SUMMARY MINUTES

of the

BRITISH PHARMACOPOEIA COMMISSION

A meeting of the British Pharmacopoeia Commission was held via videoconference on Monday 6th April 2020.

Present: Professor K Taylor (*Chair*), Professor A G Davidson (*Vice-Chair*), Dr J Beaman, Dr A M Brady, Dr G Cook, Dr A Gleadle (*lay member*), Mr R Lowe, Professor J Miller, Ms S Palser (*lay member*), Professor M Simmonds, Dr R Torano and Dr P Varley.

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

Also present: Ms H Ashraf, Ms H Bowden, Ms H Corns, Mr A Evans, Mr A Gibb, Mr G Kemp, Mr L Elanganathan, Mr S Maddocks, Mr R Smith, Mr M Whaley and Mr S Young.

356 **Introductory Remarks**

Welcome The Chair welcomed members to 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. The Chair reminded members of the confidential nature of the meeting and that the papers should not be disclosed.

Expert Advisory Group HCM: Herbal and Complementary Medicines Dr Linda Anderson would be standing down from EAG HCM as she would shortly be retiring from the MHRA. Dr Anderson had been associated with the work of EAG HCM and of its former incarnation, Committee G: Crude Drugs and Galenicals, since 1994 and had served as Vice-Chair between 2001 and 2018. Her contributions would be greatly missed. A formal letter of thanks would be sent to her on behalf of the Commission.

BPC Appraisals The appraisal process was due to be completed by the end of May and would be carried out by correspondence this year.

Dr Beaman, Dr Cook and Dr Torano declared interests in one or more agenda items and appropriate action was taken.

I MINUTES

357 The minutes of the meeting held on 11th November 2019 were confirmed.

II MATTERS ARISING FROM THE MINUTES

358 The following matters arising from the meeting held on 11th November 2019 were noted.

Minute 330 – Lay Members Forum; Role of a Lay Member Dr Gleadle and Ms Palser had provided testimonials for inclusion in the Lay Members role document.

Minute 338 – Expression of Related substances Limits It was intended to publish a consultation on the proposed introduction of numerical limits into BP monographs during one of the website consultation windows.

Minute 339 – New Analytical Technologies It was intended to publish a consultation on the proposed introduction of LC/UV-DAD methods into the BP during one of the website consultation windows.

Minute 340 – Aide Memoire; Minute 341 – Policy List The Aide Memoire and Policy List had been updated to reflect the changes agreed at the last meeting and further comments received from Professor Davidson and Professor Miller.

III REPORTS AND CORRESPONDENCE

GOVERNANCE

359 Coronavirus

Mr Pound provided an update on how the BP and MHRA were responding to the current global Coronavirus (Covid-19) outbreak.

OPERATIONAL

360 British Pharmacopoeia Commission: Membership COM(20)1

A review of the membership of the British Pharmacopoeia Commission had been undertaken during 2019 in collaboration with the Department of Health and Social Care Public Appointments Unit. Dr Gerard Lee and Professor Matthew Almond had retired from the Commission at the end of 2019. The following members had been re-appointed for periods between two and four years with effect from 1st January 2020: Professor Davidson (*Vice-Chair*), Dr Beaman, Dr Brady, Dr Gleadle, Mr Lowe, Ms Palser and Professor Simmonds.

The campaign to appoint new members had been delayed.

361 Innovation Board Update COM(20)2

Members were provided with an update on the recent progress made by the joint BP-TSO Innovation Board.

Track Changes The first phase of the online track changes project had been implemented on 1st April 2020. The timeline feature now appeared as part of the default view option. The other significant change allowed the user to view the updated monographs in different ways.

User Research Further user research had been undertaken between January and March. A survey had been included on the website seeking views on the value of the "How to Use the BP" guide, the updated timeline and track change features, on communication with industry and other interested parties and online searching. The introduction of the new features had received a positive response, but it had been recognised that steps should be taken to increase awareness of future changes.

362 **Analytical Quality by Design: Project Update** COM(20)3

Consultation response and future activities A draft agency response to the consultation undertaken during 2019 had been prepared. The final version would be shared with members and published on the GOV.UK website at the earliest opportunity.

363 **Working Party ATMP: Advanced Therapy Medicinal Products** COM(20)4

In accordance with the course of action agreed at the last meeting, members had endorsed the establishment of the ATMP Working Party and its Terms of Reference by correspondence.

