

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 Monday, 12 September 2016.

Present: Dr R Horder (Chair), Dr B R Matthews (Vice-Chair), Mrs E Baker, Dr D Elder, Dr J Lim, Mr R Lowe, Dr T Purewal, , Prof K Taylor and Prof S Wicks.

In attendance: Mr J Pound and Ms C Pitt.

Apologies for absence were received from Dr M Ahmed, Mr J Beach, Mrs J MacDonald (an alternate member of EAG PCY), Mr J McGuire and Mr L Randon.

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

Dr Matthews, D Elder, T Purewal, K Taylor and S Wicks declared an interest in one or more agenda items and appropriate action was taken.

I GENERAL MATTERS

466 Opening Remarks PCY(16)14

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

The list of the current membership and contact details had been made available on the Forum section of the BP website. Members were asked to inform the Secretariat of any amendments that might be needed to their contact details.

Ms B Granell-Villen had tendered her resignation from the EAG.

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.

II MINUTES

467 The minutes of the meeting held on 5 February 2016 were confirmed.

III MATTERS ARISING FROM THE MINUTES

468 The following matters arising from the meeting held on 5 February 2016 were noted.

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Minute 454 - Ph. Eur Monograph Titles – Degree of Hydration Revision to affected BP texts to reflect the removal of the word anhydrous from certain substance names in the Ph Eur 9.0 Edition had been published in the BP 2017.

Minute 456 - Dispensing and supply statements Once the discussions had been completed, the intention was for a paper to be presented to BPC.

IV REVISION OF MONOGRAPHS

469 EAG PCY Work Programme PCY(16)15

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 by members.

470 Inhaled Products- Planned Review PCY(16)16

A planned review to the BP policy on inhaled product monographs to incorporate further feedback gathered by the Secretariat was discussed. A number of changes were proposed, and the revised policy would be presented to the BP Commission for approval. It was suggested that the policy could be reviewed again in 5 years, as necessary, to incorporate any further feedback received during the implementation of the policy.

471 Dissolution – *Discussion workshop* PCY(16)17

The Secretariat explained a number of drivers to review the current BP Commission policy on Dissolution testing for both conventional and prolonged-release solid oral dosage forms.

An informal workshop discussion took place and members' initial thoughts were encouraged on how the current BP Commission policy could be improved.

Stakeholder consultation and further discussions would need to take place at the BP Commission and EAG PCY before a policy could be agreed.

472 Extemporaneous Preparations PCY(16)18

A review of BP monographs containing extemporaneous preparation information was discussed.

473 Assays Based on the Results of Uniformity Tests PCY(16)19

The wording in BP monographs that currently included Assays based on the average of the results of the Uniformity tests was discussed.

474 Doxorubicin Preparations PCY(16)20

A number of recommendations on the Title and Definition statement would be referred for further discussion at the Expert Advisory Group on Antibiotics (EAG ABS). The impact of these discussions on BP monographs for epirubicin preparations would be checked.

475 Surgical Spirit PCY(16)21

Recommendations on the formula in the current Definition statement would be referred to the Panel of Experts on Inorganic and General Chemicals (Panel IGC).

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- 476** **Ferrous Gluconate; Ferrous Fumarate** PCY(16)22
- Recommendations on the statement statement 'Ferrous [salt] contains in x mg about y mg of iron' in the non-mandatory top part of the monograph would be referred to the Panel of Experts on Inorganic and General Chemicals (Panel IGC).
- V** **EUROPEAN PHARMACOPOEIA**
- 477** **Report of Group of Experts Number 12** PCY(16)23
- Members noted that a meeting of Group 12 had taken place in the April 2016.
- 478** **Comments from the BP Commission** PCY(16)24
- Members noted the list of texts relevant to the EAG that had been published for comment in recent editions of Pharmeuropa.
- VI** **REPORTS AND CORRESPONDENCE**
- 479** **Issues arising through the BP Commission** PCY(16)25
- 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.
- Heavy metals** The changes to remove the heavy metals test in line with the Ph. Eur policy in relation to ICH Q3D had been made in the BP 2017.
- Triennial Review Update; Public Consultation on Draft Monographs** A link to the summary of the current status of the recommendations of the Triennial Review of the British Pharmacopoeia Commission had been provided.
- There was now a regular commenting period for draft new and revised BP monographs on the BP website.
- Monograph Lifecycle Review: Development; Publication; Revision- Prioritisation review**
The BPC had agreed that a process and criteria should be followed for prioritising revision and development of monographs.
- Paracetamol Capsules** The matter had been discussed further at the BP Commission meeting and the minute had been provided to members information.
- VII** **ANY OTHER BUSINESS**
- 480** There was no other business.
- VIII** **NEXT MEETING**
- 481** To be confirmed.