SUMMARY MINUTES

of the

BRITISH PHARMACOPOEIA COMMISSION

A meeting of the British Pharmacopoeia Commission was held at Market Towers, 1 Nine Elms Lane, London SW8 5NQ on Monday 10th December 2007.

Present: Mr V Fenton-May (Vice-Chairman), Dr A H Andrews, Professor D Cairns, Mr B J Capon (Lay Member), Professor A G Davidson, Mrs M A Dow, Dr T D Duffy, Mr C T Goddard, Dr R L Horder, Dr A M T Lee, Professor A C Moffat, Dr L Tsang, Mrs J M Turnbull (Lay Member), Professor E Williamson.

In attendance: Dr M G Lee (Secretary & Scientific Director), Dr F J Swanson.

Apologies for absence were received from Professor A D Woolfson (Chairman), Professor G Buckton and Professor P York. In the absence of Professor Woolfson, Mr Fenton-May chaired the meeting.

Also present: Dr P Holland, Miss N Thomas, Dr R A Pask-Hughes, Dr A Ruggiero, Mr R Turner, Mrs M Vallender and Mr S Young.

321 Introductory Remarks

Welcome The Acting Chairman welcomed Dr Andrea Ruggiero, a new member of the Secretariat, who was attending the meeting for training purposes. Dr Ruggiero would be helping mainly with the work on Biologicals, Unlicensed Medicines and Medicinal Chemicals (MC2).

Appointments to the Commission Members were pleased to learn that Dr Keith Helliwell (William Ransom & Son) had been appointed to the Commission for a four year term starting from 1st January 2008.

Staff Ms Lorraine Phillips had left the Secretariat and a replacement General Office Manager would start work in January 2008. Miss Jancinta Paine had recently joined the administrative staff and members were asked to send their completed expense claims to Miss Paine for the time being.

Declaration of Interests Members were reminded of the need to inform the Secretariat of any changes to their interests throughout the year.

I MINUTES

322 The minutes of the meeting held on 17th September 2007 were confirmed.

II MATTERS ARISING FROM THE MINUTES

323 The following matters arising from the meeting held on 17th September 2007 were noted.

Minute 303 – Aide Memoire The finalised document had been issued to members of the Commission and to all members of the Expert Advisory Groups, Panels of Experts and Working Parties.

Minute 303 – Uniformity of Dosage Units A paper would be presented at the meeting of the Pharmacy EAG on 11th December 2007 and the outcome of the discussion would be brought to Commission’s attention in due course.
Minute 305 – Use of the terms Response Factor and Correction Factor  A member had raised the issue of the use of correction factors outside the normal range of 0.2 to 5.0 with the EP Secretariat. Their response had been that if an external standard could not be used, the use of a different wavelength would be examined; if this approach was not successful, use of a correction factor outside the normal range would be considered.

Minute 309 – Monograph Initiation: Veterinary Monographs A meeting had been held with members of the Veterinary Pharmacists Group (VPG) at the end of October and they had undertaken to provide the Secretariat with sales lists of veterinary medicines.

Minute 312 – Unlicensed Medicines Mr Rothwell had accepted the invitation to join the Expert Advisory Group on Unlicensed Medicines.

III REPORTS AND CORRESPONDENCE

324 Annual Report for 2007 of the British Pharmacopoeia Commission COM(07)41

A first draft of the 2007 Annual Report of the British Pharmacopoeia Commission was presented and accepted, subject to any comments received from members before 20th December 2007. The BP Annual Report would be published in the Medicines Act 1968 Advisory Bodies Annual Reports (2007), along with the reports of the other Section 4 Committees.

325 Microbial Limits for Oral Liquids COM(07)42

Many unlicensed oral liquids formulated for paediatric or neo-natal use were unpreserved as there was the possibility of clinical adverse reactions in this population due to the use of chemical preservatives. The Expert Advisory Group on Unlicensed Medicines had raised concerns about microbial contamination of such formulations, particularly during storage and after opening multi-dose preparations.

It was proposed that a suitable Production statement should be included in the General Monograph for Unlicensed Medicines under the section on Oral Liquids. A draft form of words had been prepared covering both preserved and preservative-free formulations and was accepted, subject to specifying that compliance with pharmacopoeial requirements applied throughout shelf-life. The draft text would be amended appropriately and included in the British Pharmacopoeia 2009.

It was also intended to include further advice on preservative-free oral liquids in the Supplementary Chapter on Unlicensed Medicines and members agreed with this approach.