Membership; Meetings An item had been included on the BP website in January inviting expressions of interest to join the ATMP Working Party. There had been 43 responses and the candidate members had been identified jointly by the Secretariat and Dr Varley and Dr Brady in their roles as Chair and Vice-Chair of EAG BIO: Biological and Biotechnological Products respectively. The proposed candidates had been circulated to the Commission in February and the membership had been endorsed by correspondence. Dr Jacqueline Barry (Chief Clinical Officer at the Cell and Gene Therapy Catapult) had agreed to act as Chair. It was intended to hold two meetings of the Working Party in 2020.

364 **Nitrosamines: Update on Activities** COM(20)5

A proposed revision to the General Monograph for Substances for Pharmaceutical Use to include a requirement for manufacturers to address the risk of nitrosamine contamination had been included in Pharmeuropa 32.1.

365 **Reports of BP Related Activities Presented to the Agency Board** COM(20)6

As part of the programme to ensure that the MHRA Board was informed about all areas of the agency's work, two papers relating to current BP activities had been presented at recent Board meetings. These focussed on the work of the Laboratory and on BP activities related to innovation.

366 **British Pharmacopoeia Laboratory** COM(20)7

British Pharmacopoeia Laboratory Reports The list of reports concerning new and revised monographs that had been prepared by the Laboratory since the November 2019 meeting was provided for information.

British Pharmacopoeia Chemical Reference Substances Tables providing information on BPCRS up to the end of February 2020 were provided for information.

Covid-19 The status of the BPCRS related to potential Covid-19 medicines was provided on a dedicated page on the website (https://www.pharmacopoeia.com/html/331) which was updated regularly.

IV FUTURE PUBLICATIONS

367 **British Pharmacopoeia 2021 Publications** COM(20)8

BP 2021 The Secretariat was currently preparing text for inclusion in the British Pharmacopoeia 2021 and the British Pharmacopoeia (Veterinary) 2021. All items included

in the 10th Edition of the European Pharmacopoeia, together with those from Supplements 10.1 and 10.2, would be incorporated in either the BP 2021 or the BP (Vet) 2021, as appropriate. The 2021 publications would be published in August and would come into effect on 1st January 2021.

Electronic updates The text from the Ph Eur 10th Edition had been added to the online BP in December 2019, in advance of its implementation on 1st January 2020. The text from Supplements 10.1 and 10.2 would be available in advance of their implementation dates on 1st April and 1st July 2020 respectively.

Text for approval The first batch of new and technically revised monographs for the BP 2021 publications had been reviewed by members during February. The final batch of text would be available on the Document Review Tool (DRT) between 3rd April and 19th April.

Preliminaries Members recommended that the British Pharmacopoeia 2021 and the British Pharmacopoeia (Veterinary) 2021 should be published and confirmed that the draft Prefaces to both publications were acceptable.

Approved Synonyms; Ph. Eur. Supplement 10.2 No approved synonyms were required relating to new monographs included in Supplement 10.2. In view of the new monograph for Olanzapine Embonate Monohydrate, the BAN entry for Olanzapine would be amended to include Olanzapine Embonate as a BAN (Modified) in a future British Approved Names publication.

Technical/Editorial Changes In addition to the changes arising through EAG discussions, the following changes would also be made in the BP 2021: (i) the titles of any remaining monographs containing split standard terms would be updated as previously agreed (minute 174 refers); (ii) minor changes would be made to the General Notice on Storage and several other texts following replacement of the term “tamper-proof” by “tamper-evident” in the 10th edition of the European Pharmacopoeia; (iii) several monographs would be updated to revise the description of GC stationary phases, in line with the Ph. Eur.

368 **Monographs for Omission from the BP 2021 and BP (Vet) 2021** COM(20)9

At the last meeting members endorsed the omission of a number of monographs from the BP 2021 and BP (Vet) 2021 which had been identified through the monograph portfolio review. The list had subsequently been included on the BP website and had been sent to several international organisations and contacts in countries where the BP was used and/or where the BP had a Collaboration Agreement or Memorandum of Understanding. The list had also been sent to the Expert Advisory Group on Unlicensed Medicines to ascertain if any of the items on the list were used as unlicensed formulations.

The finalised list of proposed omissions, which included additional items identified through EAG work, was endorsed by the Commission. Members were reminded that, in accordance with regulation 252 (2c) of the Human Medicines Regulations 2012, these monographs would continue to remain in force.

369 **Monograph Portfolio Review** COM(20)10

The process to identify monographs for omission from the BP 2021 publications had demonstrated that the principles developed for the monograph portfolio review were fit for purpose. The following steps had been taken: (i) Secretariat review and omissions identified; (ii) EAG review, followed by BPC oversight of the items proposed for omission;

(iii) consultation, followed by BPC approval of the final list; (iv) omission of monographs from the BP 2021 and the BP (Vet) 2021.

