvements/Innovation** COM(22)24

How to use the BP Guide The guide had been developed following user feedback that had indicated the need for a short user guide to help users follow a monograph and navigate through the BP publication. It had been included on the BP website in 2019 and was also available as a free download option.

Performance Since the guide had been launched positive feedback had been received stating that it was a useful document, especially for new and occasional users of the BP.

Future Improvement and Innovation Members were invited to share their ideas for improvements and additions to the guide and were encouraged to send proposals to the Secretariat for consideration.

BP Website Members were encouraged to send any suggestions for improvements to the website to the Secretariat so that they could be escalated with the publisher.

546 **GSE Fast Stream Placement Projects: Update and Forward Look** COM(22)25

Digital Health Technologies A copy of the final report from Ms Rebecca Hunter, who had been with the BP for six months as part of the Government Science and Engineering Fast Stream Programme, was presented for information.

Members agreed that it would be useful for the BP to be kept informed of developments in this field and it was agreed to revisit the topic after a year.

GSE Fast Stream Future Projects A new bid had been submitted for a fast stream placement to lead a project on reducing the environmental impact of the BP, taking definitive steps to support global sustainable development and climate action goals.

Members were encouraged to share any insights into initiatives and networks in this area of which they were aware.

V ANALYTICAL ISSUES

None.

VI EXPERT ADVISORY GROUPS / PANELS OF EXPERTS

547 **Expert Advisory Groups, Panels of Experts and Working Parties: Membership Review; EAG BIO** COM(22)26

Membership Review The term of office for all current members of the Expert Advisory Groups, Panels of Experts and Working Parties was due to end on 31st December 2022. After careful consideration, and in light of the need to prioritise key areas of work and ensure that business as usual activities continued, the decision had been taken to defer the review and to extend the terms of office for all members for a year.

Members were assured that if a particular EAG was in urgent need of new members, either to fill a vacancy or to cover gaps in expertise, it would still be possible to appoint members in advance of the full review.

Chairs and Vice-Chairs Following the retirement of five long-standing BP Commission members at the end of 2021, several changes had been or would be made to the Chair and Vice-Chair positions.

Expert Advisory Group BIO: Biological and Biotechnological Products Members endorsed the recommendation to appoint Mr Gill to EAG BIO.

548 **Expert Advisory Group HCM: Herbal and Complementary Medicines** COM(22)27

The report of the EAG HCM meeting (13:09:21) was endorsed and the following point was raised.

Work programme The EAG had agreed to add several items to the work programme that had the potential for use in the treatment of Covid-19, providing there was scientific evidence to support the development of such monographs.

549 **Working Party BIO-DPS: Alternative Approaches to Documentary and Physical Standards for Biotechnological Products** COM(22)28

The report of the WP BIO-DPS meeting (06:12:21) was endorsed and the following points were raised.

Round robin data analysis The meeting had mainly focussed on the results obtained from the interlaboratory study carried out on a monoclonal antibody. A large amount of statistical data had been analysed and the results from different laboratories had been compared.

Dr Kemp, who had been responsible for the BIO-DPS Working Party, would soon be leaving the BP. Dr Brady thanked Dr Kemp for his hard work on the Working Party and wished him well for the future.

550 **Expert Advisory Group MC1: Medicinal Chemicals** COM(22)29

The report of the EAG MC1 meeting (08:02:22) was endorsed and the following points were raised. This had been the first meeting for Dr Marshall since taking on the role of Vice-Chair.

Doxazosin Preparations; Production; Related substances The draft new monographs had included the BP Production statements relating to the control of mesilate impurities, subject to the outcome of the current consultation. Further information on Related substances was required.

Trazodone Tablets; Definition The current monograph included the phrase “They are coated.”. Members had discussed whether reference to the coating should be deleted if it was not performing a function and it had been noted that this could have implications for other monographs that currently included this wording.

Sumatriptan Preparations The revision of the Related substances tests and Assays in these monographs had been designed to incorporate the concepts of Analytical Quality by Design. The online version of the updated monographs would include some supporting information in the “More Resources” section to help users understand how the AQbD concepts had been applied to the monograph tests.

Mycophenolate Preparations Clinical advice had been received indicating that the proposed content limits of 93.0 to 105.0% for the infusion formulation were appropriate and should be supported.

