SUMMARY MINUTES

of the

BRITISH PHARMACOPOEIA COMMISSION

A meeting of the British Pharmacopoeia Commission was held via videoconference on Monday 15th March 2021.

Present: Professor K Taylor (*Chair*), Professor A G Davidson (*Vice-Chair*), Dr E Amirak, Dr A Barnes, Dr J Beaman, Dr A M Brady, Dr G Cook, Dr A Gleadle (*lay member*), Dr V Jaitely, Mr R Lowe, Dr P Marshall, 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, Dr H Bowden, Ms H Corns, Mr P Crowley, Mr L Elanganathan, Mr A Evans, Mr A Gibb, Mr G Kemp, Mr S Maddocks, Mr R Smith, Ms A Thomson, Mr M Whaley and Mr S Young.

435 **Introductory Remarks**

Welcome The Chair welcomed members to the meeting. Dr J Barry (Chief Clinical Officer at the Cell and Gene Therapy Catapult and Chair of the Working Party on Advanced Therapy Medicinal Products) attended the meeting for the item recorded under minute 441.

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.

MHRA Dr June Raine had been appointed as Chief Executive of the MHRA in February, after having served as the interim Chief Executive since September 2019.

Appraisals The appraisal process was due to be completed by the end of May.

Obituary Members were saddened to learn of the death of Mr Edward Godly, who had been an active member of the former Committee on Nomenclature for almost 30 years between 1975 and 2003.

I MINUTES

436 The minutes of the meeting held on 9th November 2020 were confirmed.

II MATTERS ARISING FROM THE MINUTES

437 The following matters arising from the meeting held on 9th November 2020 were noted.

Minute 417 – Nitrosamines The next step would be to consult with stakeholders regarding the inclusion of a Production statement in BP monographs for drug substances and products at high risk of nitrosamine contamination.

Minute 423 – Panel VIP: Review of Membership Dr Martin Ilott had accepted the invitation to join Panel VIP.

III REPORTS AND CORRESPONDENCE

GOVERNANCE

438 Updates from the Secretary & Scientific Director

Mr Pound provided an update on how the BP and MHRA were responding to the global Coronavirus (Covid-19) outbreak and other key issues. He also wanted to place on record his thanks to the Commission and to all members of BP Expert Advisory Groups, Panels of Experts and Working Parties for their efforts over the past year.

439 Declaration of Interests; Code of Practice COM(21)1

Guidance for Members

Members agreed that the additional guidance was helpful and should be incorporated into future advisory documents.

Action for Chairs

It was agreed that further guidance for EAG Chairs should be provided.

OPERATIONAL

440 AQbD Project Update COM(21)2

The response to the MHRA Consultation on the "Application of Analytical Quality by Design Concepts to Pharmacopoeial Standards for Medicines" had been issued in August 2020. The AQbD Working Party had subsequently undertaken several workshops to identify the next steps for the project.

Supporting and Enabling Innovation It was intended that further practical evaluations would be carried out and the Secretariat was currently seeking to identify suitable future projects.

Application to Public Quality Standards The outcomes from the consultation had indicated support for the use of AQbD concepts in monographs. The first BP monograph to incorporate these concepts was scheduled for publication in the BP 2023.

A new Supplementary Chapter had been prepared for inclusion in the BP 2022, which would provide practical guidance on the application of AQbD including details on risk assessment, experimental design, statistical processing and ongoing monitoring of methods. The text would be included on the BP website for public comment and members would be invited to review the text as part of the second batch of BP 2022 DRT text.

Collaboration, Engagement and Knowledge Transfer Stakeholders were keen to receive information on the application of AQbD and the BP and MHRA were actively engaging with interested parties and organisations to raise awareness and promote the exchange of information.

Discussion The Secretariat and the Working Party would be looking at all aspects and one of the next key steps for the work would be to build a framework for the decision-making process.

It was expected that any changes in approach for BP monographs would be brought in gradually and that once the general AQbD principles were established the need for laboratory evaluation could be reduced. It was predicted that in the longer term more robust monographs would be developed which would not require updating.

441 **Working Party ATMP: Progress Report** COM(21)3

Background The Working Party on Advanced Therapy Medicinal Products (ATMP) had been established in March 2020. Due to the unique and complex nature of these products the group had operated in a different way from that of the more traditional BP Expert Advisory Groups and Working Parties.

Sub-groups Two sub-groups of the Working Party had been established to focus on specific topics, consisting of experts from the industry, the NHS and academia The guidance had been developed by the members of the sub-groups with support from the Secretariat and two secondees from the Cell and Gene Therapy Catapult. The first sub-group was developing guidelines on Flow Cytometry and the second sub-group was developing guidelines on Vector Copy Number quantification.

