

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 in person at 10 South Colonnade on Tuesday 12 March 2024.

Present: Dr J Aronson (*Chair*), Mr R Lowe (*Vice-Chair*), Mr A Brelsford, Dr R Horder, Dr O Kavanagh, Mr J McGuire, Dr G Moss, Prof K Taylor, Dr R Thorpe.

In attendance: Mr J Alam, Mrs S Begum, Mrs M Guler and Ms A Thomson.

I GENERAL MATTERS

50 Opening Remarks PCN(24)01

50.1 Welcome, Introductions, and Membership

Dr Aronson welcomed members to the fifth meeting of EAG: PCN.

The meeting was held in person and via videoconference.

Members were informed of Mr M Ahmed's retirement from the Agency.

Members were introduced to two new expert members of the Committee, Mr A Brelsford and Dr O Kavanagh.

50.2 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 Munise of any changes to their previously stated interests.

Members were informed that any media requests should be sent to the secretariat, who will forward to the MHRA press team for an appropriate response.

50.3 Expenses

Members were reminded to complete an expenses form and submit it in a timely manner. Members were informed that expenses forms would only be accepted digitally. If there were queries or questions, members were reminded to contact Mrs M Guler. (munise.guler@mhra.gov.uk).

51 General matters

Members were informed of the outcome of the membership review of EAGs, panels of experts, working parties, and BPC, which ended on 31 December 2023.

Members were informed of staff changes within the BP Secretariat.

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- II MINUTES PCN(24)02**
- 52** The Minutes and Summary Minutes of the previous meeting of EAG: PCN held on 6 September 2023 were confirmed, with one minor amendment, specifically the removal of Dr R Horder's name from the Summary Minutes.
- The Secretariat agreed to provide minutes to members, after they had been signed off by the Chair/vice-Chair.
- III MATTERS ARISING FROM THE MINUTES PCN(24)03**
- 53** The following matters arising from the meeting held on 6 September 2023 were noted.
- 53.1 Adrenaline Labelling**
Once a new labelling approach for adrenaline ampoule products has been agreed, variation procedures and timelines would be set out, along with communication plans for the labelling changes and revision of the relevant BP monographs.
- The group noted that the recommendation to change the expression of strength for adrenaline had been made by CHM in 2021; consequently, safety concerns were raised over the delay in this change.
- 53.2 Albumin-bound Paclitaxel**
Assessors are yet to identify a legal and systematic approach to include albumin in the product name, similar to 'liposomal' products.
- 53.3 Titanium dioxide in medicines**
Discussions with industry groups and the Food Standards Agency (FSA) continue. Members would be updated when discussions had taken place.
- 53.4 Herbal Infusions**
EAG: HCM did not want to replace the term infusions with herbal infusions or tisanes at their meeting in October, and considered the potential risk to be very low.
- It was noted that the EDQM standard term for infusion did not specify the nature of the infusion, and the definition for this should also be amended, in order to reduce confusion.
- 53.5 MHRA Patient Safety Alerts**
Members agreed with the recommendation to request the production of a BP monograph for cannabis by ULM.
- 52.6 Capsules for Opening**
The term 'capsules for opening' is still being discussed by the standard terms working party at EDQM.
- 52.7 Sinemet interchangeability**
Members would be informed of the outcome of the MHRA investigation into the matter of Sinemet interchangeability. This would determine the need to include an interchangeability statement in the monograph for co-careldopa.
- IV STANDING ITEMS**

- 53 MHRA Patient Safety Alerts PCN(24)04**
- The MHRA alerts for recalls of medicines since the last meeting of the EAG were provided for information.
- Members noted a reduction in recalls because of particulate contamination.
- Posaconazole Gastro-resistant Tablets had an out-of-specification result for unspecified impurities during testing for stability. Ms Thomson informed the group that an API monograph was in progress at EDQM for Posaconazole. Members discussed the need for a monograph and agreed that it should be included in the work programme for AIM.
- 54 BAN 2022 – Supplement 3 PCN(24)05**
- Members were thanked for their contributions to the annual BAN supplement. The group was informed of the successful transition of the BAN to HTML format on the new BP website. Future BAN supplements would be produced as online-only publications.
- Members agreed to share any further amendments to the BAN by correspondence.
- 55 Monograph Titles & Action and Use Statements PCN(24)06**
- Several new and revised monographs for inclusion in the BP 2025 were presented to the EAG for review. The information provided included the titles of the monographs and the Action and Use statements.
- Several of the Action and Use statements required review. Members agreed to adopt these.
- 56 Co-names PCN(24)07**
- The group was informed of a few instances in which MAHs have abandoned the use of co-names in favour of the (usually two) individual rINNs that make up the product. Members agreed that this could cause confusion. The group noted the improved safety and transparency associated with the use of clearly defined rINNs on medicinal products.
- As the use of co-names is not compulsory. The group agreed naming should include the rINNs as well as the co names in any order, in an effort to reduce confusion for patients.
- The group were informed that for some Co-name product monographs, legacy Dispense and Supply statements still exist. Members agreed that statements of this nature should be removed following approval by commission.
- VI NEXT MEETING**
- September 2024 – TBC