

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 6th July 2015.

Present: Professor K Taylor (*Chair*), Professor A G Davidson (*Vice-Chair*), Mr B J Capon (*Lay Member*), Professor D Cairns, Dr G Cook, Mr C T Goddard, Dr K Helliwell, Dr R L Horder, Dr M G Lee, Dr B Matthews, Professor J Miller, Dr R Torano, Mrs J M Turnbull (*Lay Member*), Dr P Varley, Professor E Williamson.

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

Apologies for absence were received from Mr A Coulson and Dr L Tsang.

Also present: Mrs M Barrett, Ms H Corns, Mr P Crowley, Mr A Evans, Mr A Gibb, Dr C Howard, Dr P Holland, Dr R A Pask-Hughes, Mr J Pound, Mr M Whaley and Mr S Young.

970 **Introductory Remarks**

Staff Following the retirement of Mrs Matilda Vallender at the end of May, Mr James Pound had taken over the role of Editor-in-Chief. Mr Alistair Gibb would take over the role of Publications Manager from 1st August 2015.

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

971 The minutes of the meeting held on 30th March 2015 were confirmed.

II MATTERS ARISING FROM THE MINUTES

972 The following matters arising from the meeting held on 30th March 2015 were noted.

Minute 941 – Inhaled Products The updated policy document had been added to the BP website and the revised Supplementary Chapter had been included in the BP 2016 as agreed.

Minute 946 – Monographs for Omission from the BP 2016 and BP (Vet) 2016 Members noted that a number of changes had been made to the previously agreed list of monographs to be omitted from the BP 2016 publications: the monograph for Phenobarbital Sodium Tablets had been retained, pending further review of its availability; the monograph for Concentrated Peppermint Emulsion had been omitted (minute 981 refers).

Minute 951 – Analytical Methods – Evaluation Assessment The additional guidance for experts was not yet available.

Minute 967 – Appraisals Appraisals had been completed for all members and forms returned to the Department of Health.

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III REPORTS AND CORRESPONDENCE

973 Triennial Review

COM(15)24

The Triennial Review of the British Pharmacopoeia Commission had been published at the end of March and a copy was provided for information. As noted at the March meeting the review had confirmed that the functions of the BP Commission were still required and that the Commission should be retained as an advisory Non-Departmental Public Body. A number of recommendations had been made and a progress report on how these were being implemented had to be provided to the Cabinet Office in the autumn. The Chair said that the BPC had been praised for its innovative work, the dedication of its members and liaison with industry and noted that a further review would be undertaken in three years. Members would be kept informed of developments at future meetings.

Recommendation 6 – Commission Appointments Members noted the recommendation that the Secretariat and the Department of Health should meet to agree an appropriate model for future appointments processes. A teleconference had been held with DH before any action had been taken and the Secretariat was in regular communication with the Appointments Team.

Recommendation 8: the BPC and Secretariat should consider draft monograph publication to a specific predictable time-table, including a deadline for comment The review had recommended publication of draft monographs at agreed times and with a set date for comments. The Ph Eur and the USP had established mechanisms for seeking feedback on draft new and revised text (Pharmeuropa and Pharmacopoeial Forum respectively) and it was agreed that a similar approach should be adopted for the BP in order to encourage wider input, thereby leading to more meaningful and robust monographs.

Members endorsed the recommendation to post draft text on the website at regular, agreed intervals but there was some concern at the proposed 2 month commenting period (particularly the one starting in August).

The Secretariat agreed to reconsider the proposed timings before the new system was formally established.

974 British Pharmacopoeia Commission: Governance

COM(15)25

Principles of Good Corporate Governance As an advisory Non-Departmental Public Body, the BPC was required to comply with the Cabinet Office Principles of Good Corporate Governance, a copy of which were provided for information. Following the Triennial Review, the BPC had been found to be mostly compliant with the principles. The Secretariat had held discussions with the Chair to discuss areas where steps could be taken to improve the transparency of the governance of the BP Commission.

Roles and Responsibilities Information on the role and responsibilities of the Chair and members of the BP Commission was included in the preliminary pages of the BP publications.

Communications Provision 3 Summary minutes were publicly available on the BP website and these included all of the agenda items under discussion.

Provision 4 Members were reminded of the restrictions on political lobbying and attending Party Conferences in a professional capacity. The Secretariat would continue to provide copies of the Cabinet Office guidance at the time of general elections.

Conduct and Behaviour Members were reminded of the requirement to comply with the Code of Practice on Declaring Interests in the Pharmaceutical Industry and to complete a Declaration of

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Interests form each year. Attention was drawn to the rules on confidentiality outlined in the British Pharmacopoeia Commission Rules Governing Proceedings.