Ways of Working Dr Barry thanked the Commission for their interest in the work of the Catapult. She said that ATMPs were rapidly evolving and she had welcomed the opportunity to work with the BP/MHRA in the development of important guidelines on Flow Cytometry and Vector Copy Number. She acknowledged that the sub-group approach had been a new way of working for the BP but noted that it had enabled the work to progress rapidly.

On behalf of the Commission the Chair thanked Dr Barry for her contributions and he acknowledged the amount of work undertaken by the Working Party and the Secretariat in a short period of time.

442 **Innovation Board Update** COM(21)4

Members were provided with an update on recent projects being undertaken by the joint BP-TSO Innovation Board.

Revision History A new feature (“Revision History”) would be included in the online version of the BP 2022, which would be used to indicate the nature of changes made to individual monographs and the rationale behind the change(s). This had been developed in response to user research which had highlighted the need for greater visibility of the changes to monographs over time.

OKO User Research A fourth round of user research was currently being undertaken by an external organisation seeking targeted input from two separate user groups. In addition, an online survey was being undertaken in March to seek wider views on how to improve the BP. Members would be provided with feedback from the survey and user research in due course.

443 **British Pharmacopoeia Laboratory** COM(21)5

British Pharmacopoeia Laboratory Reports The list of reports concerning new and revised monographs that had been prepared by the Laboratory since the November 2020 meeting was provided for information.

British Pharmacopoeia Chemical Reference Substances Tables providing information on BPCRS up to the end of January 2021 were provided for information.

444 **BPCRS Principles, Availability and Strategy** COM(21)6

Further to recent discussions relating to BPCRS and the set of principles agreed at the July 2020 meeting, the Secretariat updated members on (i) how the principles were being formalised into BP policy, (ii) how BPCRS issues were being addressed at EAG level and (iii) how the improved monitoring process was being expanded across the whole BPCRS catalogue.

BPCRS Monitoring in Response to Covid-19 Based on the latest information from the Department of Health and Social Care the enhanced monitoring that had been introduced for BPCRS associated with medicines that might be used for the treatment of Covid-19 had been reduced to 71 items, all of which were currently in stock. The Laboratory had subsequently looked at the feasibility of carrying out enhanced monitoring across the whole BPCRS catalogue and a suitable and proportionate approach was agreed.

IV FUTURE PUBLICATIONS

445 **British Pharmacopoeia 2022 Publications** COM(21)7

BP 2022 The Secretariat was currently preparing text for inclusion in the British Pharmacopoeia 2022 and the British Pharmacopoeia (Veterinary) 2022. All items included in the 10th Edition of the European Pharmacopoeia, together with those from Supplements 10.1 to 10.5, would be incorporated in either the BP 2022 or the BP (Vet) 2022, as appropriate. The 2022 publications would be published in August and would come into effect on 1st January 2022.

Electronic updates The text from Supplement 10.3 to the 10th Edition of the European Pharmacopoeia had been added to the online BP in December 2020, in advance of its implementation on 1st January 2021. The text from Supplements 10.4 and 10.5 would be available in advance of their implementation dates on 1st April and 1st July respectively.

Text for approval The Chair thanked members for their comments on the first batch of text and encouraged them to review the second batch in due course. He also thanked the Secretariat for providing feedback in response to the comments raised.

Preliminaries Members recommended that the British Pharmacopoeia 2022 and the British Pharmacopoeia (Veterinary) 2022 should be published and confirmed that the draft Prefaces to both publications were acceptable, subject to the addition of a statement highlighting the use of the BP internationally.

References to EU Requirements in the BP There were several references to EU requirements in the BP and BP (Vet). These would be updated for the BP 2022 publications in accordance with recommendations received from the Department of Health and Social Care legal advisers.

Approved Synonyms; Ph. Eur. Supplements 10.4 and 10.5 One new approved synonym was required relating to a new monograph included in Supplement 10.4 and was approved. This would be added to Appendix XXI B by means of the BP 2022 and would be incorporated within the online updates to the BP 2021 publications.

446 **Monographs for Omission from the BP 2022 and BP (Vet) 2022** COM(21)8

Since publication of the BP 2021 publications, three monographs had been identified as candidates for omission from the BP 2022 as the items were no longer the subject of UK Marketing Authorisations. 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 still international usage of these items, the list had been sent to the Expert Advisory Group on Unlicensed Medicines to check if the items were available as unlicensed formulations and a news item had been posted on the BP website.

As the items were still used overseas, it was agreed that these monographs should be retained in the BP for the time being.

447 **British Approved Names 2022** COM(21)9

A new edition of the British Approved Names publication (BAN 2022) would be published in August. This would be a consolidation of the 2017 edition and its four supplements, together with the addition of 38 new names.

Members were provided with the draft new entries 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. Mr Evans thanked the Chair for his input on the proposed action and use statements for the new entries.