The first phase of the portfolio review had focussed on rationalising the BPCRS catalogue and was now complete. The next phases of the review would focus on (1) identifying and addressing outdated methodology and (2) introducing a regular monograph review protocol into routine EAG activities.

370 **British Approved Names 2017: Supplement No. 4** COM(20)11

Supplement No. 4 to British Approved Names 2017, containing 44 new names, had been prepared and a copy was provided for confirmation. The text had been agreed by the Expert Advisory Group on 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 any comments to Mr Evans by **17th April 2020.**

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 2021 publications.

V ANALYTICAL ISSUES

None.

VI EXPERT ADVISORY GROUPS / PANELS OF EXPERTS

371 **Working Party AQbD: Analytical Quality by Design** COM(20)12

The report of the WP AQbD meeting (18:12:18) was approved.

372 **Expert Advisory Group MC3: Medicinal Chemicals** COM(20)13

The report of the EAG MC3 meeting (24:09:19) was approved. Part of the meeting had been devoted to a workshop which had looked at the proposed addition of the track-changes feature to the BP website. The outcomes from the workshop had been relayed to the publisher and had been incorporated in the first phase of the project (minute 361 refers).

373 **Working Party AQbD: Analytical Quality by Design** COM(20)14

The report of the WP AQbD meeting (04:10:19) was approved.

374 **Expert Advisory Group ULM: Unlicensed Medicines** COM(20)15

The report of the EAG ULM meeting (16:10:19) was approved and the following point was raised.

Ready to Administer Injections; Buffered Antibiotics In light of the increasing use of continuous/extended use infusion antibiotics in the home environment, the EAG had discussed the possible development of monographs for buffered antibiotics and expansion

of the Supplementary Chapter on the Aseptic Preparation of Unlicensed Medicines to include a section on Ready to Administer Injections.

375 **Expert Advisory Group MC2: Medicinal Chemicals** COM(20)16

The report of the EAG MC2 meeting (22:10:19) was approved.

376 **Expert Advisory Group MC1: Medicinal Chemicals** COM(20)17

The report of the EAG MC1 meeting (03:12:19) was approved and the following point was raised.

Fluconazole Preparations A member questioned the inclusion of correction factors for the determination of impurities B and C when these were not included in the monograph for Fluconazole. It was noted that the Laboratory had recommended the use of these correction factors and that this had been accepted by EAG MC1.

377 **Expert Advisory Group ABS: Antibiotics** COM(20)18

The report of the EAG ABS meeting (09:12:19) was approved.

VII EUROPEAN PHARMACOPOEIA

378 **European Pharmacopoeia Update** COM(20)19

European Pharmacopoeia Commission Members discussed items from the 165th Session of the EP Commission (November 2019) and advised the UK delegation accordingly.

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

379 **International Update** COM(20)20

Members were provided with an update on international activities.

MHRA Visit to India Dr Atkinson and Mr Pound had represented the MHRA and BP during an MHRA visit to India in February. Meetings had been held with key regulatory and industry stakeholders at a series of events, including the 5th India Pharmaceutical Forum, the Industry Round Table and the Central Drugs Standard Control Organisation (CDSCO).

International Meeting of World Pharmacopoeias (IMWP) Mr Pound and Mr Gibb had attended the 11th meeting which had been held in Strasbourg in February. Areas of discussion had included the White Paper on the added value of pharmacopoeia standards for public health and nitrosamine contamination.

Chinese Pharmacopoeia Mr Pound and Mr Evans had held a teleconference with the Chinese Pharmacopoeia (CP) in March. Continued collaboration had been discussed.

IX REPORTS OF THE SECRETARY AND SCIENTIFIC DIRECTOR

380 **Pharmacopoeial Compliance** Attention was drawn to a series of articles on pharmacopoeial compliance that had been published on the PharmTech website.

X ANY OTHER BUSINESS

381 **Date of next meeting**

Monday 6th July 2020.

FOR INFORMATION:

382 **UK Transition Period**

Following the exit of the UK from the European Union on 31st January 2020 a statement providing information for users of the British Pharmacopoeia during the Transition Period (1st February to 31st December 2020) had been included on the BP website. This assured users that the UK would continue to be a member of the European Pharmacopoeia, as the UK would continue to be a member of the Council of Europe its own right, and that the Ph Eur text would continue to be reproduced in the BP.

383 **Items for Future Meetings**

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