SUMMARY MINUTES

of the

BRITISH PHARMACOPOEIA COMMISSION

A meeting of the British Pharmacopoeia Commission was held at 151, Buckingham Palace Road, London SW1W 9SZ on Monday 3rd July 2017.

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

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

Apologies for absence were received from Mr A Coulson and Professor M Simmonds.

Also present: Ms H Corns, Ms E Cotterill, Mr P Crowley, Mr L Elanganathan, Mr A Evans, Dr A Gardiner, Dr M Kalantarzadeh, Dr G Kemp, Dr C Lenihan, Ms G Li-Ship, Dr K Radi, Ms M L Wall, Mr M Whaley and Mr S Young.

142 **Introductory Remarks**

Welcome The Chair welcomed Dr Lenihan and Dr Radi, new members of the Secretariat, Dr Kalantarzadeh from the BP-NIBSC Herbals Laboratory and Ms Li-Ship (Senior Analytical Scientist, BP and Laboratory Services).

Staff News Dr Patience Holland had left the Secretariat at the end of June after nearly 28 years of service. Dr Samantha Atkinson had been appointed as Director of Business Transformation for the MHRA on a two-year secondment. Mr James Pound would take on the role of Group Manager for British Pharmacopoeia and Laboratory Services and also delegated responsibility for the role of Secretary & Scientific Director of the British Pharmacopoeia Commission during this time. Members wished Dr Atkinson and Mr Pound well in their new roles.

Members were pleased to note that Sir Michael Rawlins, Chair of the MHRA, had been appointed *Knight Grand Cross of the British Empire* (GBE) in the Queen's Birthday Honours List for his services to the safety of medicines, healthcare and innovation.

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

I MINUTES

143 The minutes of the meeting held on 8th March 2017 were confirmed.

II MATTERS ARISING FROM THE MINUTES

144 The following matters arising from the meeting held on 8th March 2017 were noted.

Minute 115 – Monograph Lifecycle Review; BP Work Programme The Secretariat had held some preliminary discussions with the Chair regarding the most useful way to present the information included in the BP work programme to members. It was intended to present a paper for discussion at the next meeting.

Minute 122 – Monographs for Omission from the BP 2018 and the BP (Vet) 2018 The monographs for Cinnamic Acid and Paraldehyde Injection had been retained in the BP 2018 as they were still used.

Minute 132 – Alkylsulfonate Esters: Production Statements in BP Monographs Discussions with the Licensing Division were on-going regarding the proposed introduction of a Production statement in these monographs.

III REPORTS AND CORRESPONDENCE

GOVERNANCE

145 **Update on the BP Digital Transformation Project**

Ms Cotterill and Mr Crowley gave a presentation outlining the progress that had been made regarding the feasibility study on bringing the digital element of the BP publication in house.

146 **MHRA Strategy for Pharmacopoeial Quality Standards for Biological Medicines: Update** COM(17)19

The public consultation on the MHRA Strategy for Pharmacopoeial Public Quality Standards had closed on 10th April. The comments received were currently being analysed and the intention was to provide a full analysis of the outcomes at the November meeting.

Stakeholder interest and response The consultation had been received positively and had generated a lot of interest. Meetings had been held with 10 stakeholders and 14 written responses had been received. Industry had been the main responder, with some companies providing comments through trade associations rather than directly.

Next steps and timelines The results were being reviewed by the Secretariat and by the MHRA. Further cross-agency meetings would be held with representatives from the BP, NIBSC, Licensing and the Inspectorate. The aim was to publish an official response later in the year and to present the outcomes to the BPC and to Expert Advisory Group BIO: Biological and Biotechnological Products.

OPERATIONAL

147 **General Principles for Finished Product Monographs of the European Pharmacopoeia** COM(17)20

Background The EP Commission had prepared a document entitled “Finished Product Monographs: General Principles”, which summarised the policies relating to the development of Ph Eur monographs for Finished Products. The Commission discussed the proposed Ph Eur approach to impurity control in these monographs.

BP policy The current BP policy for formulated preparation monographs was to control both impurities arising from the synthesis of the drug substance and any degradants arising from the manufacture or storage of the formulated preparation, where possible and practical. This was a long-standing policy that was intended to provide some assurance to an independent analyst that a product had been prepared from starting material of pharmacopoeial quality.

