

## Committee P: Pharmacy

### BRITISH PHARMACOPOEIA COMMISSION

#### Committee P: Pharmacy

#### SUMMARY MINUTES

A meeting of this Committee was held at Market Towers, 1 Nine Elms Lane, London SW8 5NQ on Tuesday, 6 June 2006.

**Present:** Dr R L Horder (Chair), Prof. A D Woolfson (Vice Chair), Prof. M E Aulton, Mrs E Baker, Dr S K Branch, Dr G Davison, Dr G Eccleston, Dr B R Matthews, Dr W F McLean, Mr J F McGuire, Dr S Nichols, Dr P Wood.

**In attendance:** Dr M G Lee, Dr M O'Kane, Mr W Payne.

Apologies for absence were received from Prof G Buckton, Dr D P Elder, Mr R J Shaw, Dr M P Summers and Mr K Truman.

#### 176 **Opening Remarks**

The Secretary and Scientific Director congratulated Dr Horder on his appointment to the Chair of Committee P. Members noted that Professor Woolfson had been appointed as Vice-Chair.

The Chairman welcomed Mrs Baker who was attending her first meeting.

The Secretary and Scientific Director informed the Committee of the final Commission appointments and explained the process and timing for the introduction of the new Expert Advisory Groups.

Members were reminded of the requirements of the Code of Practice regarding members' interests.

Members noted that the next edition of the British Pharmacopoeia would be titled BP 2007 and published in August 2006 with an effective date 1<sup>st</sup> January 2007.

#### **I. MINUTES**

177 The minutes of the meeting held on 30 November 2005 were confirmed.

#### **II. MATTERS ARISING FROM THE MINUTES**

178 Members noted that issues required to be brought to the attention of Commission had been duly raised, and that the other actions assigned to the Secretariat had been completed or superseded with the exception of the points below.

179 **Warfarin Tablets** (minute 159) Further information received within the Secretariat required that the introductory note on the monograph be changed to state that tablets manufactured with either warfarin sodium or warfarin sodium clathrate “... are not necessarily interchangeable...”.

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180 **Ph Eur. Dissolution Text (2.9.3)** (minute 173) Clarification from MHRA Licensing and the EDQM QWP was still awaited.

181 **Nebulisation solutions** (minute 174) The matter of permitted water quality had not yet been raised formally with the Inhalanda Group.

### III. REPORTS AND CORRESPONDENCE

182 **BP Appendix XVI C : Efficacy of antimicrobial preservation** P(06)1

The Committee noted that both the 5<sup>th</sup> Edition of the Ph Eur and the BP 2005 had inadvertently omitted references to appropriate acceptance criteria for Ear Preparations and that the BP Secretariat had brought the matter to the attention of the European Pharmacopoeia Commission. The Committee agreed to amend BP Supplementary Chapter 1 J in line with the decision of EP Expert Group 12 to include aqueous ear preparations under test 5.1.3 with the same criteria as those for topical products.

183 **Particulate contamination in injections** P(06)2

The Committee noted a letter from a Quality Consultancy querying whether specific numeric criteria could be stated instead of such terms as “essentially free” and “practically free” (USP and Ph Eur respectively) for visual assessment. The Company cited the problem of misinterpretation of these statements as meaning absolute freedom from visible particles, rather than allowing a few particles to be present.

The Committee did not support the introduction of a system of numeric limits for visible particles at this time. After a discussion the members decided to maintain the current terminology but to determine current developments in the field. The matter would be reconsidered at the next meeting.

### IV. REVISION OF MONOGRAPHS

184 **General monograph : Tablets** P(06)3

Committee CX: Excipients sought guidance from the Pharmacy Committee on the need for a ‘Chewable Tablets’ sub-monograph. Members agreed that such an entry was unnecessary as it would be editorial in nature and repetitive.

185 **Gastro-resistant preparations –** P(06)4

**Identity tests** Committee A: Medicinal Chemicals had asked the members to consider a suggestion to include a disintegration test under Identification to distinguish between gastro-resistant and non-gastro-resistant preparations of the same active ingredient.

The Pharmacy Committee did not agree with the proposal since Identification tests were intended solely to identify the active ingredient, not the mode of action. By correct use of the standard term ‘Gastro-resistant’ within the title the analyst is directed to the read the general monograph in conjunction with that of the product.

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**Disintegration testing** The Committee noted that the general Tablets monograph did not contained a waiver allowing the possibility that a dissolution test can replace this test for gastro-resistant products. Members agreed that this matter should be referred to Group 12.

186    **APPENDIX XII revisions**    P(06)5

Members agreed changes made by the Secretariat to the following:

**Appendix XII A** (Disintegration) : BP requirements had been incorporated in the British Pharmacopoeia General Monographs for Tablets and Capsules by inserting the text: “Comply with the *disintegration test for tablets and capsules*, Appendix XII A, unless otherwise stated in the individual monographs.”

**Appendix XII D** (Dissolution) : BP aspects had been collated and presented in a separate section of the appendix entitled “Monographs of the British Pharmacopoeia”.

**Appendix XII B** (Disintegration – Enteric Coated Tablets) Members agreed that this Appendix was no longer required (since it was now covered by the Ph Eur monograph for Tablets) and could be omitted.

