SUMMARY MINUTES

of the

BRITISH PHARMACOPOEIA COMMISSION

A meeting of the British Pharmacopoeia Commission was held via videoconference on Monday 7th March 2022.

Present: Professor K Taylor (*Chair*), Dr A M Brady, (*Vice-Chair*), Dr E Amirak, Dr A Barnes, Dr J Beaman, Dr A Gleadle (*lay member*), Dr P Marshall, Ms S Palser (*lay member*), Professor M Simmonds.

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

Apologies for absence were received from Dr V Jaitely and Mr R Lowe.

Also present: Ms H Ashraf, Ms H Corns, Mr P Crowley, Mr L Elanganathan, Mr A Gibb, Ms R Hunter, Mr G Kemp, Ms A Thomson, Mr M Whaley and Mr S Young.

510 **Introductory Remarks**

Welcome The Chair welcomed members to the meeting. He particularly welcomed Dr Brady to her first meeting since being appointed as Vice-Chair of the BP Commission.

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.

MHRA Staff Mr James Pound had been appointed as Deputy Director, Standards & Compliance, which was part of the new core Agency function: Healthcare Quality & Access. Mr Alistair Gibb would be leaving the MHRA at the end of March.

Obituary Members were saddened to learn of the death of Professor Anthony Fell (Emeritus Professor of Pharmaceutical Chemistry, University of Bradford). Professor Fell had been a member of the BP Commission for 18 years until 2002 and had been the Chair of the former Committee B: Medicinal Chemicals for many years.

I MINUTES

511 The minutes of the meeting held on 8th November 2021 were confirmed.

II MATTERS ARISING FROM THE MINUTES

512 The following matters arising from the meeting held on 8th November 2021 were noted.

Minute 489 – Working Party ATMP: Progress Report Proposals for membership of the two new sub-groups on (1) Empty Capsids for AAV (Adeno-Associated Virus) Products and (2) T Cell and NK Cell Characterisation Assays (previously named CAR-T Cell Potency Assay) had been circulated in November 2021 and January 2022 respectively and these had been endorsed by correspondence. The members had been appointed to the sub-groups for their expertise in the relevant subject matter and were also part of the main ATMP Working Party.

Minute 491 – Alkyl Sulfonate Ester Impurities In accordance with the discussion at the last meeting the Secretariat would seek a current opinion from industry in the near future.

Minute 495 – Aide Memoire; Minute 496 – Policy List The updated documents had been added to the BPC forum in December.

III REPORTS AND CORRESPONDENCE

GOVERNANCE

513 Updates from the Secretary & Scientific Director

Mr Pound provided members with an update on the transformation of the MHRA.

514 Combined Code of Practice on Interests COM(22)1

Introduction; Scope A decision had been taken by the MHRA Executive Committee to expand the review of the CHM Code of Practice in order to develop a single agency-wide document that would apply to all the Advisory Bodies (BPC and CHM) and their supporting Expert Advisory Groups, together with the Herbal Medicines Advisory Committee, the Advisory Board for the Registration of Homoeopathic Products, the Devices Expert Advisory Committee and the United Kingdom Stem Cell Bank Steering Committee.

Implications for the BPC, EAGs, Panels of Experts and Working Parties The introduction of the new Code of Practice would introduce significant changes to the way members' interests were collected and recorded in the future and full details would be provided once the position was clear.

Members agreed that it would be beneficial for a single, unambiguous and transparent Code of Practice to be developed for all MHRA Committees.

Next steps The intention was to introduce the new Code of Practice at the earliest opportunity. A public consultation on the new text would be launched before it was implemented later in the year.

OPERATIONAL

515 Digital Therapeutics

Ms Hunter delivered a presentation on Digital Therapeutics – Review and Recommendations, outlining the work she had undertaken during her time with the BP and MHRA. The main purpose of the work had been to assess the viability and feasibility of the BP developing standards and/or guidance in Digital Therapeutics.

The recommendations from the work relating to the BP were that no current action in this field was required but that the BP should maintain an active watching brief on activities across the agency.

516 AQbD Strategy Update COM(22)2

An update on the recent activities of the Working Party on Analytical Quality by Design was provided for information, focussing on the three key strategic priorities.

Supporting and Enabling Innovation It had been agreed that further practical work should be undertaken to investigate the application of AQbD principles to different Critical

Quality Attributes. Evaluation of a Related substances method in four Sumatriptan formulations had been carried out. Draft monographs would be circulated to stakeholders in due course.

Application to Public Quality Standards The new Supplementary Chapter on the "*Use of Analytical Quality by Design Concepts for Analytical Procedures*" had been published in the British Pharmacopoeia 2022. There were plans to expand the Chapter in a future publication.

