

Expert Advisory Group: 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, 14 September 2015.

Present: Dr R Horder (Chair), Dr B R Matthews (Vice-Chair), Dr M Ahmed, Mrs E Baker, Mr J Beach, Dr D Elder, Ms B Granell-Villen, Mr R Lowe, Mr J McGuire, Dr T Purewal, Mr L Randon, Prof K Taylor and Prof S Wicks.

In attendance: Mr J Pound, Ms A Gardiner and Ms C Pitt.

Apologies for absence were received from Mrs J MacDonald (an alternate member of EAG PCY).

It was noted that Dr J Churchill was a corresponding member and that Dr J Lim was a specialist member in inhaled products.

Dr Matthews, Mr Beach and Mr Lowe declared interests in one or more agenda items and appropriate action was taken.

I GENERAL MATTERS

431 Opening Remarks PCY(15)10

Welcome, introductions and membership The Chairman welcomed members to the meeting. A special welcome was extended to Prof S Wicks, a new member of the EAG and also to Ms A Gardiner who had recently joined the Secretariat.

Each member introduced themselves and provided a brief overview of their background relevant to the work of the EAG.

A list of member contact details would be included on the BP website Forum. Members were asked to inform the Secretariat of any changes to their contact details.

Editor-in-Chief and EAG Secretary Following the retirement of Mrs Vallender, Mr Pound had been appointed as the new Editor-in Chief, and had taken over the role as Secretary to the EAG.

BP Secretariat staff changes An updated organogram of the BP Secretariat had been provided to include BP staff changes.

Confidentiality and declaration of interests Members were reminded that all papers and minutes were confidential and should not be disclosed outside the BP Commission. A guidance document had previously been provided to members.

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

BP website Members had been informed that the new BP website, [www.pharmacopoeia .com](http://www.pharmacopoeia.com) had been launched and details of how to register had been circulated. The Secretariat provided a short demonstration of how to use the BP website.

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MHRA Website In line with the websites of all government departments and agencies, the MHRA website had been merged into a single government site (www.gov.uk); the BP had been exempted from the requirement to move to gov.uk and had been allowed to retain its separate website.

II MINUTES

432 The minutes of the meeting held on 2 February 2015 were confirmed.

III MATTERS ARISING FROM THE MINUTES

433 The following matters arising from the meeting held on 2 February 2015 were noted.

Minute 420.2 Pessaries The recommendations from EAG PCY were being referred to individual EAGs. The Standard Terms Definition for Pessary had been revised.

Minute 420.5 Dispensing and supply statements The Secretariat would consult with a range of stakeholders regarding the risks and benefits of removing the statements from the BP. A paper would be presented at the next meeting.

Minute 421 Electronic Cigarettes The Secretariat would provide an update when available.

Minute 422 Preparations for Inhalation General Monograph- Uniformity of Delivered Dose
The request for revision was deferred.

IV REVISION OF MONOGRAPHS

434 **Methadone Oral Liquids** PCY(15)11

A review of the monographs was ongoing.

435 **Aminophylline Preparations** PCY(15)12

A review of the monographs was ongoing.

436 **Ph Eur monograph titles – degree of hydration** PCY(15)13

Members noted the Ph Eur proposal.

437 **Testosterone Gel** PCY(15)14

The draft monograph would be included in a future BP publication, subject to comments from manufacturers.

438 **Carmellose Sodium Eye Drops** PCY(15)15

The draft revised monograph would be included in a future BP publication.

439 **Phenol and Glycerol Injection** PCY(15)16

Definition; Content of phenol; Assay It was agreed that no changes to the expression of content of phenol in the monograph would be made at this time.

440 **Powders and Granules for Oral Suspensions and Solutions- Assay** PCY(15)17

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Assay A policy on the requirements to repeat the procedure on the reconstituted product that had been stored at the temperature and for the period stated on the label during which the Oral Suspension/Solution might be expected to be satisfactory for use was discussed.

441 Extemporaneous Preparations PCY(15)18

Members noted a progress report which had been provided for information. The Secretariat would consult with stakeholders regarding a review of monographs containing extemporaneous preparation information.

V EUROPEAN PHARMACOPOEIA PCY(15)19 to PCY(15)22

442 Members noted that recent discussions had taken place at the Ph Eur which were relevant to the work of the EAG.

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VI REPORTS AND CORRESPONDENCE

446 Issues arising through the BP Commission PCY(15)23

Inhaled products The revised Inhaled Products Policy document had been approved by the BP Commission at its March 2015 meeting. The revised Supplementary Chapter I O Inhaled Products had also been published in the BP 2016.

The recommendations were being referred to the individual EAGs responsible for the monographs, and would be reviewed in the Spring 2016 following feedback from the individual EAGs.

Chloroform-containing Preparations The agreed changes had been included in the BP 2016 (omission of monograph or removal of formula and/or method of extemporaneous preparation). It was noted that omitted monographs were still legally enforceable.

Anti-epileptic Preparations The previously agreed non-interchangeability statements had been added to the affected monographs in the BP 2016.

Monograph Lifecycle Review: Omissions A formal process for omission of monographs had been approved by the BP Commission.

VII ANY OTHER BUSINESS

447 Paracetamol Capsules A paper referred from EAG MC1 would be circulated for comments in the subsequent weeks following the meeting.

Appendix XII B. Dissolution (Ph Eur method 2.9.3) A member drew attention to recent draft FDA guidelines on the use of different volumes of dissolution media.

VIII NEXT MEETING

448 The next meeting of the EAG would be held on 28 January 2016.