

Expert Advisory Group: Pharmacy

BRITISH PHARMACOPOEIA COMMISSION

Expert Advisory Group PCY: Pharmacy

SUMMARY MINUTES

A meeting of the Expert Advisory Group on Pharmacy was held at 151 Buckingham Palace Road, London SW1W 9SZ on Tuesday, 12 September 2017.

Present: Dr R Horder (*Chair*), Dr B R Matthews (*Vice-Chair*), Dr M Ahmed, Mrs E Baker, Mr J Beach, Dr D Elder, Dr J Lim, Ms A McFarlane, Mr J McGuire, Dr T Purewal, Professor K Taylor and Professor S Wicks.

In attendance: Mr J Pound, Mr H Makwana and Miss S Gomersal

Mr Stephen Young (BP Secretariat) attended the meeting for the item recorded under minute 486 and Ms A Gardiner (BP Secretariat) also attended the meeting for the item recorded under minute 487.

Apologies for absence were received from Mr R Lowe and Mr L Randon

Dr R Horder, Mr J Beach, Dr D Elder and Professor S Wicks declared an interest in one or more agenda items and appropriate action was taken.

I GENERAL MATTERS

482 **Opening Remarks** PCY(17)01

Welcome, Introductions and Membership The Chairman welcomed members to the meeting.

The Chair welcomed new members of the EAG as well as new members of the secretariat.

Members were made aware of staff changes in the secretariat.

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

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

Expenses Members were reminded to complete an expenses form and submit this in a timely manner.

II MINUTES PCY(17)02

483 The minutes of the meeting held on 12 September 2016 were confirmed.

III MATTERS ARISING FROM THE MINUTES PCY(17)03

484 The following matters arising from the meeting held on 12 September 2016 were noted.

Minute 468 - Dispensing and supply statements The Secretariat had received external

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feedback and intended to present a paper to the BPC summarising the responses and the proposal.

Minute 473 - Assays Based on the Results of Uniformity Tests It had been agreed at a previous BPC meeting that the wording should be amended to reflect the discussion. The changes were included in the BP 2018.

Minute 474 - Doxorubicin Preparations Expert Advisory Group on Antibiotics (EAG ABS) had agreed to the changes as discussed during the September 2016 EAG PCY meeting and these were reflected in the BP 2018.

IV REVISION OF MONOGRAPHS

485 EAG PCY Work Programme PCY(17)04

The EAG PCY work programme had been amended based on the decisions at the last meeting and some relative priorities for the various activities had been added. The revised work programme was accepted.

Members requested an update on the position of the BP in line with current Brexit concerns. The Chair provided information that indicated that the BP would continue to work with the European Pharmacopoeia (Ph. Eur.) and the European Directorate for the Quality of Medicines & HealthCare (EDQM).

486 Dissolution – Responses to the consultation workshop PCY(17)05

Members were reminded that the consultation had been made publicly available for comment from January to April 2017 and was aimed at generating feedback from stakeholders on the current approach and application of dissolution within the BP.

A workshop discussion took place to identify the key themes that emerged from the stakeholder feedback received.

Dissolution – Antiepileptic Drugs (AEDs)

Members were asked to comment on the dissolution tests for antiepileptic drugs and the criteria that should be included in the monographs for Marketing Authorisation Holders (MAHs) to ensure that the products meet the quality standards and that a dissolution test is always considered.

487 BIO Pancreatin Capsules PCY(17)06

A review of the different formulations pertaining to Pancreatin Capsules was discussed.

488 Inhaled Products, update on revised policy implementation PCY(17)07

An update on the Inhaled products changes that were approved at a meeting of the BP Commission in 2016 was presented. Questions and matters arising from these updates during revision of affected monographs were discussed.

489 Extemporaneous Preparations PCY(17)08

Following the agreement at the July 2016 meeting of the BP Commission to review all monographs that contained extemporaneous preparation instructions and formulae, EAG PCY had developed a set of criteria to assess whether the extemporaneous information should be moved to a new supplementary chapter. The criteria had been reviewed by the

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Expert Advisory Group on Unlicensed Medicines (EAG ULM) and the revised, more concise criteria were presented to members for discussion.

490 **Standard terms split within monograph titles** PCY(17)09

Members agreed that the Secretariat's proposal for amending the split standard terms within the monograph title was the best option to follow for new and revised monographs published in the BP 2019. The Chair noted that there should be a timeline on the revision of all existing monographs and this should be set at a maximum of 5 years. When the monograph title is changed, the old title will be added to the monograph as a subsidiary title, which will be present on both the hard copy and online publication of the BP.

V EUROPEAN PHARMACOPOEIA

491 **Report of Group of Experts Number 12** PCY(17)10

Members noted the Summary of Decisions and informal notes of the meeting of Group of Experts Number 12 (Group 12) which had taken place in February 2017.

492 **Comments from the BP Commission** PCY(17)11

The comments provided on the Granules test published in Pharmeuropa 28.4 was provided for information.

VI REPORTS AND CORRESPONDENCE

493 **Issues arising through the BP Commission** PCY(17)12

Members noted a paper summarising the items that had been recently discussed by the BP Commission which were relevant to the work of the EAG for discussion at the next meeting.

VII ANY OTHER BUSINESS

VIII NEXT MEETING

495 Thursday 22nd February 2018