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, 2 February 2015.

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

In attendance: Mrs M Vallender and Ms C Pitt.

Apologies for absence were received from Dr B Matthews (Vice-Chair), Dr D Elder, Mr J McGuire and Mrs J MacDonald (an alternate member of EAG PCY).

It was noted that Dr J Churchill was a corresponding member.

I GENERAL MATTERS

418 Opening Remarks PCY(15)1

Welcome The Chairman welcomed members to the meeting. A special welcome was extended to the new members and specialist members of the EAG.

Membership Following the membership review undertaken in 2014, the BP Commission had appointed a number of new members of EAG PCY and each member introduced themselves and provided a brief overview of their background relevant to the work of the EAG.

Members were asked to inform the Secretariat of any changes to their personal details.

Introduction to the BP Mrs Vallender gave a presentation providing the new members with an overview of the BP and its role within the MHRA. It was agreed that the Secretariat should send members a list of the various BP Expert Advisory Groups.

Data Integrity Mrs Vallender gave a presentation in relation to the recent review of data integrity procedures. A data handling guidance document for external experts had been circulated and Mrs Vallender summarised the main points.

Aide Memoire Members noted that the revised Aide Memoire had been included on the Forum section of the BP website.

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 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.

Expenses policy The revised expenses policy had been included on the Forum section of the BP website and had been circulated to new members for information.

Forum The Secretariat would be available to demonstrate how to use the Forum section of the BP website to new members.

II MINUTES

419 The minutes of the meeting held on 12 September 2014 were confirmed.

III MATTERS ARISING FROM THE MINUTES

420 The following matters arising from the meeting held on 12 September 2014 were noted.

Minute 407.5 Antiepileptics The recommendations of EAG PCY had been drawn to the attention of the BP Commission. The BP Commission had agreed that suitable statements should be included in monographs for oral preparations in both category 1 and category 2, and a suitable statement would be added to monographs for unlicensed medicines.

Minute 408 Pessaries The recommendations of EAG PCY were being referred to the individual EAGs for review. The request for revision of the Standard Term Definition for Pessaries had been referred to the European Pharmacopoeia Commission.

Minute 409 Carmellose Sodium Eye Drops The request for revision was deferred until further information was available.

Minute 410 Dimethyl Phthalate Comments on the proposed revision to the GC method would be requested from the Panel of Experts on Excipients.

Minute 411 Dispensing Information in the BP The recommendations were being referred to the EAGs responsible for the monographs for review, in consultation with stakeholders.

Minute 412 Extemporaneous Preparations The item had been discussed at the November 2014 meeting of the Expert Advisory Group on Unlicensed Medicines. A number of further recommendations had been generated which were being referred to the EAGs responsible for the monographs.

IV REPORTS AND CORRESPONDENCE

421 Electronic Cigarettes PCY(15)2

For information, members noted that the BP Commission had agreed that the EAG on Medicinal Chemicals 1 should elaborate a BP monograph for electronic nicotine cigarettes licensed as medicinal products.

422 Preparations for Inhalation General Monograph PCY(15)3

Uniformity of Delivered Dose The request for revision of the dose collection volume from 4 L to 2 L was deferred to await further information.

V REVISION OF MONOGRAPHS

423 Inhaled Products PCY(15)4

A revised Policy Document would be uploaded on the BP website once approved by the BP Commission.

Supplementary Chapter I O: Inhaled Products A draft revised Supplementary Chapter had been prepared and it was agreed that it should be published in the BP 2016 subject to approval by the BP Commission.

424 Chloroform-containing Preparations: Update PCY(15)5

Members noted the BP Commission had agreed that Chloroform should be removed as an ingredient from the BP through the revision or omission of all the affected monographs. Where chloroform was included in the extemporaneous preparation, this section should be removed. It is anticipated that these changes would be made in the BP 2016.

VI EUROPEAN PHARMACOPOEIA

425 Comments from the BP Commission PCY(15)6

The comment received from on the draft revised text on Methods of Sterilisation had been referred to the Panel of Experts on Microbiology (Panel MIC).

The Chairman reminded members that it was helpful for members to inform the Secretariat even if they had no comments.

426 PaedForm Project PCY(15)7

Members noted that the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) and the European Pharmacopoeia Commission (EPC) had approved the project for the elaboration of a pan-European formulary for unlicensed formulations for paediatric use.

427 Group of Experts Number 12 PCY(15)8

Members noted the work of Group of Experts Number 12.

428 General Monographs for Pharmaceutical Dosage Forms PCY(15)9

Members noted that a number of draft revised Ph Eur general monographs for pharmaceutical dosage forms were under review by the European Pharmacopoeia Group of Experts Number 12.

429 There was no other business.

VIII NEXT MEETING

430 The next meeting of the EAG would be held on 14 September 2015.