326 Vaccine Abbreviation Position Paper for WHO COM(07)43

A draft position paper had been considered by the Panel of Experts on Biological and Biotechnological Products at their meeting on 17th October 2007. A revised version had been submitted to the EAG on Nomenclature for comment. A further revised version was presented to Commission, together with comments received from the BIO Panel and the Nomenclature EAG. The draft paper proposed that an internationally acknowledged unambiguous set of abbreviations should be established and included possible approaches to devising vaccine abbreviations and perceived potential problems with certain abbreviations already in use.

Commission endorsed the content of the draft position paper and agreed that it should be sent to WHO.
British Pharmacopoeia Laboratory

British Pharmacopoeia Chemical Reference Substances  The list of reports concerning British Pharmacopoeia Chemical Reference Substances (BPCRS) that had been circulated for approval since the September 2007 meeting was provided for information.

A summary of the status of procurement, testing and release of new BPCRS was also provided for information. The aim was to ensure that BPCRS were available as soon as possible and in advance of implementation of the edition of the BP in which they were first specified.

British Pharmacopoeia Laboratory Reports  The list of reports concerning new and revised monographs that had been prepared by the Laboratory since the June 2007 meeting was provided for information. A number of reports had also been prepared in connection with the BP Laboratory’s participation in the EDQM Proficiency Testing Scheme which was part of the LGC Quality System.

Frequency and Timing of Meetings

For many years there had been four meetings of the BP Commission per year (in March, June, September and December). The Chairman, Vice-Chairman and Secretary & Scientific Director had discussed the matter taking note of the key dates for the publication cycle of the British Pharmacopoeia, meetings of the Expert Advisory Groups and the European Pharmacopoeia Commission and also sub-optimal meeting dates for Secretariat and Commission members. It had been suggested that it might be appropriate to reduce the number of meetings to three per year and Commission concurred.

Quorum for BP Commission and Expert Advisory Groups

At a recent meeting of EAG MC1: Medicinal Chemicals, it had been questioned whether there was an agreed minimum number of members required to be present before a meeting can go ahead. There was currently nothing formally agreed with regard to a quorum for the BP Commission and the Expert Advisory Groups and it was agreed that the same approach should be adopted as that taken for the Commission on Human Medicines and its Expert Advisory Groups.

FUTURE PUBLICATIONS

Approved Synonyms

The draft list of new Approved Synonyms relating to items added to the European Pharmacopoeia by means of Supplement 6.1 to the Sixth Edition was approved. The list would be presented to the Commission on Human Medicines for their recommendation to publish. The items would be added to Appendix XXI B in the next edition of the British Pharmacopoeia and would be brought into effect on 1st April 2008 by publication in the Belfast, Edinburgh and London Gazettes.

Desflurane; Niflumic Acid; Selamectin  These names had not yet been adopted as British Approved Names and would be incorporated in the BAN 2007 publication by means of Supplement No. 2.

EXPERT ADVISORY GROUPS / PANELS OF EXPERTS

Membership

Expert Advisory Group ULM: Unlicensed Medicines  Mr Mark Oldcorne (Quality Assurance Pharmacist, Wrexham Maelor Hospital) had been nominated as a member of the EAG on Unlicensed Medicines. Mr Oldcorne should be able to assist in the practical evaluation of draft monographs and Commission endorsed his appointment to the EAG.
Panel of Experts RAD: Radioactive Materials  Mr Dominic Lui had resigned from the Panel of Experts on Radioactive Materials following his retirement from University College Hospital. A letter had been sent to Mr Lui thanking him for his service over the years.

332  Duties and Role of a Member  COM(07)49

British Pharmacopoeia Commission  Members were reminded that “duties” of Commission members were listed in the preliminary pages of the British Pharmacopoeia and that the “role” of a Commission member was outlined in the application form for membership of the Commission.

Expert Advisory Groups, Panels of Experts and Working Parties  At the present time there were no defined duties and roles for members of the Expert Advisory Groups, Panels of Experts and Working Parties and it was proposed that these should be established. The Secretariat had prepared draft forms of words and these were accepted.

333  Expert Advisory Group MC3: Medicinal Chemicals  COM(07)50

The report of the EAG MC3 meeting (25:9:07) was approved and the following points were raised.

Propylene Glycol; Diethylene glycol test limit  In the final sentence, reference to “each container of a preparation” should be replaced by reference to containers of propylene glycol raw material.

Fluticasone Nasal Drops; Content  It was noted that, unusually, the nasal drops were presented in ampoules.

Orodispersible Mirtazapine Tablets  This was the first specific monograph for an orodispersible formulation prepared for inclusion in the BP.