[**SECRETARIAT NOTE** *Guidance on the establishment of rINNs is available on the WHO website (https://www.who.int/teams/health-product-and-policy-standards/inn).*]

Members were invited to review the text and to send any comments to Mr Evans by 31st March 2021. Subject to any comments received, the Commission approved the text for inclusion in British Approved Names 2022 and recommended that it should be published. The new edition would be published at the same time as the BP 2022 publications.

V ANALYTICAL ISSUES

448 **Analytical Methods – Evaluation Assessment** COM(21)10

A Laboratory Evaluation Risk Assessment (LERA) process had been agreed in March 2016. This was intended to introduce a robust and standardised evaluation procedure that could be used to decide whether laboratory evaluation of draft monographs was required. The process had subsequently been used by Expert Advisory Groups ABS, MC1, MC2 and MC3 and it was timely to review the application and success of the process.

Enhanced Approach EAG ABS: Antibiotics had recently applied a further risk-based review approach on outstanding laboratory requisitions with a view to reducing the need for practical evaluation of methods.

Current process Members were invited to share their views on how the current process was working and to advise if there were any other areas that should be considered. The aim was to develop an enhanced laboratory risk assessment process for use by the main monograph producing EAGs that would be presented at a future meeting.

The Secretariat would review the current process, taking note of the comments raised by members and the enhanced approach adopted by EAG ABS, and proposals for an updated and an enhanced process would be presented at a future meeting.

VI EXPERT ADVISORY GROUPS / PANELS OF EXPERTS

449 **Working Party ATMP: Advanced Therapy Medicinal Products** COM(21)11

The report of the WP ATMP meeting (19:08:20) was approved.

450 **Expert Advisory Group BIO: Biological and Biotechnological Products** COM(21)12

The report of the EAG BIO meeting (11:09:20) was approved.

451 **Expert Advisory Group MC3: Medicinal Chemicals** COM(21)13

The report of the EAG MC3 meeting (29:09:20) was approved and the following point was raised.

Acarbose Tablets The method proposed for determination of Related substances and Assay had not been found suitable for use as a pharmacopoeial method and it had been agreed that further options should be explored before the monograph was published.

452 **Expert Advisory Group MC2: Medicinal Chemicals** COM(21)14

The report of the EAG MC2 meeting (6:10:20 and 9:10:20) was approved and the following points were raised.

Salbutamol Preparations; Levothyroxine Preparations; Liothyronine Preparations Further work on these items was required before new and revised monographs could be published.

Adrenaline Preparations Data had been received and would be presented at the next meeting of EAG MC2 relating to the title and labelling of adrenaline monographs.

453 **Expert Advisory Group ULM: Unlicensed Medicines** COM(21)15

The report of the EAG ULM meeting (14:10:20) was approved and the following point was raised.

Compliance with BP Impurity Limits The group had discussed situations where unlicensed formulations were unable to comply with BP impurity limits and where there was no BP monograph for a particular formulation but there was a corresponding monograph in a different pharmacopoeia. It had been agreed that it would be helpful for some guidance to be published on these matters.

454 **Expert Advisory Group MC1: Medicinal Chemicals** COM(21)16

The report and summary report of the EAG MC1 meeting (19:01:21) was approved.

VII EUROPEAN PHARMACOPOEIA

455 **European Pharmacopoeia Update** COM(21)17

European Pharmacopoeia Commission Members discussed items from the 168th and 169th Sessions of the EP Commission 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

456 **International Update** COM(21)18

Members were provided with an update on international activities.

United States Pharmacopeia A teleconference with the USP had been held in November 2020 to discuss areas of mutual interest.

Chinese Pharmacopoeia The draft Memorandum of Understanding between the BP and the Chinese Pharmacopoeia had been sent to China for comment. The China Prosperity Fund for the MHRA had been approved and the BP would be working closely with the MHRA Inspectorate and Chinese authorities with the aim of holding a workshop in 2021/2022 focussed on the BP and UK inspection requirements.

Indian Pharmacopoeia A Memorandum of Understanding between the BP and the Indian Pharmacopoeia had been signed. This would allow opportunities for cooperation in the development of harmonised standards, the exchange of information on the quality of medicines and the sharing of technical expertise between the two pharmacopoeias.

International Meeting of World Pharmacopoeias (IMWP) The 12th IMWP meeting had been held (remotely) in February. The participants had discussed the outcome of the IMWP Scientific Priorities Survey, international harmonisation, impurity control and nitrosamine contamination, together with activities related to COVID-19.

IX REPORTS OF THE SECRETARY AND SCIENTIFIC DIRECTOR

None.

X ANY OTHER BUSINESS

457 **Date of next meeting**

Monday 5th July 2021.

XI BPC WORKSHOP: LESSONS LEARNED

458 A workshop was held after the meeting to seek views from members about their time on the BP Commission. The information obtained would be used to identify possible areas for development and improvement and would be incorporated into future training/induction sessions for new members as appropriate.

FOR INFORMATION:

459 **Items for Future Meetings**

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