**BRITISH PHARMACOPOEIA COMMISSION**

**Expert Advisory Group MC2: Medicinal Chemicals**

**SUMMARY MINUTES**

A meeting of this Expert Advisory Group (EAG): Medicinal Chemicals 2 (MC2) was held virtually over two sessions on Tuesday 11 November and Wednesday 12 November 2025.

**Present:** Dr G Cook *(Chair)*, Mr C Goddard (*Vice-Chair*), Mr J Rickard (*Vice-Chair)*, Mr M Ali, Prof J Birchall Dr K Boon, Dr K Chan, Dr S Ho, Dr A Ruggiero, Dr J Cowie and Dr Z Smith.

**In attendance:** Ms H Corns, Ms R Feltham, and Dr S Greatorex (BP Lab, 11 November 2025 only).

**Apologies:** Mr E Hook, Dr K Foster and Mr C Natarajan

**663 Introductory Remarks**

**Welcome** The Chair informed members of Prof John Miller's retirement from EAG: MC2 and recognised his superb service and support to the BP over 15 years. His technical experience and participation in meetings would be missed.

**Confidentiality** Members were reminded that all papers and minutes were confidential and should not be disclosed outside the BP Commission.

**Declaration of interests** Members were reminded that they are required to inform the BP Secretariat of any changes to their interests throughout the year via email to Agency's Committee Services Team.

**664 BP Update** **MC2(25)01**

Members were provided with an update on recent BP activities and personnel changes.

**665 MINUTES**

The Minutes and Summary Minutes from the meeting held on 11 May 2025 were confirmed without amendment.

**666 MATTERS ARISING FROM THE MINUTES** **MC2(25)02**

Matters arising and correspondence items from the meeting held on 11 May 2025 were presented.

**MONOGRAPHS**

*Dr G Cook and Mr M Ali declared interests in one or more agenda items and appropriate action was taken.*

**667 SERTRALINE PREPARATIONS: MC2(25)20**
**SERTRALINE ORAL SOLUTION (NEW)**
**SERTRALINE TABLETS (REVISED**

The draft new monograph for Sertraline Oral Solution would be included in a future BP publication, subject to laboratory work and comments from manufacturers.

**Dissolution (Tablets only)** Members endorsed aligning the dissolution medium with Appendix XII Recommendations on Dissolution Testing Acetate buffer solution pH 4.5 preparation directions. A revision to dissolution test solution concentrations to accommodate a lower strength product, subject to laboratory investigation, was agreed by members.

**Related substances (Tablets only)** Members endorsed revision to the limits in the monograph for impurity C, D and E; as well as revision to the total impurity limit, subject to stakeholder comment.

**668 LIDOCAINE PREPARATIONS: MC2(25)21**
**LIDOCAINE MEDICATED PLASTER (New)**
**LIDOCAINE GEL (Revised)**
**LIDOCAINE INJECTION (Revised)**
**LIDOCAINE OINTMENT (Revised)**
**LIDOCAINE CREAM (New)**
**LIDOCAINE STERILE SOLUTION (Omission)**
**LIDOCAINE CUTANEOUS SOLUTION (New)**
**LIDOCAINE OROMUCOSAL SPRAY, SOLUTION (New)**

The draft new monographs for Lidocaine Medicated Plaster, Lidocaine Cutaneous Solution and Lidocaine Oromucosal Spray, Solution would be included in a future BP publication, subject to laboratory work and comments from manufacturers.

The monograph Lidocaine Sterile Solution would put forward for omission from the BP 2027, subject to stakeholder comments and BPC approval.

**Content (Lidocaine Injection)** Members accepted the request to express the content in terms of anhydrous lidocaine hydrochloride, which matched the innovator product and recently granted generic applications.

**Identification (Lidocaine Gel, Lidocaine Injection and Lidocaine Ointment)** Members accepted the drafted HPLC-UV/DAD identification test, subject to laboratory assessment, to replace the series of identification tests in the published monographs.

**2,6-dimethylaniline (Lidocaine Gel, Lidocaine Injection and Lidocaine Ointment)** Members confirmed that the test for 2,6-dimethylaniline (impurity A) should be deleted, subject to confirmation that impurity A could be controlled by the proposed related substances test.

**Related substances** (**Lidocaine Gel, Lidocaine Injection and Lidocaine Ointment)** A new related substances test had been drafted, based on the Ph Eur

Lidocaine Hydrochloride Monohydrate method. Members supported the adoption of the new test, subject to laboratory evaluation. A limit for unspecified impurities of 0.2% and a reporting threshold of 0.1% had been included, aligned with ICH Q3B and a total impurity limit of 1.0% had been drafted, with the established limit of 400 ppm limit for impurity A retained from the 2,6-dimethylaniline test.

**Sterility** (**Lidocaine Gel)** Members confirmed that the sterility required should be removed from the monograph, as no marketed products were presented as sterile and, if the label indicated a product was sterile, the sterility requirement was stated under the general monograph for Topical Semi-solid Preparations.

**Assay** (**Lidocaine Gel, Lidocaine Injection and Lidocaine Ointment)** Members endorsed the revision of the Assay procedure, to be harmonised with the proposed related substances chromatographic conditions.