The new monograph for Atorvastatin Tablets included an Assay which had been developed using the principles of Analytical Quality by Design. The publication of this monograph would be a significant milestone for the BP and represented many years of hard work from the BP and Laboratory and the members of the Working Party.

Collaboration, Engagement and Knowledge Transfer The BP had continued to engage and collaborate with peers within the MHRA and externally. In addition to the two successful joint BP/USP webinars held during 2021, presentations had also been given at several international webinars and training events.

517 **British Pharmacopoeia Laboratory** COM(22)3

British Pharmacopoeia Laboratory Reports The list of reports concerning new and revised monographs that had been prepared by the Laboratory since the November 2021 meeting was provided for information.

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

ISO Accreditation The BP Laboratory was accredited to ISO 17025:2017 by the UK Accreditation Service (UKAS). Members were informed that following implementation of the new UKAS publication "GEN 6 – *Reference to Accreditation and Multilateral Recognition Signatory Status by UKAS Accredited Bodies*", all future monograph and BPCRS reports would be required to reference UKAS accreditation.

IV FUTURE PUBLICATIONS

518 **British Pharmacopoeia 2023 Publications** COM(22)4

BP 2023 The Secretariat was currently preparing text for inclusion in the British Pharmacopoeia 2023 and the British Pharmacopoeia (Veterinary) 2023. All items included in the 10th Edition of the European Pharmacopoeia, together with those from Supplements 10.1 to 10.8, would be incorporated in either the BP 2023 or the BP (Vet) 2023, as appropriate. The 2023 publications would be published in August and would come into effect on 1st January 2023.

Electronic updates The text from Supplements 10.6 and 10.7 to the 10th Edition of the European Pharmacopoeia had been added to the online BP in September 2021 and January 2022 respectively, which was significantly earlier than in previous years. The text from Supplement 10.8 would be made available in advance of its implementation on 1st July 2022.

Text for approval The first batch of new and technically-revised monographs for the BP 2023 publications had been reviewed by members during February. The final batch of text would be available for review between 1st April and 17th April. The Chair thanked those members who had commented on the first batch of text and encouraged all members to

review the second batch in due course. He also thanked the Secretariat for providing helpful feedback in response to the comments raised.

Preliminaries Members recommended that the British Pharmacopoeia 2023 and the British Pharmacopoeia (Veterinary) 2023 should be published and confirmed that the draft Prefaces to both publications were acceptable.

Ph. Eur. Supplement 10.8 No new approved synonyms were required relating to the new monographs included in Supplement 10.8. The title of one monograph had been changed and this would be reflected in the BP 2023 appropriately.

519 **Monographs for Omission from the BP 2023 and BP (Vet) 2023** COM(22)5

Since publication of the BP 2022 publications, several monographs had been identified as candidates for omission from the BP 2023 and the BP (Vet) 2023. 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 and to Panel VET: Veterinary Medicines concerning the proposed omissions from the BP (Vet).

The list of proposed omissions was endorsed. Members were reminded that, in accordance with regulation 252 (2c) of the Human Medicines Regulations 2012, these monographs would continue to remain in force.

520 **Monograph Development: Unlicensed Medicines** COM(22)6

A new Supplementary Chapter entitled “Monograph Development: Unlicensed Medicines” had been prepared for inclusion in the British Pharmacopoeia 2023. The proposed text was intended to provide information on the development of monographs for unlicensed medicines and to highlight the type of data required. It incorporated information previously included in an internal guidance document prepared for members of EAG ULM and some of the information included in Supplementary Chapter III C – Monograph Development: Guidance to Manufacturers.

The draft text had been included within the first round of text on the Document Review Tool and an updated version, which reflected changes proposed by members of the BPC and EAG ULM, had been provided. Commission approved the updated text and recommended that it should be published in the BP 2023.

521 **Veterinary Immunological Products** COM(22)7

A new Supplementary Chapter entitled “Inactivated Autogenous Vaccines for Veterinary Use” had been prepared for inclusion in the British Pharmacopoeia (Veterinary) 2023. Autogenous Veterinary Vaccines were not commercially available but were prepared in response to a specific and immediate local need and were subject to different regulatory requirements depending upon their region of origin. Panel VIP: Veterinary Immunological Products had agreed that the preparation of a non-mandatory Supplementary Chapter would be more appropriate than developing specific monographs for these products.

The most recent version of the text had been included in the meeting papers and was currently out for public consultation. An updated version would be available for comment within the second batch of text on the Document Review Tool in April. Members were asked to send any significant comments on the current text without delay.

522 **British Approved Names 2022: Supplement No. 1** COM(22)8

Supplement No. 1 to British Approved Names 2022, containing 49 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. All the entries were either recommended International Nonproprietary Names (rINN) which had UK product licences or were Ph Eur monograph titles which had previously been approved for inclusion in the list of BANs. Members were invited to examine the draft text and to send comments to Mr Evans by **25th March 2022.**

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 2023 publications.

