Expert Advisory Group: Pharmacy and Nomenclature

BRITISH PHARMACOPOEIA COMMISSION

Expert Advisory Group PCN: Pharmacy & Nomenclature

SUMMARY MINUTES

A meeting of Expert Advisory Group: Pharmacy & Nomenclature was held via videoconference on Wednesday 30th June 2021.

Present: Dr J Aronson (*Chair*), Mr R Lowe (Vice-chair), Dr R Horder, 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 S Maddocks, Mr A Evans and Ms H Corns*
** Ms H Corns attended for minutes 9 and 10 only.*

Apologies: Dr M Ahmed.

I GENERAL MATTERS

1 Opening Remarks **PCN(21)01**

Welcome, Introductions and Membership
The Chair welcomed the group together for the inaugural meeting of the Expert Advisory Group for Pharmacy and Nomenclature (EAG PCN).

Dr Horder was thanked for his major contribution to EAG PCY and the British Pharmacopoeia in his role as chair and the group expressed appreciation for his ongoing commitment as a member of EAG PCN.

Confidentiality and declaration of interests
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 **PCN(21)02**

2 The Minutes of the EAG PCY meeting held on 29th May 2020 were confirmed with editorial amendments for minutes 522 and 525.

III MATTERS ARISING FROM THE MINUTES **PCN(21)03**

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

EAG PCY 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.

EAG PCY Minute 513 and minute 514: Dissolution
The ongoing efforts to revise the monographs to Q were being performed by the individual EAGs, progress would be reviewed at a later date. The Supplementary chapter would be updated with the help of experts across the technical EAGs and presented to PCN and BPC at a future date.

3.3 **EAG PCY Minute 525: Future look of EAG PCY**
The proposal from EAG PCY to merge responsibilities with EAG NOM had been presented to the British Pharmacopoeia Commission in July 2020 and approved based on an initial review into the effectiveness. The new EAG was to be called EAG PCN: Pharmacy and Nomenclature.

IV REVISION OF MONOGRAPHS

4 EAG PCN Work Programme PCN(21)04; Annex 1

The previous EAG PCY work programme was presented to members. The Secretariat introduced a new way of working for the newly formed EAG. Members agreed that the proposals were suitable.

4.1 **Workstreams**
The work of the EAG was proposed to be split into 4 distinct areas:

- Standing Items (eg: BAN Publication, Monograph titles, Action and Use statements)
- Projects (eg: Legacy monograph titles, Dispensing and Supply Statements)
- EAG Advice (eg: Liposomal formulations, Adrenaline Injection)
- Reactive issues (eg: MHRA Patient safety alerts/product recalls)

Members agreed that the workstreams were reasonable and acknowledged they would see a refreshed work programme at a future meeting of the EAG.

5 MHRA Patient Safety Alerts PCN(21)05; Annex 1

Members were given an introduction to MHRAs alerts for medicinal products. It was agreed that the EAG may be required to look into these on specific occasions.

It was agreed that the Secretariat would circulate any relevant alerts for consideration by the members in-between meetings.

6 BAN Publication PCN(21)06

The Secretariat provided background to the British Approved Names publication, the frequency of publications and the details required for the individual entries. Members were introduced to the information that the Secretariat would provide and acknowledged that there would be in the region of 35 new entries each year.

7 Monograph titles review PCN(21)07

The Secretariat explained the current policy for naming of monograph titles and the information within the definition. There was often discussion around this information for specific products where there were differences in available products or there were non-routine processes involved during manufacture. Members agreed that the EAG should review the monograph titles and definitions for new and revised monographs of the British Pharmacopoeia to ensure acceptability.

There would be in the region of 50 monographs to consider annually. Members agreed that the BNF entry for the products would aid the review along with the information provided by the Secretariat.

8 Action and Use statements PCN(21)08

Mr Evans explained that the action and use statements within BP monographs included the pharmacological action, followed by the major indication for the product and were not

intended to be a complete list of licensed indications that would be contained in the SmPC. The statements provided a useful level of detail to the analyst who may not be familiar with the uses of the products they are testing.

The statements in the BP were not always accurate for a given pharmaceutical form or were outdated where products were more widely used for new indications and members agreed that the review would be useful to keep finished product monographs up to date. Members further agreed that the international use of some products could be helpful, especially where there was limited use of a product in the UK. The Secretariat agreed to include international use and the BNF information for review purposes and generate a template for the EAGs to request the reviews.