Agenda for Meetings It was agreed that the format of current agendas should be retained but that for future meetings any governance issues should be grouped together.

975 **Herbal and Complementary Medicines: Progress Report** COM(15)26

Members were provided with an update on the MHRA-NIBSC Herbal Project which was aimed at (i) authenticating herbal drugs using DNA barcoding and other relevant techniques and (ii) designing molecular-based methods for the identification of herbal drugs. It was stressed that in order to avoid overburdening the herbal industry, such methods would not routinely be included in monographs, but only where they added value.

BP 2016 The Appendix on Deoxyribonucleic Acid (DNA)-Based Identification Techniques for Herbal Drugs had been published in the BP 2016.

British Pharmacopoeia Nucleic Acid Reference Material (BPNARM) A new BP reference material had been established, *trnH-psbA* BPNARM, to support the new Appendix.

Future of the Herbals Project It had been agreed to extend the pilot project for another 3 years.

976 **British Pharmacopoeia Laboratory** COM(15)27

British Pharmacopoeia Laboratory Reports The list of reports concerning new and revised monographs that had been prepared by the Laboratory since the March 2015 meeting was provided for information.

British Pharmacopoeia Chemical Reference Substances The list of reports concerning British Pharmacopoeia Chemical Reference Substances (BPCRS) that had been tested since the March 2015 meeting was provided for information.

A list showing BPCRS stock levels between October 2014 and May 2015 was also provided. The target stock level was 96%. The Laboratory was aware of the concerns regarding out of stock items and steps were being taken to address the issue.

It was agreed that stock levels should be provided at every meeting.

BPC Laboratory Management Review A copy of the BPC Laboratory Annual Management Review was provided for information.

977 **Summary Minutes** COM(15)28

For transparency, it was agreed that a brief statement on interests should be included in summary minutes of meetings of the BP Commission and the Expert Advisory Groups and Panels of Experts.

IV FUTURE PUBLICATIONS

978 **BP Website: Update** *Oral*

Mr Gibb provided Commission with an update on the project to consolidate the current BP websites. The Secretariat was currently in the final checking stages and the beta version of the new website would be available for testing shortly. This would be made available to those Commission and EAG

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members who had previously indicated that they would be willing to be involved in the testing process.

The new website would include all of the BP 2016 material and all European Pharmacopoeia material up to and including Supplement 8.5. All of the non-publication text had been updated in line with Government guidelines on writing for websites and some text had been included or updated in order to address a number of issues raised under the Triennial Review.

V ANALYTICAL ISSUES

979 Assay Limits COM(15)29

Current policy The standard assay limits for BP formulated preparation monographs were “95.0 to 105.0% of the stated amount”, unless wider limits were justified.

New Monographs Limits of 95.0 to 105.0% were included, unless data had been received to support wider limits or a company had registered wider limits.

Revised Monographs Concern was expressed at the large number of published monographs that contained wider limits. The current approach to revision of monographs was that when specific aspects were being revised the opportunity was taken to review the whole monograph and this might result in a tightening of limits.

It was pointed out that ICH limits were $\pm 5\%$ and it was suggested that the Secretariat should introduce a formal revision programme with a view to updating monographs that contained out of date specifications. While members were supportive of this proposal it was noted that other aspects needed to be taken into consideration, for example the process capability and the accuracy/precision of a method.

VI EXPERT ADVISORY GROUPS / PANELS OF EXPERTS

980 Expert Advisory Groups, Panels of Experts and Working Parties COM(15)30

Ms Belen Granell-Villen, Professor Stephen Wicks, Dr Brian Alexander and Dr Ian Feavers had accepted the invitations to join EAGs NOM, PCY, Panel MIC and WP DNA, respectively.

Panel VIP: Veterinary Immunological Products Members endorsed the proposed appointment of Dr Rory Cooney (Biological Assessor, Veterinary Medicines Directorate; UK specialist member on Ph Eur Group 15V: Veterinary Sera and Vaccines) to the Panel.

981 Expert Advisory Group HCM: Herbal and Complementary Medicines COM(15)31

The report of the EAG HCM meeting (26:11:14) was approved and the following point was raised.

Concentrated Peppermint Emulsion The monograph had been omitted from the BP 2016. Following the previously agreed removal of the extemporaneous preparation details, the remaining monograph only included a Definition.

982 Panel MIC: Microbiology COM(15)32

The report of the Panel MIC meeting (2:12:14) was approved. This was the first meeting of the Panel since it had been established and had been held in order to discuss a number of draft European Pharmacopoeia texts and other issues.

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983 **Working Party DNA: Identification Techniques** COM(15)33

The report of the DNA Working Party meeting (21:1:15) was approved. This was the first meeting of the Working Party since it had been established (September 2014).

