

BRITISH PHARMACOPOEIA

EXPERT ADVISORY GROUP: HERBAL AND COMPLEMENTARY MEDICINES (HCM)

SUMMARY MINUTES

A meeting of Expert Advisory Group (EAG): Herbal and Complementary Medicines (HCM) was held virtually on the 6th of February 2025.

Present: Professor M Simmonds (Chair), Dr D Middleton (Vice-chair), Mr J Sumal (MHRA), Dr N Wilson (MHRA), Professor A Slater, Mr B Moore, Dr C Etheridge, Mr C Welham, Dr E Reich, Professor E Williamson, Dr K Zhao, Dr R Thanacoody

Observing: Ms. C Nicholson

In attendance: Mr S Young, Ms R Feltham

Apologies: Mr B Moore and Professor K Strohfeldt-Venables

I GENERAL MATTERS

HCM(24)01

724 Opening Remarks

Welcome

The Chair welcomed members to the meeting of the Expert Advisory Group (EAG) on Herbal and Complementary Medicines (HCM).

The Chair asked everyone to introduce themselves as there was a BP commissioner observing and Miss R Feltham was new to the Secretariate.

Membership

The Chair welcomed Claire Nicholson, a BP Commissioner, who was observing the meeting.

Confidentiality and declaration of interests

The Chair reminded members that the meeting discussions were confidential, and that they should declare any interests that arose. Members had been asked prior to the meeting to note any interests from the agenda. Members were reminded they could declare any interests on topics prior to the commencement of discussions; these would be noted in the minutes.

If Members had any queries relating to interests, they were reminded to contact the Committee Services team.

Fees and Expenses

Members were reminded that any queries regarding expenses should be sent to the Committee Services Team.

Herbal and Complementary Medicines (HCM)

The BP policy on fees and expenses was unchanged, but Members must now send all claims directly to the Committee Services team rather than to the BP Secretariat.

Organisational update

Mr Young provided some organisational updates. Professor Anthony Harden had been appointed as the new Chair of the MHRA. Mr Young outlined Professor Harden's experience and main priorities for the agency.

Mr Young reminded members that Dr June Raine was to step down from her role as CEO in June and informed members that there will be a new CEO announced in the upcoming months.

Mr Young reminded members that the MHRA Laboratory at LGC will be relocating from the site in Teddington to Guilford in April.

Mr Young confirmed that Mr Tong will return to the Secretariat later in February.

II MINUTES HCM(25)02

- 725 The minutes of the meeting held on 27th June 2024 were confirmed, with some amendments for accuracy provided by members.

III MATTERS ARISING FROM THE MINUTES HCM(25)03

- 726 The following matters arising and correspondence items from the meeting held on 27th June 2024 were confirmed.

Mint

No further progress due to resource constraints. The Secretariat still need to source some "uncut" samples.

Lemon Verbena Extract

Samples to be sourced – quite difficult to find so we have been focusing on Wormwood and Chinese Goldthread (agenda items).

Juniper Tincture

On the agenda.

Bacopa Monnieri

The Secretariat to update the Related Substances method to harmonise with the *Ph. Eur.*

Tagetes erecta Extract

The Secretariat had written to the manufacturer to say that the EAG did not wish to add this monograph to the work program.

Ispaghula Husk Effervescent Granules

Herbal and Complementary Medicines (HCM)

The Secretariat need to review and harmonise the Identification as previously agreed.

Senna Liquid Extract

This monograph will be omitted from the BP2026.

Senna Tincture products

The Secretariat has highlighted these products to the MHRA Borderline team, who agreed that these products should not be on the market and would write to the manufacturers.

Senna Granules

This monograph will be omitted from the BP2026.

Senna Tablets

The Secretariat has updated the definition to refer to the new Senna Pods monograph title.

HPTLC new concepts

The Secretariat are including these concepts in drafting monographs.

Professor Slater and Mr Welham declared interests in one or more agenda items and appropriate action was taken.

IV REPORTS AND CORRESPONDENCE

727 EXTRACT MONOGRAPHS FRAMEWORK DOCUMENT

HCM(25)04

The Secretariat presented an updated framework document for extract monographs, based on the feedback received at the previous meeting. Members were welcomed to comment on the current draft.

Information sources

A member commented that herbal monographs should not be diluted for practitioners. Another member noted that most monograph users will be herbal suppliers rather than practitioners. Although occasionally herbal practitioners may need the labelling information when dispensing. Practitioners may require information from the supplier such as quantity of the extract equivalence to the original herb.

A member, continued the discussion, questioning if it is the pharmacopoeia's responsibility to say who the users of herbal monographs are and recommended not drawing attention to a specific user by naming practitioners in text.

A member raised that practitioners often do not have the time or facilities to check monographs and rely on suppliers to work to BP standards.

The Secretariat commented that the document's purpose is to provide an overview of the structure of herbal monographs and is for internal use only. Members agreed to remove the reference to practitioners from the information sources section.

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Monograph title

A member recommended the bullet points and italicised text in the monograph title section to be replaced with reference to the *Ph. Eur.* general monograph on dry extracts instead.