The action and use statements would be reviewed on an annual basis prior to the monographs being revised or published for the first time.

9 Adrenaline Injection PCN(21)09

The Secretariat presented an update on the labelling statements within the British Pharmacopoeia for Adrenaline Injection monographs.

9.1 **Statement of strength in monograph**

The BP were asked to consider revision of these monographs (which were currently separated into separate high strength and low strength monographs) to a single, open strength BP monograph for Adrenaline Injection/Epinephrine Injection, which will be made available on the BP website as a notice of intent to revise in addition to the usual stakeholder consultation process.

Members agreed that the proposal for a single open strength monograph for Adrenaline Injection/Epinephrine Injection was suitable in principle.

9.2 **Expression of strength**

Expert advice had been sought regarding how the strength should be labelled, from the Medication Safety Officer network and CHM, amongst others. EAG: PCN were also invited to provide advice on the proposals

If mg/mL was to be used, the more dilute formulations have zero's after the decimal point, whereas using micrograms for the higher strength solution would involve very large numbers in the statement of total strength/total volume (i.e. 10 mL vial would be 10,000 mcg/ 10 mL).

10 Dissolution update and policy request PCN(21)10:

Members were updated on the implementation of the dissolution policy for solid oral dosage forms. An update to the supplementary chapter would be made through engagement with a range of experts across the small chemical EAGs of the BP. Which would subsequently be reviewed by the BP Commission.

EAG MC2 requested advice from EAG PCN on potentially having separate requirements for dissolution within a monograph where some older products may be sugar coated, rather than film coated tablets.

10.1 **Coated Tablets**

The secretariat presented a request from EAG MC2 to EAG PCN members for guidance with dissolution requirements. The issues observed were contextualised in a question surrounding the policy if certain formulations will not be able to meet the pharmacopoeial requirements, despite having comparable bioequivalence to each other.

Members discussed the potential risks of having two separate requirements for the dissolution criteria, however, suggested that due to the nature of the sugar-coated products, it may be appropriate on an individual basis. It was agreed that the Secretariat would draft appropriate wording in case this approach was to be adopted in individual finished product monographs.

11 Acidity and Alkalinity **PCN(21)11:**

EAGs MC1 and MC2 had encountered an issue with the setting of specific specification requirements controlling the pH in finished product monographs.

Members discussed the merits of the requirements across a range of finished product formulations and concluded there would be too large a risk if these were omitted from BP finished product monographs.

Members agreed that the appropriate action for EAGs to take would be to review the requirements on an individual basis and take an evidence-based decision for setting or removing the specification for pH in the monograph.

12 Liposomal formulations **PCN(21)12; Annexes 1 – 9**

EAG ABS requested EAG PCN to provide guidance on production of liposomal formulations monographs within the BP. The Secretariat gave a brief history of the naming of these products within the MHRA and presented a review of liposomal finished product critical quality attributes for discussion. Members were asked to advise on a suitable approach to generate a template for these products.

Due to the complication surrounding these monographs, it was proposed that an informal group would be put together to propose how these monographs may look in the British Pharmacopoeia. This group would be formed from experts across the BP EAGs who have the appropriate expertise.

V EUROPEAN PHARMACOPOEIA

13 **Update on Group 12 activities** **PCN(21)13**

Members discussed the content of the draft texts produced for PharmEuropa and made comments based on the texts.

VI BRITISH PHARMACOPOEIA COMMISSION

14 **British Pharmacopoeia Update** **PCN(21)14**

The following updates were given to the EAG based on product improvement and BP project advancements.

14.1 **Biological Standards**

In March 2020, 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.

This working party had produced a significant guidance document for the use of “Flow

Cytometry" which was to be published following stakeholder consultation. The original document and consultation questions were introduced to the members.

14.2 **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 strategy for continuation of this work was published in 2020.

The consultation highlighted the will, across the industry, to see wider access to AQbD principles as well as further support and guidance in the pharmacopoeia. The Secretariat had prepared a supplementary chapter following stakeholder consultation in April.

14.3 **EU Exit**

Following the end of the transition period, the BP considered the required changes and communications for its publication and users. All the details were held on the BP Website.

VII ANY OTHER BUSINESS

VIII NEXT MEETING

TBC