984 **Expert Advisory Group NOM: Nomenclature** COM(15)34

The report of the EAG NOM meeting (9:2:15) was approved.

985 **Expert Advisory Group ABS: Antibiotics** COM(15)35

The report of the EAG ABS meeting (27:2:15) was approved and the following points were raised.

Azithromycin Preparations; Dissolution It was questioned why the basket method had been selected for the Capsules formulation rather than the paddle method.

Clindamycin Tablets for Veterinary Use In view of the high level of water in Clindamycin Hydrochloride, members agreed that the EAG should reconsider the inclusion of a test for water in the tablets monograph.

Tylosin Granules for Veterinary Use Data had been received for products presented as Granules and as a Premix. In veterinary medicine granules and premixes were used differently and would be covered by separate monographs. The EAG had been of the opinion that a single monograph for Tylosin Premix should be elaborated. The discussion had identified potential anomalies in the General Monographs for Granules published in the BP and the BP (Vet) and these would be drawn to the attention of EAG PCY: Pharmacy and the Panel of Experts on Veterinary Medicines.

EMA Guideline Revision of monographs in accordance with the Guideline on Setting Specifications for Related Impurities in Antibiotics had proved challenging in light of the greater number of impurities now being specified and issues with the additional reference materials that were now required.

VII EUROPEAN PHARMACOPOEIA

986 **European Pharmacopoeia Update** COM(15)36

European Pharmacopoeia Commission A summary of the decisions taken at the 152nd Session of the EP Commission (June 2015) was provided for information.

e-Cigarettes Members were informed that the Department of Health had launched a consultation on the provisions of the Tobacco Products Directive. The MHRA had been named as the national competent authority responsible for implementing various areas of legislation around e-cigarettes (consumer products). The BSI Publically Available Specification (PAS) had been published and could be provided to members on request.

Rules of Procedure Mr Pound had attended the recent meeting of the Rules of Procedure Working Party.

VIII INTERNATIONAL COLLABORATION

987 **International Collaboration** COM(15)37

Members were provided with an update on international activities.

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WHO 5th International Meeting of World Pharmacopoeias Dr Atkinson and Dr Swanson had attended this meeting which had been held at the offices of the United States Pharmacopeia. The meeting had focussed on the continued development of the guidance on Good Pharmacopoeial Practices and had been followed by a USP Stakeholders meeting attended by pharmacopoeial and industry representatives.

USP Convention Dr Atkinson and Mr Pound had attended the USP Convention which was held every 5 years in Washington DC.

Chinese Pharmacopoeia; Indian Pharmacopoeia; State Pharmacopoeia of Ukraine; State Pharmacopoeia of the Republic of Kazakhstan Meetings had been held with representatives of these pharmacopoeias during the WHO meeting and the USP Convention. Current activities and future collaboration opportunities had been discussed.

Therapeutic Goods Administration Mr Young had visited the Australian TGA and had provided an overview of the BP Secretariat and Laboratory work and discussed a number of BP issues with representatives from the TGA.

National Pharmacopoeial Authorities Dr Atkinson had attended the annual NPA Secretaries meeting, which had been held in The Netherlands.

Official Medicines Control Laboratories Network Dr Atkinson, Mr Young and Ms Li-Ship (Secretariat) had attended the annual meeting of the OMCL network, which had been held in Brussels. The remit of the group covered all aspects of regulatory control laboratory testing.

IX REPORTS OF THE SECRETARY AND SCIENTIFIC DIRECTOR

988 Appointments to the BP Commission

A significant number of members were due to retire from the BP Commission at the end of the year as they had served for the maximum allowable term (10 years) and all remaining members would reach the end of their current term of office. The Secretariat was working closely with the Department of Health to ensure that the process to appoint and re-appoint members was successful. If members were aware of anyone who might be interested in becoming a member, they were encouraged to alert them to the advert and to apply.

989 Customer Insight Research Project

The Secretariat had been working with the Communications Division of the MHRA in order to increase the profile of the BP. Funding had been received for a Customer Insight Research Project, which had taken the form of an online survey and a number of interviews. The findings of the report would be provided to Commission at a future meeting.

X ANY OTHER BUSINESS

990 Panel CX: Excipients It was agreed that the Secretariat should ensure that relevant monographs and texts were provided to Panel CX.

991 Date of next meeting

Wednesday 4th November 2015.

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992 Meeting dates for 2016

Monday 7th March 2016

Monday 4th July 2016

Monday 14th November 2016

993 Text for the BP 2017

The Secretariat would be identifying dates for the review of text for the BP 2017. These dates would be provided at the next meeting.