

**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 Friday, 5 February 2016.

**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 and Ms C Pitt.

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

Dr J Churchill was a corresponding member and Dr J Lim was a specialist member in inhaled products, and as such, they were not present at the meeting.

*Prof Wicks declared an interest in one or more agenda items and appropriate action was taken.*

**I GENERAL MATTERS**

**449 Opening Remarks**

PCY(16)1

**Welcome, introductions and membership** The Chairman welcomed members to the meeting.

A list of member contact details had been included on the BP website Forum. Members were asked to inform the Secretariat of any amendments that might be needed to their contact details.

**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.

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** A revised expenses policy had been provided for information.

Members were asked to send any queries about expenses to Ms Pitt who would refer them to the most appropriate person.

Members were reminded that a new system for booking travel arrangements (Clariti) was being introduced.

**II MINUTES**

**450** The minutes of the meeting held on 14 September 2015 were confirmed.

**III MATTERS ARISING FROM THE MINUTES**

**451** The following matters arising from the meeting held on 14 September 2015 were noted.

## Expert Advisory Group: Pharmacy

**Minute 446.1- Inhaled Products** A planned review of the revised inhaled products policy was scheduled for 2016. The Secretariat had included the policy on the new website and would obtain further stakeholder comments in advance of this review. A report would be presented at the next meeting, to include a review of the published Supplementary Chapter I O Inhaled Products.

The Secretariat invited members to circulate a link to the BP website to their contacts who might have an interest in providing feedback on the revised inhaled products policy.

### IV REVISION OF MONOGRAPHS

#### 452 Paracetamol Capsules PCY(16)2

**Dissolution** The Secretariat thanked members for their comments on a paper from EAG MC1 which had been circulated via correspondence.

It was understood that the matter would be brought to the attention of the BP Commission for further discussion.

#### 453 EAG PCY Work Programme PCY(16)3

A draft EAG work programme had been developed. It was intended to provide transparency to members on the major projects/work planned for the next 5 years. Other items would be added to the work programme at a later date as necessary. The remit of the work plan was current and future items and revision programmes discussed by EAG PCY. Other projects which were being undertaken by other EAGs and the Secretariat were outside the scope.

The rationale for the work programme included the actions from EAG discussions, stakeholder consultation and feedback and proactively anticipating wider discussions. The work programme was in line with the BP 5 year strategy and customer research in relation to stakeholder engagement and collaboration, updating monographs, streamlining content, reviewing processes and meeting the customer's needs.

It was suggested that further detail could be added on the input required from members to facilitate workload planning.

**Dissolution specifications** Following feedback from the BP Commission, the intention was for the Secretariat to consult widely regarding the risks and benefits of reviewing the policy on Dissolution specifications in the BP. A report would be presented at a future meeting.

**Monograph titles- Standard Terms** The intention was for the Secretariat to consult widely with regard to the risks and benefits of reviewing BP finished product monograph titles to incorporate Standard Terms.

It was agreed that separate sections should be included for revision of BP monographs, and for providing feedback on Group 12 monographs respectively.

**Heavy metals** The revision programme in line with the Ph Eur policy in relation to ICH Q3D was being led by another EAG and was not included in the EAG PCY work programme.

#### 454 Ph. Eur monograph titles – degree of hydration PCY(16)4

Members noted the Ph Eur proposal and the plan for managing the impact of the changes from a BP perspective.

## Expert Advisory Group: Pharmacy

### 455 Extemporaneous Preparation PCY(16)5

As agreed, the Secretariat had completed a stakeholder consultation exercise regarding which monographs containing extemporaneous preparation could be omitted from the BP, and the revisions that should be made to monographs containing extemporaneous preparation information that were retained in the BP. The Secretariat would bring the discussions, and additional proposals, to the attention of EAG ULM and the BP Commission before a decision was made.

### 456 Dispensing and supply statements PCY(16)6

Further stakeholder feedback had been obtained on the inclusion of these statements in the BP.

It was agreed that the discussions should be brought to the attention of the BP Commission, subject to comments from several key stakeholders identified.

## V EUROPEAN PHARMACOPOEIA PCY(16)7 to PCY(16)12

### 457 Subvisible particulate matter in therapeutic protein injections; to Particulate Contamination Visible Particles; 462 Tablets Ph Eur General Monograph; Accuracy of Mass of Delivered Doses from Multidose Containers; Comments from the British Pharmacopoeia Commission; Report of Ph Eur Group 12

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

## VI REPORTS AND CORRESPONDENCE

### 463 Issues arising through the BP Commission PCY(16)13

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.

**Criteria for appointment and re-appointment of members** The BP Commission had approved criteria that would be used to consider whether proposed new members were suitable for appointment and whether existing members should be re-appointed had been approved by the BP Commission.

**Triennial Review** The Triennial Review of the British Pharmacopoeia Commission had been published in 2015 and was publically available.

**Prolonged-release Dissolution** The Secretariat would consult widely regarding possible changes to the current policy on new monographs for prolonged-release formulations, following a project that had been undertaken by the University of Reading.

## VII ANY OTHER BUSINESS

464 There was no other business.

## VIII NEXT MEETING

465 The next meeting of the EAG would be held on 12 September 2016.