Expert Advisory Group: Pharmacy and Nomenclature

BRITISH PHARMACOPOEIA COMMISSION

Expert Advisory Group PCN: Pharmacy & Nomenclature

SUMMARY MINUTES

A meeting of the Expert Advisory Group: Pharmacy & Nomenclature was held via videoconference on Wednesday 2 March 2023.

Present: Dr J Aronson (*Chair*), Dr R Horder, Ms A McFarlane, Mr J McGuire, Dr G Moss, Professor K Taylor, Dr R Thorpe.

In attendance: Mr A Evans and Mrs S Begum.

Apologies: Dr M Ahmed, Mr J Beach, Dr D Elder, Mr R Lowe (*Vice-Chair*).

I GENERAL MATTERS

Opening Remarks **PCN(23)1**

Welcome, Introductions and Membership
Dr Aronson welcomed members to the third meeting of EAG PCN.

Members were introduced to Sumaya Begum, a new member of the Secretariat.

Confidentiality and declaration of interests
Members were reminded that all papers and minutes were confidential and should not be disclosed.

Members were reminded to declare any specific interests at the beginning of any topic and to inform the Secretariat of any changes to their previously stated interests.

II MINUTES **PCN(23)2**

The Minutes of the EAG PCN meeting held on 7 December 2021 were confirmed, with the following amendment. A footnote to be added stating that two papers had been published on the naming of monoclonal antibodies.,

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III MATTERS ARISING FROM THE MINUTES **PCN(23)3**

The following matters arising from the meeting held on 7 December 2021 were noted.

Adrenaline
The recommendations from the experts had been discussed with MHRA colleagues, and were now with the Royal College of Emergency Medicine and the British Cardiovascular Society.

Paclitaxel albumin-bound
The group are awaiting updates.

Vancomycin for infusion
EAG ABS had considered recommendations from EAG PCN regarding the requirement of the definition statement when Vancomycin Infusion solution was being used off-label as an

oral solution (permitted by its secondary indication in the SmPC). EAG ABS had agreed that unlicensed use of the infusion as an oral solution would be included in the revised monograph for Vancomycin Infusion in the BP 2024.

Dissolution testing of oral suspensions
Advice had been received against a general dissolution requirement for all oral suspensions. EAGs had been asked to risk assess the need for a dissolution test when developing monographs for oral suspensions. Members had previously agreed that a change in the general monograph could affect many existing products without significant improvements in patient safety.

Implementation of pharmacopoeial procedures
The Ph. Eur. text had been published..

Titanium dioxide in medicines
Discussions with industry groups and the Food Standards Agency (FSA) were continuing. Members would be updated when discussions had taken place.

Herbal infusions
EAG HCM had been asked to rename the Infusions monograph to read “Herbal Infusions” to avoid confusion with parenteral infusions. PCN suggests that the monograph should be renamed as “Tisanes”, a tisane being defined as “a medicinal tea or infusion made from herbs” (OED), a more accurate description. These recommendations would be taken to EAG HCM.

IV STANDING ITEMS

EAG PCN Work Programme **PCN(23)4**

The work programme for the EAG was presented, to give members the opportunity to add/remove sections as necessary.

MHRA Patient Safety Alerts **PCN(23)5**

The MHRA alerts for medicine recalls since the last meeting of the EAG were provided for information. Members discussed whether the controls that the BP published were sufficient to identify and characterise problems with defective medicines. Members also noted that the BP was useful, as the BP standards were picking up problems with medicines in the marketplace.

Members noted that several failures had arisen from the presence of particles in parenteral formulations. The general monograph for Parenteral Preparations had since been updated to include tests for visible particles. There was also current work to update monographs for intravesical and immunosuppressant solutions. This should identify problems with particle failures in these formulations. However, it was noted that better understanding about the reasons for these failures was needed, to stop them happening in the first place.

