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 18th September 2007.

Present: Professor A D Woolfson (Chairman), Mr V Fenton-May (Vice-Chairman), Professor G Buckton, 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, Mrs J M Turnbull (Lay Member), Professor E Williamson, Professor P York.

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

Apologies for absence were received from Dr A H Andrews and Dr L Tsang.

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

301 Introductory Remarks

European Pharmacopoeia Commission  The Chairman informed members that Dr M G Lee had been elected as the Second Vice-Chair of the European Pharmacopoeia Commission.

Awards  Members were pleased to learn that Dr Linda Anderson, Vice-Chairman of the EAG on Herbal and Complementary Medicines, had been awarded an Honorary Fellowship of the School of Pharmacy for services to pharmacognosy and the pharmaceutical regulation of medicines, and that Dr Alistair Millar, a member of the Panel of Experts on Radioactive Materials, had been awarded the 2007 Guild of Healthcare Pharmacists Gold Medal for his contribution to the practice of hospital pharmacy.

2006 Annual Report  A letter had been received from the Department of Health thanking Commission for the 2006 Annual Report and for the work carried out during the year.

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

I MINUTES

302 The minutes of the meeting held on 4th June 2007 were confirmed.

II MATTERS ARISING FROM THE MINUTES

303 The following matters arising from the meeting held on 4th June 2007 were noted.

Minute 284 – Uniformity of Dosage Units  The Secretariat had sought advice on the intended application of the test. It was intended to present a paper on this matter at the December meeting.

Minute 285 – Unlicensed Medicines  Mr Charvill had accepted the invitation to join the new Expert Advisory Group on Unlicensed Medicines.

British Approved Names 2007: Supplement No. 1  The Commission on Human Medicines had recommended publication of the Supplement at their June meeting and it had been published at the end of August.
Minute 289 – Membership
Dr Warner had accepted the invitation to join the EAG on Nomenclature and a letter of thanks had been sent to Professor Cousins.

III REPORTS AND CORRESPONDENCE

304 Former Monograph Titles – Removal of Statement

Members were reminded that, with the exception of the adrenaline/epinephrine and noradrenaline/norepinephrine monographs, dual-labelling had been removed from the British Pharmacopoeia by means of the BP 2003. The titles of the affected monographs had been changed to include the recommended International Nonproprietary Names and a statement referring to the former British Approved Names had been included at the head of the monographs.

It had been intended to remove the introductory statement after five years and Commission endorsed the recommendation to delete the statements from the BP 2009.

305 Use of the Terms “Response Factor” and “Correction Factor”

Members were informed that the Secretariat had received several queries requesting clarification of the terms “response factor” and “correction factor” and how they should be applied. The terms, and variations thereof, were usually included in HPLC methods and were defined in Supplementary Chapter I A: Control of Impurities. It had been proposed that, to avoid confusion, a single term should be used throughout the BP and members concurred. The most commonly used term was correction factor and it was agreed that relevant BP monographs should be amended to specify correction factor in the BP 2009.

306 Heavy Metals

In response to a query regarding the meaning of the term “Heavy metals”, the Secretariat had found that there was no definitive definition of the term either in the British or European Pharmacopoesias or in the published literature.

It was not intended to create a pharmacopoeial definition for Heavy metals, as this might exacerbate confusion. However, it had been suggested that a section entitled “Additional points for monographs of the British Pharmacopoeia” should be included in Appendix VII listing those elements that were known to be detected by the test for Heavy metals. A draft form of words had been prepared and was tentatively agreed.

307 British Pharmacopoeia Laboratory

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

IV FUTURE PUBLICATIONS

308 Approved Synonyms

The draft list of new Approved Synonyms relating to items added to the European Pharmacopoeia by means of 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 January 2008 by publication in the Belfast, Edinburgh and London Gazettes.

Vinpocetine

Vinpocetine had not yet been adopted as a British Approved Name and would be incorporated in the BAN 2007 publication by means of Supplement No. 2.
**Monograph Initiation**

**Human Monographs** The list of candidate monographs that had been identified in accordance with the previously agreed criteria had been added to the work programme and was provided for information. Additional items had been identified which did not fall within the specified criteria and Commission was invited to consider whether these items should be added to the work programme.

