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 and online via Microsoft Teams on Friday 7 February 2025.

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

In attendance: Mrs S Begum, Ms A Thomson and Mr J Alam (*Committee Services*).

Apologies: Dr D Elder and Mr J McGuire.

I GENERAL MATTERS AND BP UPDATE

59 General Matters PCN(25)01

Welcome Dr J Aronson welcomed members to the sixth meeting of EAG: PCN, held in person and via videoconference.

Declaration of Interests Members were reminded to declare specific interests as they arose during the meeting and to inform the Agency's Committee Services team of any changes to their interests throughout the year.

Confidentiality Members were reminded of the confidential nature of the discussions and minutes of the meeting, with all papers marked OFFICIAL-SENSITIVE.

60 BP Update

Members received an update on recent BP activities, personnel changes, and broader MHRA activities.

II MINUTES PCN(25)02

61 The Minutes and Summary Minutes of the previous meeting of EAG: PCN held on 12 March 2024 were confirmed.

III MATTERS ARISING FROM THE MINUTES PCN(25)03

62 Matters arising and correspondence items from the meeting held on 12 March 2024 were noted.

IV STANDING ITEMS

63 MHRA Patient Safety Alerts PCN(25)04

The MHRA alerts for recalls of medicines since the previous meeting of the EAG were provided for information.

Members discussed the atomoxetine and cyanocobalamin recalls, concluding that a new BP monograph should be developed for Atomoxetine Capsules, and an updated monograph published for Cyanocobalamin Tablets, most importantly including a test for related substances.

64 BAN 2026 PCN(25)05

Members were thanked for their contributions to the annual BAN supplement. Members agreed to share any further amendments to the BAN by correspondence.

The draft publication would be presented to the BPC at the March meeting for recommendation for publication.

65 Monograph Titles & Action and Use Statements PCN(25)06

Several new and revised monographs for inclusion in the BP 2026 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 with minor changes.

66 Dispense and Supply Statements PCN(25)07

Members were informed of the presence of dispense and supply statements in the BP and asked to review the appropriateness of these statements considering the BP is not an information source used by clinicians.

Members concluded that all dispense and supply statements should be removed from the BP.

67 Aide Memoire: Consistency in Powders for Oral Liquid Monographs PCN(25)08

EAG: AIM raised concerns regarding consistency in monographs for powders used to prepare oral solutions and suspensions. A draft template aligning with BP policy was developed and approved. Members discussed 21 monographs, most specifying separate shelf lives for dry ingredients and the constituted liquid, with inconsistencies in how formulations were described. To address this, it was agreed to create separate monographs for granules and those requiring reconstitution.

The group also approved replacing "liquid" with "medium" for solid granule dosage forms while retaining "liquid" for reconstituted suspensions. Additionally, members agreed that end-of-shelf-life testing for granules that do not require reconstitution was redundant and impractical.

‘Suitable Flavoured Vehicle’ The standard Definition statement wording for Oral Solution monographs in the BP ‘suitable flavoured vehicle’ was discussed. Given that not all licensed oral solution products contain flavourings, members recommended the template be updated to ‘suitable vehicle’.

68 3D Printed Tablets PCN(25)09

The Secretariat presented a preliminary supplementary chapter on 3D-printed tablets, for potential inclusion in the BP. Members were asked to either endorse its inclusion, submit it to the Ph. Eur. general monograph for tablets, or take no action.

The group agreed to await the conclusion of the MHRA consultation on highly personalised medicines and any regulations before proceeding.

69 European Pharmacopoeia Group 12 Update PCN(25)10

Members were updated on Group 12 activities, including the topics of sub-visible particles and upper limits for extractables volumes.

70 Any Other Business

Bung Coring The issue of bung coring in NHS aseptic units was raised, associated with product failure, medication wastage and financial implications. The 2014 Sharps Directive introduced blunt-fill needles to reduce needle stick injuries, but this has resulted in complaints of rubber particles in containers.

Current BP penetration tests use hypodermic needles, which do not reflect real-world practice.

Members agreed that the Secretariat would contact DMRC to assess the scope of the problem in the first instance.

Tamper evident seal The group were informed of concerns raised regarding a MAH request to remove the tamper-evident seal from eye drop bottles, leaving it only on the outer carton. The BP states that the primary container of eye drops must contain a tamper-evident seal. This has traditionally been interpreted as requiring a seal on the bottle itself to ensure sterility until first use. This interpretation is being opposed by the MAH.

Members unanimously agreed that the BP is clear on that matter and that a tamper-evident seal must be on the bottle to maintain sterility.

WHO INN – Colchicine It was noted that Colchicine currently does not have a BAN or an INN. This would be discussed at the WHO INN meeting in March, where it is expected to be assigned an INN. Once an INN is assigned, the Secretariat agreed to include colchicine as a BAN.

VI NEXT MEETING

The Secretariat confirmed that the next meeting would be held virtually in September 2025.