

Expert Advisory Group PCY: Pharmacy

BRITISH PHARMACOPOEIA COMMISSION

Expert Advisory Group PCY: Pharmacy

SUMMARY MINUTES

A meeting of this Expert Advisory Group was held at 151 Buckingham Palace Road, London SW1W 9SZ on Monday, 10 March 2014.

Present: Dr R Horder (Chair), Dr B Matthews (Vice-Chair), Prof M Aulton, Mrs E Baker, Dr G Davison, Prof G Eccleston, Mr R Lowe (for items PCY(14)2 to PCY(14)11) and Mr J McGuire.

In attendance: Mrs M Vallender, Ms C Pitt, Dr R Pask-Hughes for items PCY(14)7 and PCY(14)8. Dr J Lim attended the meeting for item PCY(14)09.

Apologies for absence were received from Dr N Broad, Dr D Elder, and Mrs J MacDonald (an alternate member of EAG PCY).

I GENERAL MATTERS

385 Opening Remarks PCY(14)2

Welcome The Chairman welcomed members to the meeting. A special welcome was extended to Dr J Lim, Senior Pharmaceutical Assessor within the MHRA and a former member of the Inhaled Products Working Party.

Membership An updated list of membership had been provided. The Secretariat would undertake a membership review in 2014.

Declaration of Interests Members were reminded of their responsibility to declare interests throughout the meeting and to keep the Secretariat informed of any changes to their interests.

II MINUTES

386 The minutes of the meeting held on 9 September 2013 were confirmed.

III MATTERS ARISING FROM THE MINUTES

387 The following matters arising from the meeting held on 9 September 2013 were noted.

Minute 371.1 Sterile Concentrates The review of the monographs for Sterile Concentrates was deferred for further consideration.

Minute 371.2 Chewable, Soluble and Effervescent Tablets A review of monograph titles would apply to such dosage forms.

Minute 371.3 Monograph Titles The proposed Monograph Titles Project was on the Agenda.

Minute 372 Monograph Structure The recommendations from this EAG relating to specific monographs were being referred to the EAGs responsible for the individual monographs.

Minute 373 Dissolution Sinkers The recommendations of this EAG had been referred to the

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EAG for Medicinal Chemicals 2 (MC2).

Minute 374 Paediatric Oral Solutions The recommendations of this EAG had been referred to EAG MC2.

Minute 376 Emulsifying Wax The request for revision had been deferred to await further information.

Minute 378 Definition statements for topical preparations The EAG for Medicinal Chemicals 3 (MC3) had been informed of the recommendations of EAG PCY.

Minute 379 Injections for Epidural, Intracisternal or Intrathecal Use The recommendations of EAG PCY had been referred to the EAG for Medicinal Chemicals 1 (MC1).

Minute 382 Intraruminal Devices The request for revision had been referred to the European Pharmacopoeia Commission.

IV REPORTS AND CORRESPONDENCE

388 Chloroform-containing preparations PCY(14)3

Members noted that a review of monographs containing chloroform as a listed ingredient was taking place.

389 Antiepileptics PCY(14)4

The need for inclusion of a statement regarding non-equivalence in monographs for antiepileptics (AEDs) was discussed in view of updated advice from the MHRA.

390 Effervescent Tablets PCY(14)5

Further information was awaited in order to continue the discussions.

391 BP Commission-related items PCY(14)6

The following matters which had recently been discussed by the British Pharmacopoeia Commission were brought to the attention of members.

150th Anniversary of the British Pharmacopoeia The BP would be celebrating its celebrating its 150th Anniversary in 2014. Several events had been planned for the week commencing 7 April.

Monographs for Individual Pharmaceutical Forms It had been agreed that separate monographs for Shampoos and Scalp Applications should be developed as these were separate pharmaceutical forms.

Monograph Titles for Intracameral and Intraocular Preparations The BP Commission had discussed the need to include the route of administration in monograph titles for Intracameral and Intraocular Injections.

Aide memoire A revised document would be provided when available.

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- 392 Pancreatin Capsules** PCY(14)7
- The draft monograph would be included in a future publication, subject to resolution of outstanding points.
- 393 Pancreatin Oral Powder** PCY(14)8
- The draft monograph would be included in a future publication, subject to resolution of outstanding points.
- V REVISION OF MONOGRAPHS**
- 394 Inhaled Products** PCY(14)9
- A review of the recommendations of the Inhaled Products Working Party was still under discussion.
- 395 Carmellose Sodium Eye Drops** PCY(14)10
- A request for revision of the Acidity limit from a manufacturer was still under discussion.
- 396 Dispensing information in the BP** PCY(14)11
- A review of statements in BP monographs relating to dispensing and supply would take place in consultation with the EAGs responsible for the monographs and other stakeholders.
- 397 Extemporaneous Preparations** PCY(14)12
- A review of monographs containing Extemporaneous Preparation information would take place in consultation with the EAGs responsible for the monographs and other stakeholders.
- 398 Monograph Titles Project** PCY(14)13
- A project to review monograph titles in the BP was being considered.
- VI EUROPEAN PHARMACOPOEIA**
- 399 Comments from the British Pharmacopoeia Commission** PCY(14)14
- A comment had been received on Pharmeuropa volume 25.3 regarding the monograph Sodium lauroylsarcosinate for external use. No comments had been received on the European Pharmacopoeia monographs relevant to WPCX (Excipients Working Party) in Pharmeuropa volume 25.4. Comments on Pharmeuropa Volume 26.1 had been requested from members of WPCX.
- 400 Report of Group of Experts Number 12** PCY(14)15
- Members noted that a meeting of Group of Experts Number 12 had taken place in December 2013.
- 401 Paediatric Formulary Project** PCY(14)16
- Members noted the project plan for the pan-European Paediatric Formulary Project

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(PaedForm).

402 **European Pharmacopoeia Finished Product** PCY(14)17
Monographs

Members noted a *Ph Eur* proposal to develop monographs for finished products.

403 There was no other business.

VIII **NEXT MEETING**

404 [*Post-Meeting Note: The next meeting of the EAG would be held on 12 September 2014.*]