551 **Expert Advisory Group ABS: Antibiotics** COM(22)30

The report of the EAG ABS meeting (22:02:22) was endorsed and the following points were raised.

Vancomycin for Infusion; Definition The monograph for Vancomycin for Infusion had been amended in the BP 2023 to highlight that the material could be used to prepare a solution for oral administration.

Work Programme Following the BP Portfolio review undertaken in 2021, about 60 monographs had been transferred from EAG MC1: Medicinal Chemical to EAG ABS. Steps were being taken to try and identify usage data on veterinary formulations.

552 **Working Party ATMP: Advanced Therapy Medicinal Products** COM(22)31

The report of the WP ATMP meeting (06:04:22) was endorsed. The members had been provided with an update on the progress of the various sub-groups.

VII EUROPEAN PHARMACOPOEIA

553 **European Pharmacopoeia Update** COM(22)32

European Pharmacopoeia Commission The 172nd Session of the EP Commission had taken place in March 2022, during which Professor Salvador Cañigueral Folcará (from the Spanish delegation) had been elected as the new Chair. He had taken over as Chair at the 173rd Session, which had taken place on 21st and 22nd June.

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

554 **International Update** COM(22)33

Members were provided with an update on international activities.

United States Pharmacopeia Regular teleconferences between the BP and the USP had been held between March and June to continue discussions on areas of mutual interest,

Chinese Pharmacopoeia A successful joint webinar/workshop between the BP and the ChP had been held on 24th March. This had been arranged by the Foreign, Commonwealth and Development Office and had been attended by BP and ChP staff.

Indian Pharmacopoeia Since the teleconference between the BP and the Indian Pharmacopoeia (IP) in February there had been a focus on harmonising standards for new monographs of the BP and IP and the first monograph to be developed jointly had been selected.

Mr Pound had visited India in June to attend a conference to celebrate the publication of the 2022 edition of the Indian Pharmacopoeia.

Ukraine Pharmacopoeia The Memorandum of Understanding between the BP and the State Pharmacopoeia of Ukraine had been renewed. The MoU permitted the reproduction of an agreed number of BP monographs in the Ukraine Pharmacopoeia.

World Health Organization Mr Evans had attended the 74th WHO Consultation on International Non-proprietary Names in person in April. Over 250 new names for new chemical and biological substances had been discussed, including many new drugs that were being assessed for their potential use in the treatment of Covid-related diseases. Ms Corns had attended the WHO Expert Committee on Specifications for Pharmaceutical Preparations in April which had included discussions on monographs for inclusion in the International Pharmacopoeia.

Compendial Policy, Process and Quality Stakeholder Organisation Discussion Group (CPPQ) BP staff had met with the CPPQ organisational leads regarding a potential joint BP/CPPQ symposium on the BP.

IX ANY OTHER BUSINESS

555 **Compliance** Mr Rickard noted that some small companies might not have access to the most recent edition of the BP.

556 **Patient needs** Dr Gleadle informed members that she had recently been involved in discussions with a representative from MHRA Communications. This had addressed the need for using clear English in documents and websites (including the BP website) as part of the wider agency work to ensure that the patient is at the heart of everything we do.

557 **BPC Chair** This was the last meeting for Professor Kevin Taylor who would be retiring from the BP Commission at the end of September after serving for nine years as Chair. Mr Pound paid tribute to Professor Taylor and thanked him for the enormous part he had played during his term of office in helping ensure that the BP was in a good place for the future and wished him a happy and healthy retirement.

Professor Taylor thanked Mr Pound for his kind words. He said that it had been a pleasure and a privilege to lead the BP Commission for nine years and that although sad to depart it was now appropriate for someone new to take on the role of Chair. He said that the BP was extremely important and made a difference.

Professor Taylor shared some of the highlights during his tenure. He thanked the members for their contributions and for helping to ensure that, although sometimes challenging, the meetings were enjoyable, friendly and held in a professional manner. He paid tribute to the staff of the Secretariat and Laboratory and said he was amazed at the amount of high-quality work that was regularly completed by such a small team. He also thanked Mr Pound and Dr Atkinson for their support and strategic input.

558 **Date of next meeting**

Monday 7th November 2022 or Monday 14th November 2022, subject to the availability of the new Chair.

FOR INFORMATION:

559 **Items for Future Meetings**

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