187    **Review of Supplementary Chapter 1E**    P(06)6

The Committee was asked to advise if the guidance given under Section 6 (Dissolution testing of low solubility preparations) was still appropriate when read in conjunction with the current Ph. Eur. General test (2.9.3).

Members agreed that the BP text would require amendment as it was in disagreement with that of the internationally harmonised guidance notes, particularly with respect to the use of surfactants versus organic solvents and the use of the flow-through apparatus. The Secretariat agreed to revise the Chapter for the following publication.

188    **General Monographs: list of preparations**    P(06)7

Members agreed with a proposal from the Secretariat to remove lists of relevant preparations from the end of general monographs for formulated preparations of the British Pharmacopoeia (e.g. Capsules of the British Pharmacopoeia). These changes would not take place until BP 2008.

189    **Liquids for Cutaneous Application of the BP**    P(06)8

**Lotions prepared by addition of a liquid to a dry powder** In response to an enquiry from Committee E: Antibiotics, Members agreed that requirements for shelf-life following constitution are necessary and should be placed in the Labelling section.

**Collodions : Storage** Members agreed with the need to amend this statement and suggested “Collodions should be stored away from naked flames or other sources of ignition or heat”.

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- 190    **Insulin Preparations: titles**    P(06)9
- Members agreed with a proposal from Panel H : Biological and Biotechnological Products to amend the titles of products to include the delivery method, since newer, non-invasive insulin treatments were under development. The Ph Eur titles using Standard Terms would replace the existing BP synonyms such that e.g. ‘Insulin Zinc Suspension’ will become ‘Insulin Zinc Injectable Suspension’.
- 191    **Oral Powders:  
Monograph titles and definition**    P(06)10
- Titles** The Committee agreed with the proposal from the Secretariat to rename a number of Oral Powder monographs to Powder for Oral Solution/Suspension as appropriate. Members decided that the Committee D monograph for Compound Sodium Picosulfate Powder for Oral Solution should contain the labelling statement: “The powder must be reconstituted before use”.
- Definition** In order to cover both the powder and reconstituted product, members agreed that the Definition section for such monographs should contain “*The Powder complies with the requirements for Powders and Granules for Oral Solutions and Suspensions stated under Oral Liquids and with the following requirements*”.
- Reconstituted product** The Committee reiterated their previous advice that individual monographs for Powders for Oral Solution/Suspension need not include specific analysis on the reconstituted product since this was a requirement of the general monograph.
- 192    **Vancomycin Injection**    P(06)11
- The Committee noted the decision by Commission (minute: 160) to amend the title and definition sections of this monograph to reflect that this product was for use as an intravenous infusion only. Members also agreed that all such monographs should be reviewed in order to introduce similar changes if necessary.
- V.    **NEW MONOGRAPHS**
- 193    **Goserelin Implants**    P(06)12
- A member declared an interest in this product. The Committee reviewed the pharmaceutical aspects of this draft monograph and their advice will be given to Committee H.
- 194    **Gentamicin and Hydrocortisone Acetate  
Ear Drops**    P(06)13
- The Committee reviewed the pharmaceutical aspects of this draft monograph and their advice will be given to Committee E.
- 195    **Propofol Injection:**    P(06)14

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A member declared an interest in this product. The Committee reviewed the pharmaceutical aspects of this draft monograph and their advice will be given to Committee A.

### **BP (Veterinary) :-**

196    **Albendazole Preparations**    P(06)15

The Committee agreed with the proposal from Committee A to elaborate two separate monographs for these products, titled Albendazole Oral Suspension and Albendazole Oral Suspension with Minerals. Members agreed that the Definition section of the latter should state that the product contained added selenium and cobalt.

## **VI. EUROPEAN PHARMACOPOEIA**

197    **Comments from the BP Commission**    P(06)16

The Committee noted that comments were required for the following draft Ph. Eur texts:-  
Eye Preparations  
Preparations for nebulisation: characterisation (2.9.44.)  
Drop point (2.2.17)

198    **Group of Experts No. 12: Progress Report**    P(06)17

Members noted the informal and formal reports of the meetings of European Pharmacopoeia Group of Experts No. 12.

199    **Working Party on Inhalations**    P(06)18

Members noted the informal and formal reports of the European Pharmacopoeia Working Party on Inhalations.

200    **Working Party on Powders**    P(06)19

Members noted the formal report of the 12<sup>th</sup> meeting of European Working Party on Powders. It was noted that the UK currently has no serving delegate on this Working Party.

201    **International Harmonisation**    P(06)20

(Pharmacopoeial Discussion Group – PDG)  
Members noted the PDG work programme status and projected timetable for Ph Eur / USP / JP activities relating to the harmonisation of Q6A general chapters and monographs.

202    **Definitive Texts**    P(06)21

Members noted new, revised and corrected texts (general chapters and monographs) that had been issued in Ph.Eur. Supplement 5.5.

203    **EMA Inspection Quality Working Party**    P(06)22

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Members noted a 'question and answer' document produced by the Joint CHMP/CVMP Quality Working Party.

### **VII. ANY OTHER BUSINESS**

#### **204 Eye Preparations – Group 12**

A member requested clarification of the requirements for minimum volume applicable to 5-mL presentations and it was agreed to refer the matter to the European Pharmacopoeia Commission.

#### **205 Closing Remarks**

The Chairman thanked the members for their past or continuing contributions.

#### **206 Date of Next Meeting**

12 December 2006