Tibolone Tablets  The issue relating to the test for Uniformity of dosage units would be discussed at the meeting of the Pharmacy EAG on 11th December 2007.

334  Panel BIO: Biological and Biotechnological Products  COM(07)51

The report of the BIO Panel meeting (17:10:07) was approved and the following points were raised.

Interferon Alfa-2 Injection  The Panel had proposed that two separate injection monographs should be prepared, based on information received from manufacturers, and Commission endorsed this proposal.

Human Glucagon Injection  The EAG had recommended that the BP monograph should be progressed, rather than waiting till the USP monograph had been finalised, and further advice would be sought.

Low-Molecular-Weight Heparins  A member questioned whether Low-molecular-weight Heparins should be renamed as Low-molecular-mass Heparins, in line with the European Pharmacopoeia. It was noted that Low-molecular-weight was used in the BNF and that prescribers would use Low-molecular-weight rather than Low-molecular-mass. It was agreed that no changes should be made at the present time, but that the Secretariat should review the matter at a suitable time in the future.

335  Expert Advisory Group HCM: Herbal and Complementary Medicines

The following matter had been raised at the November meeting of the Expert Advisory Group on Herbal and Complementary Medicines.

The EAG had agreed that a recommendation should be made to the UK delegation to the EP Commission requesting that the word “potentisation” should be deleted from the title of the
monograph for *Methods of Preparation of Homoeopathic Stocks and Potentisation* and from the Ph Eur. After a wide ranging discussion it was agreed that a request would be submitted to the EPC.

VI EUROPEAN PHARMACOPOEIA

336 129th Session of the EP Commission

Members were informed of issues discussed at the 129th Session of the EP Commission (November 2007).

337 UK Members of Expert Groups and Working Parties

The list of UK members and Chairs of Ph Eur Expert Groups and Working Parties elected at the 129th Session of the European Pharmacopoeia Commission was provided for information. Members were pleased to note that UK representatives now Chaired three Expert Groups and two Working Parties.

It was agreed that Mr Brian White, the new UK member of Group 7 (Antibiotics), should be invited to join the Expert Advisory Group on Antibiotics.

VII REPORTS OF THE SECRETARY AND SCIENTIFIC DIRECTOR

338 British Pharmacopoeia 2008

Members noted that an article entitled “Setting the Standards for Medicines – the British Pharmacopoeia” had been published in a recent issue of the Pharmaceutical Journal (Volume 279, 17 November 2007, p. 566-567). The article provided information on the history of the BP and a section promoting the BP 2008.

339 Confidentiality

Members were reminded that any items provided to the Commission should be treated as confidential; this also applied to work associated with the Expert Advisory Groups and Panels of Experts. The need for members to declare any relevant interests during meetings was stressed and it was noted that these would be recorded in the formal Minutes of relevant meetings.

Completion of an annual declaration of interests form was a requirement for all Commission members. The Secretary & Scientific Director requested that the forms be completed by the requested deadline.

340 BP Laboratory

In collaboration with the Laboratory of the Government Chemist, the BP Laboratory were now able to provide customers with Dissolution Performance Verification Tablets.

341 Relations with other Pharmacopoeias

Members were pleased to note that the US Food and Drug Administration (FDA) had issued a statement announcing that the FDA now recognised alternative compendia including the British, European and Japanese Pharmacopoeias.

The Secretary & Scientific Director had been invited to attend the Indian Pharmaceutical Conference later in the month and would be making a presentation on the work of the BP Commission. This would provide an excellent opportunity to promote the BP 2008 in India.
VIII ANY OTHER BUSINESS

342 Long-standing BP Commission Members

This had been the last meeting for Dr Andrews and Professor Moffat. On behalf of the Commission, the Acting Chair thanked both members for their contributions over the years. Dr Andrews had been a member of the BP Commission since 1998. He was currently a member of the EAG on Antibiotics and the Panel of Experts on Veterinary Immunological Products and had previously served as a member of the Panel on Microbiology. Professor Moffat had been a member of the BP Commission since 1996. He was the current Chairman of the EAG on Herbal and Complementary Medicines and would continue to serve as a member of the EAG after his retirement from Commission; he had also previously served as a member of the Pharmacy Committee.

343 Retired EP Group Members

A number of long-standing UK members of Ph Eur Groups of Experts and Working Parties had retired following the November session of the EP Commission. On behalf of the Commission, the Acting Chair thanked Dr Aileen Lee and Professor Elizabeth Williamson for their contributions to Groups of Experts 15V (Veterinary Sera and Vaccines) and 13A (Phytochemistry) respectively over the years.

344 Date of next meeting