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 Tuesday 7th December 2021.

Present: Dr J Aronson (*Chair*)#, Mr R Lowe (Vice-chair), Dr M Ahmed, Mrs E Baker, Dr D Elder, Dr E Gray, Dr R Horder, Dr J Lim, Ms A McFarlane, Mr J McGuire, Dr G Moss, Professor K Taylor, Dr R Thorpe.
Dr Aronson attended for items 11 onward, Mr Lowe chaired the meeting.

In attendance: Mr A Evans, Ms H Corns*, Ms R Hunter
* *Ms Corns attended for items 7 and 8 only.*

Apologies: Mr J Beach, Mrs J MacDonald.

I GENERAL MATTERS

1 Opening Remarks

Welcome, Introductions and Membership
Mr Lowe welcomed members to the second meeting of EAG PCN.

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

II SUMMARY MINUTES PCN(21)16

2 The Summary Minutes of the EAG PCN meeting held on 30th June 2021 were confirmed with minor amendments.

III MATTERS ARISING FROM THE MINUTES PCN(21)17

3 The following matters arising from the meeting held on 30th June 2021 were noted.

Legacy Terms
The Secretariat would present a report at a future meeting.

Adrenaline
The labelling of these products would be discussed by the EAG at a future meeting.

IV STANDING ITEMS

4 EAG PCN Work Programme PCN(21)18

The work programme for the EAG was presented to members. The four sections for the Agenda was accepted along with the work programme in Annex 1.

5 MHRA Patient Safety Alerts PCN(21)19

The MHRA alerts for medicine recall since the last meeting of the EAG were provided for information. The reasons for the recalls had been summarised where there could be issues for the BP. Members noted that the BP was useful as it contained requirements that included the testing for which the recalls had occurred.

6 BAN Publication (BAN 2022 Supplement 1) PCN(21)20

The draft supplement 1 was presented to members for review. The entries would be published in a future publication of the British Approved Names.

7 Monograph titles review PCN(21)21

Several new and revised monographs were presented to the EAG for review. The agreed titles and 'action and use' statements would be included in future publications of the British Pharmacopoeia.

V PROJECTS

See item 9 in the minutes

VI EAG ADVICE

8 Phenytoin Capsules/Phenytoin Tablets – Dissolution PCN(21)22

These medicines were used to treat epilepsy and were included in the MHRA antiepileptic medicines advice instructing healthcare professionals to maintain patients on products from one manufacturer.

Members agreed to include a production statement for controlling the dissolution requirement in these monographs. The production statement would be included in a future publication of the British Pharmacopeia.

9 Liposomal/albumin formulated products

Following the successful project to ensure amphotericin, doxorubicin and daunorubicin products were named, labelled, prescribed and dispensed including the terms liposomal, pegylated liposomal or lipid complex where used in the formulation, the EAG discussed other products that had similar formulations.

Bupivacaine Liposomal Injection a new formulation for this product had recently been licensed. As the product was a 'liposomal formulation, the term 'liposomal' was included as part of the name of the product and on the label. The term was already being used for prescribing and dispensing purposes. Members agreed that the entry in the BAN publication for bupivacaine should be amended to include liposomal bupivacaine as a BANM in line with the entries for amphotericin, doxorubicin and daunorubicin.

Paclitaxel Albumin Injection a new formulation for paclitaxel injection had been developed and licensed. At least two products were available using the albumin formulations, with multiple MAH for non-albumin formulated products.

The Secretariat agreed to review the term albumin-bound with MHRA colleagues involved in the original liposomal project to develop a strategy for the control of these products in the same way as the liposomal formulated products.

10 Secondary Routes of Administration PCN(21)23

Vancomycin for Infusion products had been licensed with a secondary route of administration (oral solution) and could be taken orally for limited indications. EAG ABS had published separate monographs for the two uses, however, the appropriateness of this was questioned given there were no oral solution products available that were only licensed as the oral solution (vancomycin was used orally to achieve a local action rather than where it required to be absorbed).

Members recommended that the oral solution monograph be omitted, also the infusion monograph be amended to include two sections. This would permit both general pharmaceutical form monographs to be referenced and then the specific analytical requirements/specifications could be included after to ensure the quality of the available products.

VII REACTIVE ISSUES

11 European Pharmacopoeia Group 12 update PCN(21)24

Cross references in European Pharmacopoeia general monographs A project to review text of the European Pharmacopoeia (general monographs) that contained cross references had been completed. Members agreed to review these recommendations and provide comments to the Secretariat for discussion by the UK representative at the Ph. Eur. expert group meeting.

Labelling statements for general monographs A project had begun to review the labelling statementing in the Ph. Eur. text to try to retain the information that would be of value to the analyst or product formulator and to omit anything that was for the patient as best practice for the healthcare professionals would not be taken from pharmacopoeias but from licensing and other more focussed resources.

12 Dissolution testing of oral suspensions

EAG ULM (unlicensed medicines) had produced several monographs for oral suspensions where the starting material for the API could be a licensed product (for example ground up tablets). Because of this a dissolution test had been included in the monographs which refers to the ‘dissolution test for unlicensed medicines’ in the BP. Monographs for licensed oral suspension products in the BP do not routinely have a dissolution test, however, in the case of midazolam oral suspension, the BP was asked by Licensing to include one.

Members debated the need for all oral suspensions to include a dissolution test. There was agreement that the EAG should consider a risk-based process when developing or revising monographs of this type to ascertain if there would be a requirement for dissolution on a case by case basis.

13 Implementation of pharmacopoeial procedures PCN(21)25

Members were informed that the Ph. Eur. monograph for *'Implementation of pharmacopoeial procedures (5.26.)'* had been finalised. This text had been developed through Group 12 over several years and had been the subject of significant comments from pharmacopoeia stakeholders.

VIII ANY OTHER BUSINESS

Titanium dioxide in medicines Medicines had been temporarily exempt from the proposed ban of titanium dioxide in foods following the European Food Safety Authority paper. A paper would be discussed by the EAG at a future meeting.

IX NEXT MEETING

TBC