V ANALYTICAL ISSUES

None.

VI EXPERT ADVISORY GROUPS / PANELS OF EXPERTS

523 **Expert Advisory Group MC3: Medicinal Chemicals** COM(22)9

The report of the EAG MC3 meeting (22:09:21) was endorsed.

524 **Expert Advisory Group ABS: Antibiotics** COM(22)10

The report of the EAG ABS meeting (12:10:21) was endorsed and the following points were raised.

Vancomycin for Oral Solution The Oral Solution monograph would be omitted from the next edition of the BP and the Definition of the Infusion monograph would be amended to indicate that it could also be used to prepare an Oral Solution.

Cefalexin Oral Suspension The EAG would be reviewing the content limits for antibiotic Oral Suspensions presented as dry ingredients for reconstitution.

525 **Expert Advisory Group ULM: Unlicensed Medicines** COM(22)11

The report of the EAG ULM meeting (13:10:21) was endorsed and the following points were raised.

Parenteral Nutrition Solutions The EAG was continuing to seek data to ensure that the monograph limit for Aluminium was appropriate.

Pemetrexed Infusion The members had agreed that a monograph for Pemetrexed Infusion should be added to the work programme of one of the Medicinal Chemicals Expert Advisory Groups since licensed products with extended shelf-lives were now available.

526 **Expert Advisory Group MC2: Medicinal Chemicals** COM(22)12

The report of the EAG MC2 meeting (3:11:21 & 4:11:21) was endorsed and the following point was raised.

Atorvastatin Tablets The Assay in the draft new monograph has been developed using the principles of Analytical Quality by Design. Members would be able to comment on the proposed text during the second round of DRT text for inclusion in the BP 2023.

527 **Expert Advisory Group PCN: Pharmacy and Nomenclature** COM(22)13

The report of the EAG PCN meeting (7:12:21) was endorsed and the following points were raised.

MHRA Patient Safety Alerts Recent safety alerts had been provided for information and specific issues relating to BP monographs had been discussed.

Phenytoin Preparations; Dissolution A Production statement approach had been agreed for the control of Dissolution in the monographs for Phenytoin Capsules and Phenytoin Tablets.

Dissolution Testing of Oral Suspensions A requirement for Dissolution was currently included for unlicensed Oral Suspension monographs but not for licensed products. EAG PCN had agreed that where considered necessary to confirm that sufficient of the active ingredient had been released a Dissolution test should be included in monographs for licensed Oral Suspensions but that this should not be routinely included.

528 **Working Party AQbD: Analytical Quality by Design** COM(22)14

The report of the WP AQbD meeting (14:12:21) was endorsed and the following points were raised. This had been the first meeting since the appointment of five new members.

Global Updates Members had been provided with updates on BP activities, including publication of the Supplementary Chapter in the BP 2022 and the second joint BP-USP webinar, together with updates on key developments at the USP and within ICH.

Workshop A significant part of the meeting had been held as a workshop which was aimed at exploring how the Analytical Target Profile could be applied to compendial procedures. The Working Party had split into three groups to discuss specific issues and the outcomes would be discussed at future meetings of the group.

VII EUROPEAN PHARMACOPOEIA

529 **European Pharmacopoeia Update** COM(22)15

European Pharmacopoeia Commission The 171st Session of the EP Commission had taken place in November 2021 and the draft report of the Session was available on the BPC forum.

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

530 **International Update** COM(22)16

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.

BP-USP Webinars on AQbD Following the success of the two joint BP and USP webinars held in 2021, the Secretariat would be discussing the potential for future similar events with USP colleagues.

Chinese Pharmacopoeia Comments were still awaited on the draft Memorandum of Understanding between the BP and the Chinese Pharmacopoeia (CP).

Indian Pharmacopoeia A further teleconference between the BP and the Indian Pharmacopoeia (IP) had been held in February.

Ukraine Pharmacopoeia The Memorandum of Understanding between the BP and the State Pharmacopoeia of Ukraine was due to be renewed.

IX ANY OTHER BUSINESS

531 **Editor-in-Chief** This was the last meeting for Mr Alistair Gibb (current BP Editor-in-Chief).. The Chair thanked Mr Gibb for his contribution to the work of the BP over the years and for his role as UK member of the Ph Eur Rules of Procedure Working Party. Mr Gibb thanked the Chair for his kind words and also wished to acknowledge the help he had received from Dr Brady and Dr Varley (former BPC member) over the years. Mr Pound added his thanks and wished Mr Gibb well in his new role outside the MHRA.

532 **Date of next meeting**

Monday 11th July 2022.

FOR INFORMATION:

533 **Items for Future Meetings**

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