Definition

A member raised the issue of including the word 'dry' in the definition section of the framework document as the framework document includes monographs for other extracts such as tinctures. The Secretariat will remove the word from the paragraph.

Content

A member raised the need for a statement in the framework document to clarify how to assess commercial samples during monograph development including checking that the raw materials that are used in the production of an extract are compliant. The member recommended the Secretariat use Good Agriculture and Collection Practice (GACP) questionnaires when procuring samples for monograph development. Another member echoed this recommendation to prevent potentially using contaminated material during method development as contaminated material is becoming an increasing issue.

Another member noted that content usually refers to an assay of a marker compound. Therefore, if there is no identification marker available, a total extractive test in combination with a semi-quantitative HPTLC method would be required which would allow for qualitative assessment by including band descriptives such as "faint" and/or "intense"

During discussion a member recommended the section was reworded to "Where an assay is established (for the extract) and the available products have quantitative compositions, a content statement will be included."

Identification

A member requested the removal of the 'TLC' from the section. Another member noted that "these identification tests" needs to be corrected to "the identification tests".

Loss on Drying/ Water (for dry extracts)

A member requested "with limits set at around 5%" to be changed to "with limits not more than 5% unless otherwise justified". Reference to the herbal drug monograph should also be removed as it is not related to the water content of the dry extract.

Ethanol (or other solvent) content (for liquid extracts)

Members requested "and tinctures" to be added to the sections title.

Labelling

A member raised that monographs are not aimed at practitioners. The member recommended cross-referencing the general herbal drug extra monograph in replace of the draft labelling section of the document.

Another member noted that through other work of the BP Secretariat, there will be further insight into who is accessing herbal monographs.

Herbal and Complementary Medicines (HCM)

A member highlighted that the statement “If the extract is intended for administration to patients, a suitable labelling section should be added” covers the labelling section.

A member suggested the labelling advice could be considered as a separate guidance text.

A member stated if the labelling section is kept in the extract framework, then clarity is required for whether the Latin binominal or monograph naming is used.

Several members recommended keeping the labelling section in the document or for it to be captured in a separate document. A member raised that if monographs are not intended for practitioners, then it is not required in the document and is better to keep it as a separate section.

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| 728 | Chair’s update for BP Commission | HCM(25)05 |
| | <p>Members were presented with the proposed update to commission that the HCM chair and BPC member hopes will raise the profile of HCM to the BP commission after recent changes and pauses to the expert advisory group. Members were positive and endorsed an update being presented to BPC at the next meeting.</p> <p>A member suggested to highlight the importance of the EAG HCM, that figures should be included in the update for BPC.</p> <p>A member offered to provide figures on the variability seen across the market where herbal extracts content does not match the labels. Additionally, another member will also provide figures on poor quality herbal products that have been detected.</p> | |
| 729 | New and Revised monographs for BP2026 | HCM(25)06 |
| | <p>The Secretariat provided members with an update on the changes made to HCM monographs for the BP 2026.</p> | |
| V | NEW MONOGRAPHS | |
| 730 | Senna Preparations | HCM(25)07 |
| | <p>The draft monograph would be included in a future BP publication, subject to comments from manufacturers.</p> | |
| 731 | Juniper Tincture | HCM(25)08 |

Herbal and Complementary Medicines (HCM)

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

732 Wormwood Tincture HCM(25)09

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

733 Chinese Goldthread Preparations HCM(25)10

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

VI REVISED MONOGRAPHS

734 Capsicum Tincture HCM(25)11

Members were reminded that at the previous expert advisory group meeting, that one of the experts brought to the group's attention a potential issue with the performance of Merck RP-18 plates and procurement issues of 2,6-dichloroquinone-4-chloroimide for derivatisation.

The Secretariat presented the results of the work performed by the laboratory, where it was determined the plates performed as expected and the laboratory did not encounter any issues with procurement of the derivatisation reagent.

Members endorsed the monograph remaining as is.

735 Podophyllum Preparations HCM(25)12

Podophyllum Resin
Compound Podophyllum Paint

Experts endorsed the replacing chloroform with dichloromethane in the monographs and the addition of HPTLC conditions.

736 Ocimum tenuiflorum HCM(25)13

Members endorsed the correction of the DNA sequence for *Ocimum tenuiflorum* in the supplemental chapter and reminded the Secretariat that Appendix XI V needed correcting.

A member brought to the group's attention that *Ocimum tenuiflorum* was being added to the HOA list due to toxicity and will potentially be added to Article 8 of the ECEC agenda.

737 Restricted herbs list HCM(25)14

Herbal and Complementary Medicines (HCM)

The Secretariat proposed include a short statement to highlight monographs for herbal drugs that included in the *BP/Ph.Eur.* that are subject to restrictions for safety reasons. The inclusion of the statement was endorsed by experts.

VII EUROPEAN PHARMACOPOEIA

HCM(25)15

738

The Secretariat thanked members for their contributions to the Pharmeuropa 36.4 review. The Secretariat also confirmed that texts in the Pharmeuropa 37.1 review had been assigned to HCM, with a deadline at the end of March.

VIII ANY OTHER BUSINESS

IX NEXT MEETING

The date would be confirmed by the Secretariat.