

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 Thursday, 22 February 2018.

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, Mr R Lowe, Dr T Purewal, and Professor S Wicks.

In attendance: Mr J Pound, Mr H Makwana and Mr S Maddocks.

Apologies: Ms A McFarlane, Mr J McGuire, Mr L Randon and Professor K Taylor.

I GENERAL MATTERS

495 **Opening Remarks** PCY(18)01

496 **Welcome, Introductions and Membership** The Chair welcomed members to the meeting.

The Chair informed members that his term as a member of the British Pharmacopoeia Commission (BPC) had ended after the last meeting of the BPC in November 2017 and confirmed that he would remain in his current role on the Expert Advisory Groups on Pharmacy and Antibiotics.

The Chair welcomed new members of 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(18)02

497 The Minutes and Summary Minutes of the meeting held on 13th September 2017 were confirmed.

III MATTERS ARISING FROM THE MINUTES PCY(18)03

498 The following matters arising from the meeting held on 13th September 2017 were noted.

498.1 **Minute 484: Dispensing and supply statements; update from BPC** Members were informed that the BP Commission had agreed that dispensing and supply statements did not fall within the remit of the BP publication. It had been agreed that the statements should be removed from all affected monographs. The Secretariat were in discussions with DHSC regarding the statements.

Minute 487: BIO Pancreatin Capsules EAG BIO members had agreed to the proposals of

EAG PCY to change the title of the current monograph and include a revised monograph for Pancreatin Gastro-resistant Capsules to be published in the BP2019, subject to any external comments.

Minute 488: Inhaled Products; update on revised policy implementation Members were informed of the update to the monograph templates for inhalation products that includes an extra statement in the content section of each monograph.

Minute 490: Split standard terms within monograph titles update from BPC Members of the BP Commission agreed with the recommendation from EAG PCY to ensure that all split standard terms are corrected over a period of 5 years.

IV REVISION OF MONOGRAPHS

499 **EAG PCY Work Programme** PCY(18)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 Chair introduced work-streams that were currently being undertaken by International groups of the European Pharmacopoeia. The members agreed that the Secretariat should monitor these topics and present papers and information at a future meeting if required.

500 **Dissolution – Public Consultation** PCY(18)05

The Secretariat informed members of the progress on the dissolution project since the last meeting. A draft public consultation response document was presented. The group made several editorial suggestions for the public consultation response, before agreeing to the text and style of the document.

501 **Dissolution – Antiepileptic Drugs (AEDs)** PCY(18)06

Members were updated with the discussions relating to antiepileptic drugs and specifically phenytoin products. Members were provided with an update on the phenytoin monograph revisions, which included the proposal for the inclusion of a production statement in the monographs for phenytoin preparations, rather than a specific dissolution test.

EAG PCY members were presented with different options relating to the next steps. The members discussed the available options and made recommendations to the Secretariat.

502 **Extemporaneous Preparations** PCY(18)07

Members were reminded of the on-going work with the Expert Advisory Group on Unlicensed Medicines (EAG ULM) to review the monographs containing extemporaneous preparation instructions. The Secretariat had worked with the EAG ULM Secretariat to develop a decision tree based on the criteria that had been agreed at previous meetings.

The decision tree was presented to members for comment. There were suggested changes to the decision tree and agreement to present to EAG ULM for final approval.

503 **Legacy Terms** PCY(18)08

After the review on the use of split standard terms within the BP, to continue the work on the naming of monographs, the Secretariat presented an investigation into 'legacy terms' to

members. The Secretariat proposed providing a full, comprehensive review of the cost/benefit analysis into the impact of modifying or changing these monographs. The review would be presented at a future meeting.

It was agreed that the project should be referred to as 'Legacy Products' to fully incorporate the scope of the investigation.

504 **Impurities in Finished Product Monographs** PCY(18)09
The Secretariat provided members with an update on the internal review carried out relating to the Ph.Eur. proposals for impurities in finished product monographs. Members discussed that the information relating to impurities already published within the BP was sufficient and the current policy was fit-for-purpose. Members agreed that the Secretariat should routinely review and monitor the relevant texts to ensure the BP remains aligned with the wider regulatory system.

505 **Nebuliser Products** PCY(18)10
The members were introduced to discrepancies in the guidance for 'Powder for Nebulisation Solution' products in the British Pharmacopoeia and the required guidance on the approach for texts to include in these monographs.

Members considered the information presented to the group and advised that a revision of the Ph. Eur. General monograph 'Preparations for Inhalation' should be requested through the UK Delegation to the European Pharmacopoeia Commission to include a section that relates to 'Powders for Nebuliser Solutions'

V **EUROPEAN PHARMACOPOEIA**

506 **Report of Group of Experts Number 12** PCY(18)11
Members were provided with a verbal update relating to the Ph. Eur. 148th Meeting of Group 12 Experts in Strasbourg on 11th/12th October 2017.

507 **BPC Update on Ph. Eur. Matters** PCY(18)12
Members were informed of the status of current EP matters.

VI **REPORTS AND CORRESPONDENCE**

508 **Issues arising through the BP Commission** PCY(18)13
Members were introduced to matters recently discussed by the BP Commission which were relevant to the work of the EAG.
Particular attention was paid to the previously released [Biological standards consultation response](#), and the high level of stakeholder feedback that had been received.

VII **ANY OTHER BUSINESS**

VIII **NEXT MEETING**

Tuesday 18th September 2018