BRITISH PHARMACOPOEIA COMMISSION

Expert Advisory Group PCY: Pharmacy

MINUTES

A meeting of the Expert Advisory Group on Pharmacy was held at 10 South Colonnade, Canary Wharf, London, E14 4PU on Tuesday 18th September 2018.

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

In attendance: Mr J Pound, Dr Catherine Lenihan, Mr H Makwana, Mr S Maddocks and Mr S Young.

Apologies: Mr J Beach, Dr D Elder and Dr B R Matthews

I GENERAL MATTERS

509 **Opening Remarks** PCY(18)14

Welcome, Introductions and Membership The Chair welcomed members to the meeting and briefly informed them of staff changes within the Secretariat. Dr Catherine Lenihan attended the meeting in her capacity as support to the UK Delegation.

The Chair thanked Dr Brian R Matthews for his work with the Expert Advisory Group (EAG) and his continued support of the British Pharmacopoeia Commission (BPC). In the absence of Dr Matthews, Mr Robert Lowe was asked to take up the role of Vice-Chair.

Confidentiality and declaration of interests Members were reminded that all papers and minutes were confidential and should not be disclosed.

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 expense form and submit this in a timely manner.

II MINUTES PCY(18)15

510 The Minutes and Summary Minutes of the meeting held on 22th February 2018 were confirmed.

III MATTERS ARISING FROM THE MINUTES PCY(18)16

511 The following matters arising from the meeting held on 22th February 2018 were noted.

Minute 484: Dispensing and Supply statements, update from BPC The Secretariat had been in contact with the Department of Health and Social Care to arrange the transfer of the information related to Dispensing and Supply statements from the BP. This was expected to continue, and the statements were going to be omitted from a future publication of the BP.

Minute 490: Split standard terms within monograph titles, update from BPC The Secretariat had arranged to make the majority of required changes to Split Standard Terms for the BP 2020. Members were made aware that monographs undergoing revision were to be updated when the revision was scheduled to be published.

Minute 505: Nebuliser Products Following the February 2018 meeting of the EAG, the Secretariat informed members that details for a Ph. Eur. request for revision had been passed onto the UKD Secretariat.

IV REVISION OF MONOGRAPHS

512 EAG PCY Work Programme PCY(18)17

The EAG PCY work programme had been amended based on the decisions at the last meeting and was presented to members.

513 BP Dissolution Policy PCY(18)18

Members were informed that the response to the public consultation on dissolution was pending. The Secretariat presented an initial update to the supplementary chapter for dissolution testing in the BP.

The Secretariat confirmed that due to the ongoing discussions relating to dissolution at the European Pharmacopoeia Commission, it was appropriate to delay the release of the public consultation response until further discussions had taken place.

Members were updated on previous proposals by EDQM to form a new working party to adapt pre-existing finished product monographs from other national pharmacopoeias to fit the range of products across the European market. Members were also reminded that there had been ongoing discussions relating to the dissolution test at EDQM's group of experts - P4 meetings.

Letters of correspondence between EDQM and the UKD were introduced to the EAG. The members discussed that dissolution was classed as a Critical Quality Attribute of the drug product under ICH Q8 guidelines. Dissolution tests contained several different parameters which underpinned the need for individual tests and acceptance criteria. Members agreed that including a dissolution test to cover the range of products across the market was generally achievable and highlighted that different pharmacopoeias have historically included dissolution test conditions and acceptance criteria for solid oral dosage forms and continue to do so, however, it was recognised by the EAG that this may not always the case.

Members considered all the given information and following discussions were in unanimous agreement that the position set out by the letters to EDQM embodied the view of the EAG on compendial dissolution testing

514 Dissolution Supplementary Chapter SC I E. PCY(18)18

A draft revision to the Supplementary Chapter on Dissolution Testing in the BP was presented to the group. Members discussed the role of the Supplementary Chapter in supporting the BP dissolution policy. Several suggestions were proposed to ensure that the layout and content of the information being portrayed in the Supplementary Chapter assisted the user of the pharmacopoeia in interpreting and performing the compendial tests.

V EUROPEAN PHARMACOPOEIA

515 Review of Group 12 Activities PCY(18)19

The available texts that were to be presented at the 150th meeting of EDQM's group of experts – 12 (Group 12), were presented to the EAG. Members discussed the content of the draft texts and provided comment to the Chair.

VI REPORTS AND CORRESPONDENCE

516 Issues arising through the BP Commission PCY(18)20

Members were given an update on matters discussed at the July 2018 meeting of the British Pharmacopoeia Commission.

VII ANY OTHER BUSINESS

517 An item was presented to the group regarding Liposomal Formulations. Members provided comment on the document.

VIII NEXT MEETING

TBC