**Dantrolene Sodium Capsules; Dexamethasone Oral Suspension; Glyceryl Trinitrate Ointment; Levothyroxine Oral Solution; Liquid Paraffin and White Soft Paraffin Ointment; Sodium Citrate Oral Solution** Commission agreed that monographs should be elaborated.

**Desloratadine; Insulin Glargine; Risedronate Sodium** Formulations containing these active substances were widely used and it was agreed that the European Pharmacopoeia Commission should be invited to add the items to their work programme.

**Nicorandil** As products containing Nicorandil were widely used in the UK, it was agreed that a BP monograph for the active substance should be prepared, if possible.

**Veterinary Monographs** The Secretariat was trying to obtain information on the extent of use of items used in veterinary medicine and a paper would be presented at the December meeting.

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**V EXPERT ADVISORY GROUPS / PANELS OF EXPERTS**

**Expert Advisory Group HCM: Herbal and Complementary Medicines**

The report of the EAG HCM meeting (5:6:07) was approved and the following points were raised.

**British Pharmacopoeias 2008 and 2009** Twelve new monographs for Traditional Chinese Medicines and Homoeopathic Preparations had been included in the BP 2008.

**Senna Tablets; Loss on drying** The EAG had questioned the need for the Loss on drying test and Commission endorsed the recommendation to delete the test from the monograph.

**Apomorphinum Muriaticum for Homoeopathic Preparations; Production of Stocks** Since some of the methods of production were still under consideration by the EP Commission the EAG had discussed whether a general production statement should be included in relevant monographs, in line with the approach used in Ph Eur homoeopathic monographs for mother tinctures. In order to fulfil the requirements of EC Directive 2001/83/EC, as amended, reference to a method of production must be included and the EAG had proposed that, for the time being, inclusion of a general statement was the way forward; Commission concurred.

**Glossary** The Secretariat would try and develop a glossary of terms used in the processing of Traditional Herbal Medicines for inclusion in a future Supplementary Chapter.

**Expert Advisory Group ULM: Unlicensed Medicines**

The report of the first EAG ULM meeting (28:6:07) was approved and the following points were raised.

**Caffeine Citrate Oral Solution; Definition** The EAG had further discussed the perceived need to include a sterility requirement for unlicensed oral liquids presented as single-dose formulations for use in neonates. It was intended to present a paper on this matter at the December meeting.
**British Pharmacopoeia 2008 Monographs**  The Secretariat would be writing to all manufacturing (Specials) licence holders to inform them of the publication of the BP 2008 monographs on unlicensed medicines.

312  Membership  

**Expert Advisory Group ULM: Unlicensed Medicines**  Mr Jeff Rothwell (Rosemont Pharmaceuticals) had been nominated as a member of the EAG on Unlicensed Medicines and Commission endorsed his appointment to the EAG.

VI  EUROPEAN PHARMACOPOEIA

313  Groups of Experts and Working Parties  
The membership of all the Groups of Experts and Working Parties would be reviewed at the November session of the EP Commission.

314  128th Session of the EP Commission  

Members were informed of issues discussed at the 128th Session of the EP Commission (June 2007).

VII  REPORTS OF THE SECRETARY AND SCIENTIFIC DIRECTOR

315  British Pharmacopoeia 2008  The BP 2008 had been published at the end of August and contained over 50 new monographs. A foreword from Professor Alastair Breckenridge, the Chairman of the MHRA, had been included. Innovations included colour printing (indicator colour charts) and requirements for unlicensed medicines.

316  Appointments  The process to recruit two new members of the Commission from 1st January 2008 was under way and interviews would be held in early November.

Members were pleased to note that Mr Fenton-May had been re-appointed to the Commission.

317  Traditional Chinese Medicines  A Memorandum of Understanding (MoU) had been signed between the MHRA and China’s State Food and Drug Administration. The MoU recognised the importance of developing close cooperation and exchange of information between the two organisations, including sharing information on materials used in Traditional Chinese Medicines and the authentication of reference materials.

318  Relations with other Pharmacopoeias  The Secretary & Scientific Director said that both the WHO International Pharmacopoeia and the Indian Pharmacopoeia were keen to develop a working relationship with the British Pharmacopoeia with a view to creating common standards.

319  Laboratory  A new member of staff had recently been appointed. Professor Kent Woods, the Chief Executive of the MHRA, had visited the Laboratory during August.

VIII  ANY OTHER BUSINESS

320  Date of next meeting  

Monday 10th December 2007.