**Impurities (Lidocaine Gel, Lidocaine Injection and Lidocaine Ointment)** A transparency section had been introduced in the draft revised monographs.

**669 NILOTINIB CAPSULES MC2(25)22**

The draft new monograph would be included in a future BP publication, subject to laboratory work and comments from manufacturers.

**670 CLOPIDOGREL HYDROCHLORIDE TABLETS (NEW) MC2(25)23**

Members agreed the draft new monograph development would not be continued at this time.

**671 SOLIFENACIN PREPARATIONS: MC2(25)24**
**SOLIFENACIN ORAL SOLUTION (REVISED)**
**SOLIFENACIN ORAL SUSPENSION (REVISED)**

**Dissolution (Oral Suspension only)** Experts approved the revision of the dissolution test to accommodate the minimum paediatric dose.

**Related substances limits (Oral Solution only)** Members agreed to increase the limit for impurity I to NMT 1.0%; as well as the revision of total impurities limit to exclude impurity I.

**Related substances limits (Oral Suspension only)** Members agreed to increase the limit for impurity I to NMT 0.5%; as well as the revision of total impurities limit to exclude impurity I.

**672 PHENELZINE TABLETS (REVISION) MC2(25)25**

**Dissolution** A new dissolution test method had been drafted into the monograph with revised limits, which was endorsed by members.

**Related substances** Members agreed that the drafted limits should be retained, based on the stability data summary submitted by a MAH and to reflect regulatory expectations.

The peak separation system suitability requirement had been amended to a resolution of at least 10.0 between impurity 2 and phenelzine to align with the Phenelzine Sulfate monograph in which the same chromatographic conditions were used.

**Assay** Members agreed the adoption of the BP method and endorsed the removal of the resolution requirement, as there were no specified impurities.

**Storage** The inclusion of a storage statement, stored at a temperature of 2° to 8°, which the Secretariat confirmed was non-mandatory, was accepted by members.

**673 PYRIDOSTIGMINE TABLETS (REVISION) MC2(25)26**

**Content** Members endorsed a content limit of 92.5 to 105.0%, following discussion and review of manufacturer data.

**Related substances limits** Members endorsed the proposed revision to limit impurity B at 4.0% following a manufacturer submitting stability data during public consultation.

**674 CO-CARELDOPA PREPARATIONS MC2(25)27**
**CO-CARELDOPA PROLONGED-RELEASE TABLETS (NEW)**
**CO-CARELDOPA TABLETS (REVISION)**

The draft new monograph for Co-careldopa Prolonged-release Tablets would be included in a future BP publication.

**Dissolution (Co-careldopa Tablets only)** Members recommended that a resolution requirement, harmonised with the Assay system suitability requirement, was included in the dissolution test.

**Related substances** Members endorsed the adoption of a gradient step to improve method sensitivity for late-eluting impurity 2.

**675 DOCETAXEL STERILE CONCENTRATE (NEW) MC2(25)28;**

The draft new monograph would be included in a future BP publication, subject to laboratory work and comments from manufacturers.

**676 FLUOXETINE CAPSULES (revision) MC2(25)29**

**Identification** Members approved the proposal to delete identification B, a peak comparison in the Assay, as IR was considered sufficiently discriminatory.

**Dissolution** A revision of the test to include a harmonised Q value limit of 80% (Q) in 30 minutes, aligned with the USP Fluoxetine Capsules monograph was accepted by members, subject to stakeholder comment.

**Related substances** Improvements to the published method, including a change to quantitative-style limits, were endorsed by members. Members approved the replacement of a limit of not more than 2 secondary peaks at 0.25% and all other secondary peaks at 0.1%, with a single 0.2% limit for all unspecified impurities. An increase to 0.7% for total impurities and the inclusion of a 0.1% reporting threshold, in line with ICH, were also accepted.

A peak separation system suitability requirement, resolution of at least 1.5 between impurities A and B was agreed, subject to stakeholder comments.

**Assay** Minor amendments to the published test, to align with BP style, were confirmed.

**Impurities** The transparency statement had been updated to include additional impurities that were known to be detected using the method.

**677 FLUDARABINE TABLETS (new) MC2(25)30**

The draft new monograph would be included in a future BP publication, subject to laboratory work and comments from manufacturers.

**IV FOR INFORMATION**

**678 MC2 Work Programme MC2(25)31**

The Secretariat presented the updated work programme to members for information.

**679 BP Lab Update MC2(25)32**

Members were informed that two MC2 BPCRS were out of stock and the retest of both was in progress.

**680 Ph Eur Updates** **MC2(25)33**

The Secretariat thanked members for their ongoing support of the Pharmeuropa review and confirmed update 37.4 was underway with a deadline of 31st December 2025**.**

**681 Alkyl Sulfonate Ester Impurities** **MC2(25)34**

An article from the Journal of Pharmaceutical Sciences, titled 'Combating pharmaceutical folklore: No alkyl-sulfonate impurities formed during the synthesis of sulfonate salts' was shared with members.

**682 ANY OTHER BUSINESS**

None raised.

**683 NEXT MEETING**

Members were notified that the next meeting would be held in-person on Wednesday 20th May 2026.