Members agreed that the current BP policy should be maintained for the time being but that a formal review should be undertaken at a suitable time in the near future.

148 **Aide Memoire** COM(17)21

The aide memoire had been updated to reflect changes and issues that had been discussed since the last version had been signed off (September 2014). A copy of the draft revised document was provided and the major changes had been highlighted for the benefit of members. The updated text was accepted, subject to minor editorial points.

149 **Policy List** COM(17)22

At the last meeting it had been agreed that a list highlighting current BP policies should be prepared. The purpose of the list would be to act as a general reminder to members and it would be especially useful when it came to the annual review of draft text for publication.

A short list of policies referred to during the March meeting had been prepared as a basis for discussion and the general format was considered appropriate.

It was noted that it might be useful to expand the list to include policies additional to those relevant to monograph development and the Secretariat would take this suggestion into consideration.

150 **British Pharmacopoeia Laboratory** COM(17)23

British Pharmacopoeia Laboratory Reports The list of reports concerning new and revised monographs that had been prepared by the Laboratory since the March 2017 meeting was provided for information.

British Pharmacopoeia Chemical Reference Substances Tables providing information on BPCRS activity over the last few months were provided for information.

IV FUTURE PUBLICATIONS

151 **British Pharmacopoeia 2018 Publications**

The BP 2018 and BP (Vet) 2018 would be published at the beginning of August. This was earlier than for previous editions and was one of the innovations introduced in the new publishing contract. A total of 41 new BP monographs had been added to the new editions (35 for the BP and 6 for the BP (Vet)).

The Chair thanked members for their contributions to the review of new and revised text via the Document Review Tool. He also thanked the Secretariat for the enormous amount of work carried out at all stages of the publication process.

V ANALYTICAL ISSUES

152 **New Analytical Technologies: *Ad-hoc* Group** COM(17)24

At the March meeting it had been agreed that a small group should be established with the remit of developing a framework for introducing new techniques into the BP which would encompass the identification, evaluation and timely introduction of such techniques. Six members had subsequently expressed an interest in becoming part of the group. A brief discussion would be held after the Commission meeting with those members present and the Commission would be kept informed of developments at future meetings.

VI EXPERT ADVISORY GROUPS / PANELS OF EXPERTS

153 **Expert Advisory Groups, Panels of Experts and Working Parties** COM(17)25

New Members Dr Reich, Ms Hartley and Mr Harrington had accepted the invitations to join EAGs ULM and HCM and the AQbD Working Party respectively.

Expert Advisory Group MC1: Medicinal Chemicals Dr Maqbool Ahmed had decided to stand down as the main Licensing representative on EAG MC1. Dr Elspeth Gray (Senior Pharmaceutical Assessor, Licensing Division) had been appointed as his replacement and members endorsed this appointment.

Retired Members Dr Adrian Bristow had resigned from EAG BIO. Professor Simon Gibbons had resigned from EAG HCM. Replacement members would be identified in due course.

154 **Expert Advisory Group NOM: Nomenclature** COM(17)26

The report of the EAG NOM meeting (14:02:17) was approved and the following point was raised.

British Approved Names 2017: Supplement No. 1 The draft Supplement had been reviewed in detail. The text has subsequently been presented to the BP Commission at the March meeting (minute 124 refers) and was scheduled for publication in August. The significant contribution of Dr Gerry Moss in the area of chemical nomenclature was acknowledged.

155 **Expert Advisory Group MC3: Medicinal Chemicals** COM(17)27

The report of the EAG MC3 meeting (21:02:17) was approved and the following points were raised.

Quetiapine Preparations; Related substances and Assay Concern was expressed at the possibility of including a resolution factor of less than 1.5 in a BP monograph. The current practice was to use the peak-to-valley ratio approach in such cases. The EAG had confirmed that current chromatographic software was capable of calculating resolutions of less than 1.5 and this approach was used in many internal methods.

Morphine Sulfate Injection It was agreed that the Secretariat should continue to seek information to ensure that the published Related substances method was suitable.

156 **Panel DNA: Identification Techniques** COM(17)28

The report of the Panel DNA meeting (22:02:17) was approved and the following points were raised. This had been the first meeting to be chaired by Professor Adrian Slater (DeMontfort University).

