Expert Advisory Group: Pharmacy

BRITISH PHARMACOPOEIA COMMISSION

Expert Advisory Group PCY: Pharmacy

SUMMARY MINUTES

A meeting of Expert Advisory Group: Pharmacy was held via videoconference on Friday 29th May 2020.

Present: Dr R Horder (*Chair*), Mr R Lowe (vice-chair), Mrs E Baker, Dr J Lim, Dr E Gray, Dr D Elder*, Ms A McFarlane, Mr J McGuire, Mr J Beach, Professor K Taylor.
* Dr D Elder joined the meeting at minute 522 and stayed for the duration

In attendance: Mr J Pound, Mr S Maddocks, Mr A Evans and Dr F Swanson**
*** Dr F Swanson attended for minute 522 and 523 only.*

Apologies: Dr M Ahmed.

I GENERAL MATTERS

518 Opening Remarks **PCY(20)01**

Welcome, Introductions and Membership
The Chair welcomed members to the meeting of the Expert Advisory Group (EAG) on Pharmacy, the first held to be held by videoconference. Members were asked to inform the Secretariat of any amendments to their contact details.

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 expense form and submit this in a timely manner. Members were informed that expense forms would only be accepted digitally at that time. If there were queries or questions, members were reminded to contact the Secretariat

II MINUTES **PCY(20)02**

519 The Minutes of the meeting held on 18th September 2018 were confirmed with 1 editorial comment to minute 515.

III MATTERS ARISING FROM THE MINUTES **PCY(20)03**

520 The following matters arising from the meeting held on 18th September 2018 were noted.

Minute 503: Legacy Terms
As agreed at the February 2018 EAG PCY meeting, the Secretariat will present the full cost/benefit analysis of making changes to these monographs at a future meeting.

Minute 505: Nebuliser Products
Following the February 2018 meeting of the EAG, the Secretariat informed members that details for the request for revision had been passed onto the UKD secretariat for discussion at the November European Pharmacopoeia Commission meeting.

Minute 513 and minute 514: Dissolution
The revision to the ordering of information in the Annexes was published in the BP 2020 along with revision to the Supplementary chapter to reflect the changes in policy. This included removal of any reference to not "retrospectively applying Q values to older monographs". The work to revise the monographs to Q was ongoing, progress would be reviewed at a later date. The Supplementary chapter would be updated and presented to the EAG at a future meeting.

IV REVISION OF MONOGRAPHS

521 EAG PCY Work Programme PCY(20)04;

The EAG work programme was presented to members. A number of projects were specifically highlighted by the Secretariat. Members agreed that the work programme was accurate and up to date.

Split Standard Terms
Majority of changes to bring monograph titles in-line with EDQMs standard term had been made for the BP 2020. The Secretariat noted that Sterile concentrate monographs had been updated for the BP 2021 and the project was completed.

Extemporaneous Preparations
Following agreement at BP Commission meeting, EAG ULM were to assess each extemporaneous preparation according to the agreed decision tree.

Dispensing and Supply Statements
The removal of the dispensing and supply statements was subject to agreement with the Department of Health and Social Care as to the location these should reside in.

Legacy monograph titles
Following the agreement at the previous PCY meeting, this project would be continued at an appropriate time and a full review was to be presented to the EAG at a future date.

Dissolution
The Secretariat highlighted that changes had been made in the publication to the order of appendices and in the supplementary chapter for dissolution to reflect the updated policy. Monographs had continued to be revised in line with the strategy for implementation.

522 BP Action and Use statements PCY(20)05

The Secretariat presented an initial investigation into the policy used to generate Action and use statements following a number of comments that were received from members of the British Pharmacopoeia Commission.

523 Oral Liquids PCY(20)06;

EAG ULM presented a information regarding the title of monographs for Oral Liquids. EAG PCY were asked to consider general advice on the matter of these monographs.

Members discussed the situations and expressed appreciation for the difficulties faced by EAG ULM when dealing with these products. Members expressed concerns about the identity of products if a general approach to publishing "Oral Liquid" was adopted by the EAG and that clarity of the monograph through the use of standard terms would be the best approach to follow.

Members discussed that although the policy should remain in-line with standard terms, in

exceptional cases, it may be appropriate to justify the use of “oral liquid” in monograph titles if no other option was available. It was agreed that these could be discussed on an individual basis when the need arose.

V EUROPEAN PHARMACOPOEIA

524 **Update on Group 12 activities** **PCY(20)07;**

Members were introduced to the activities of Group 12 of the EDQM and discussed the progress of this group with respect to the general monograph review.

VI REPORTS AND CORRESPONDENCE

525 **Future look of EAG PCY** **PCY(20)08**

The Secretariat presented the work programme of the EAG which was considered alongside the remit and responsibilities of EAG PCY.

The EAG had also taken on additional roles across the years, reacting to potential public health issues as they arise. Another of the roles PCY had adopted was acting in support of other EAG’s producing finished product monographs, clarifying policy and where appropriate, suggesting a revision to the policy.

The paper presented options for the clarification and resetting of the roles and responsibilities of the EAG which were discussed in detail.

Options
The Secretariat detailed several potential points for discussion and invited members to consider the information given when discussing the potential future options for the work of the EAG.

Members were introduced to a number of options to continue the work of the EAG effectively to maximise the benefit of the output of EAG PCY to the British Pharmacopoeia publication and public health.

It was discussed that combining the responsibilities of EAG PCY and EAG NOM
Would be presented to the British Pharmacopoeia Commission. All members agreed to this proposal.

526 **BP Commission Update** **PCY(20)10**

Biological Standards
The MHRA had continued to implement its strategy for pharmacopoeial public quality standards for biological medicines as published in 2017 and updated in 2019.
Part of the published strategy was to investigate alternative approaches to standards for biological medicines. This led to the establishment of the Alternative Approaches for Documentary and Physical Standards for Biotechnological Products Working Party (WP BIO-DPS) in 2018. WP BIO-DPS has continued to develop a deeper understanding of performance and class-based standards and consequently how documentary and physical standards may need to evolve.

A working party for Advanced Therapy Medicinal Products (WP ATMP) was established. The role of the Working Party is to provide recommendations and advice to the British

Pharmacopoeia Commission and the MHRA in the area of standardisation for advanced therapy medicinal products.

Analytical Quality by Design
The Analytical Quality by Design Working Party (WP-AQbD) had reached a key milestone in their project and had presented the findings to the British Pharmacopoeia Commission. WP-AQbD later produced a consultation on the application of the principles to pharmacopoeial methods. The results from this consultation are due out this year and will detail the next steps and the MHRAs strategy for furthering this project.

Changes to the BP online
A series of user research, conducted by research partner OKO, allowed stakeholder insight and experience to inform the decisions of the innovation board and to focus on developments that improve the products we provide. Some of these projects included;

- The How to guide
- Enhanced timeline feature
- Tracked changes

BP Portfolio Review
In 2019, the British Pharmacopoeia Commission were presented with a broad range of principles to review the entire BP portfolio of monographs with respect to omitting those monographs which added no benefit for stakeholders.

VII ANY OTHER BUSINESS

VIII NEXT MEETING

N/A