There had been two dissolution failures in solid oral dose products that had been placed on the market and appropriate action was being taken by the relevant EAGs.

Three of the recalls had failed impurity limits. Members agreed that this had been due to the presence of nitrosamines and noted that ways of controlling these impurities in pharmacopoeias were already under discussion. The Secretariat agreed to bring this to the attention of the relevant BP EAG..

BAN Publication (BAN 2022 Supplement 2) **PCN(23)6;**

The draft Supplement 2 was presented for members to review. The new entries were already INNs and included salts when these were used in products. INNs were adopted as BANs when products were first licensed for use in the UK.

Members agreed with the proposal from the Secretariat to incorporate images for the cell and gene therapy entries and agreed with the system the Secretariat had used. It was noted that the tables defining these entries would be included in a much higher resolution, the originals having been included as examples of how these materials could be defined.

Members were informed that the BP website was in the process of being updated. The new version would include BANs, making it easier to incorporate new BANs.

Members had been asked to review the BAN entries ahead of the PCN meeting and to provide comments to the Secretariat. The required changes had been made and the draft publication would be presented to the BPC at the March meeting for recommendation to publish.

Monograph titles review **PCN(23)7**

Several new and revised monographs were presented to the EAG for review. The information provided included the titles of the monographs and the action and use statements.

Protamine sulfate was a British Approved Name and not a modified British Approved Name. The sulfate form would need to be taken into consideration when referring to the strengths of protamine sulfate formulations.

Several of the action and use statements required review. Members agreed to send recommendations to the Secretariat for updating these entries and agreed that they could be signed off by correspondence.

IUPAC: Naming of impurities for BP monographs **PCN(23)8**

The Secretariat had identified 18 impurities that would be included in the new and revised monographs under consideration for the BP 2024. These impurities would need to be defined by the IUPAC chemical definitions and molecular structures with support from experts.

Monograph titles – naming of esters **PCN(23)9**

The BP policy for naming monographs for finished products was to use the BAN followed by the standard term. The modified BAN, e.g. hydrochloride, sodium salt, etc., would not be included unless different forms were available for the same pharmaceutical product. However, there were inconsistencies in that approach.

The Secretariat suggested that members should consider a pragmatic approach to this, which would include reviewing the monograph title for new and revised monographs by EAG PCN.

Prolonged-release chewable tablets **PCN(23)10**

The prolonged-release chewable tablet type of formulation had been brought to the attention of the Secretariat following a standard term request by EDQM. The patient safety issues arising from this type of formulation were presented to the group. Members were asked to identify the most appropriate solution to this problem.

The EAG agreed that the formulation pose a problem, but did not reach a consensus for resolution. The discussion would be taken back to the standard terms group.

Monographs for inhaled products **PCN(23)11**

EAG PCN's recommendations for inhaled product monographs had been adopted in the BP Supplementary Chapter for inhaled products. A stakeholder had raised questions related to this policy. Members were asked to consider the questions from the MAH and advise the Secretariat about the correct action required when responding.

This query had arisen because of updated guidelines in the label claims of inhaled products..

Members agreed to draft a response to the query with the secretariat.

Metolazone: Interchangeability of products **PCN(23)12**

A licensed formulation of metolazone was now available in the UK. Its bioavailability was different to that of other available brands of metolazone. Members were asked to consider the recommendations made by the Secretariat to mitigate the risks to patients.

Members agreed that this issue had been picked up by relevant bodies and would not require any further input from the BP at present.

European Pharmacopoeia Group 12 update **PCN(23)13**

Ph. Eur. Group 12 meeting updates were provided to the EAG.

V Any Other Business

13 **Harmonisation of pharmacopeial procedures**

Members were informed about a paper on harmonisation of pharmacopeial procedures which would be taken to the BP Commission meeting on 6 March 2023. Members were asked to review the paper and provide comments where appropriate.

VI NEXT MEETING

13 September 2023 – To be confirmed.