Molecular Characterisation Method for Detection of Pyrrolizidine Alkaloid – containing Herbal Drugs A comprehensive literature review had been undertaken on the analytical and molecular methods available for the determination of pyrrolizidine alkaloids.

BPNARM The second BPNARM reference material had been established and sequence details would be included in Appendix XI V in a future publication.

157 **Expert Advisory Group MC2: Medicinal Chemicals** COM(17)29

The report of the EAG MC2 meeting (09:05:17) was approved and the following points were raised.

Adrenaline Injection; Dilute Adrenaline Injection 1 in 10,000 The content of these monographs had been updated to include a requirement for L-adrenaline. The EAG had considered that it was important to specify a fixed strength for the L-adrenaline component for clarity.

Salbutamol Nebuliser Solution The EAG had been of the opinion that the test for Uniformity of Dosage Units should be included in the monograph and the intention was to raise this issue with EAG PCY: Pharmacy.

VII EUROPEAN PHARMACOPOEIA

158 **European Pharmacopoeia Update** COM(17)30

European Pharmacopoeia Commission

157th Session The draft report of the 157th Session of the EP Commission (March 2017) was available on the forum section of the BP website.

158th Session The 158th Session of the EP Commission had been held on 20th and 21st June and a copy of the agenda was provided for information.

Questionnaires sent to the UK National Authority Members were informed that national pharmacopoeial authorities regularly received questionnaires from the EDQM seeking information on whether or not products were licensed and/or on the market, with a view to recommending whether items should be added to or removed from the Ph Eur work programme or whether monographs should be suppressed in future publications. The Secretariat made enquiries and sought advice, as appropriate, before sending a response on behalf of the UK delegation. Examples of recent requests had been provided for information.

VIII INTERNATIONAL COLLABORATION

159 **International Strategy for the BP** COM(17)31

International Strategy Development An overview of the BP strategy relating to international work was presented.

Next steps It was important to gain a better understanding of the overseas usage of the BP so that this could feed into any future international strategy and members were asked for their ideas on how this information could be sought and utilised.

Recent activities Members were provided with an update on international activities.

CPhI China Mr Evans and Mr Gerald Heddell, Director of the Inspection, Enforcement & Standards division, had attended the recent CPhI China conference in Shanghai. There had been over 30,000 attendees at the event and a number of meetings with BP/MHRA stakeholders had been held. Mr Evans had given a presentation on the work of the BP and he had also had several informal discussions about the BP.

WHO Mr Evans had attended the 64th INN Consultations in Geneva. About 120 new names had been discussed, of which about half were biological products.

Ms Corns had attended the annual International Pharmacopoeia meeting. A number of issues relevant to BP monographs had been discussed including collaborative or harmonisation work relating to Moxifloxacin, Ritonavir and Pyrimethamine preparations.

Mr Pound and Dr Gardiner would be attending the 8th International Meeting of World Pharmacopoeias in Brazil. The meeting would focus on the continued development of the guidelines on Good Pharmacopoeial Practices and other topics of mutual interest.

IFPMA Mr Gibb had participated in a meeting of the International Federation of Pharmaceutical Manufacturers & Associations to discuss the challenges and requirements for biological monographs.

IX REPORTS OF THE SECRETARY AND SCIENTIFIC DIRECTOR

160 **Ministerial Responsibility**

Following the General Election, Lord James O'Shaughnessy, Parliamentary Under Secretary of State for Health (Lords), had been retained as the Minister responsible for the MHRA and Brexit.

161 **NPA Meeting**

Mr Pound had attended the recent meeting of Secretaries of National Pharmacopoeial Authorities and a number of issues had been discussed.

162 **Staff**

There had been a significant number of changes in staff and individual responsibilities at the Secretariat in recent months and further appointments would be in place later in the year. An update would be provided at the November meeting.

X ANY OTHER BUSINESS

163 **Appraisals**

The Chair thanked members for their participation in the appraisal process, which had now been completed.

164 **Meetings**

It was agreed that the continuing problems with the microphones in the meeting rooms should be raised with appropriate personnel.

165 **Date of next meeting**

Tuesday 14th November 2017.