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 at 10 South Colonnade, London E14 4PU on 12th November 2025.

Present: Professor M Simmonds (Chair), Ms C Nicholson (BPC), Dr S Greatorex (LGC), Dr A Booker, Mr B Moore, Dr C Etheridge, Mr P Anderson

Online attendees: Dr D Middleton (Vice-chair), Mr J Sumal (MHRA), Dr N Wilson (MHRA), Mr C Welham, Professor E Williamson

In attendance: Mr P Crowley, Mr S Young, Dr D Tong

Apologies: Professor A Slater, Dr E Reich, Professor K Strohfeldt-Venables, Dr K Zhao, Dr R Thanacoody

I	**GENERAL MATTERS**	**Verbal Update**

739 Opening Remarks

Welcome

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

Membership

There were no changes to the EAG membership to report.

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.

The BP policy on fees and expenses is unchanged. Members must now send all claims directly to Committee Services rather than to the BP Secretariat within 3 months.

Organisational update

The Secretariat reported that the BP/MHRA Laboratory team at LGC had relocated from Teddington to a new site in Guildford. The move happened in June 2025 and, due to the complexities of moving a large laboratory operation, this had caused some delays to analytical work. The Lab team had done a lot of planning and work to mitigate and minimise this but some impact was unavoidable. The move was completed successfully and all workstreams were now up and running and any issues were largely resolved.

Discussion with FSA and ASNFP

A member provided an update on engagement with the Food Standards Agency (FSA) following the BPC meeting in July. An introductory meeting was held in August with representatives from the Advisory Committee on Novel Foods and Processes (ACNFP) to explore areas of collaboration.

The group agreed that further discussions should continue, and the Secretariat will maintain contact with FSA representatives to progress collaboration.

II MINUTES **HCM(25)17**

740 The minutes of the meeting held on 6th February 2025 were confirmed, with some amendments to minute 727 for accuracy.

III MATTERS ARISING FROM THE MINUTES **HCM(25)18**

741 The following matters arising and correspondence items from the meeting held on 6th February 2025 were confirmed.

Mint

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

One of the experts volunteered to reach out and try to source samples.

Lemon Verbena Extract

Samples still needed to be sourced. It had been difficult to identify suitable samples so the Secretariat had been focusing on Wormwood and Chinese Goldthread.

Bacopa Monnieri

The Secretariat had been in contact with the EDQM Secretariat in April 2025. The *Bacopa monnieri* Ph. Eur. monograph was still in progress. Therefore, there has been no further progress as the Ph. Eur. Monograph had not yet been updated. The Secretariat had received no follow up from the original enquirer and no further queries so the Assay method will be updated once the Ph. Eur. monograph revision is finalised.

Chair’s update for BP Commission

An update on the status of the EAG HCM work programme was provided to the BPC at its July 2025 meeting, including a summary of the challenges, opportunities, and the future strategy and direction.

The BPC had seen opportunities in developing extract monographs that could be impactful and wanted to explore overlapping areas of interest between the MHRA and the Food Standards Agency.

New and Revised monographs for BP2026

The Secretariat confirmed that the following changes were made for BP 2026: a new monograph was added for Cyperus rotundus Rhizome, revisions were made to Capsicum Tincture, Compound Podophyllum Paint, Podophyllum Resin, Indian Sandalwood Oil, Senna Tablets and Squill monographs and the Supplementary Chapter VII D DNA barcoding, and the monographs for Senna Granules Senna Liquid extract and Sesame Seed were omitted, as agreed by the EAG previously.

Juniper Tincture

The draft new monograph was posted on the BP website for public consultation from April to June 2025, and no comments were received. The Secretariat will publish the monograph in BP 2027. This item was further discussed under any other business at the end of the meeting.

Wormwood Tincture

The Secretariat had submitted a laboratory requisition and was coordinating the delivery of sample aliquots.

Chinese Goldthread Preparations

The Secretariat had submitted a laboratory requisition and was coordinating the delivery of sample aliquots.

Podophyllum Preparations

Monographs for Podophyllum Resin and Compound Podophyllum Paint were revised and published in BP 2026.

Ocimum tenuiflorum

This DNA sequence was corrected in the Supplementary Chapter VII D in BP 2026. A further item is presented as “Review of the DNA sequences in supplementary chapter and appendix” on the current agenda to cover the review of the other DNA sequences in the supplementary chapter and appendix.

Prof M Simmonds, Mr B Moore and Mr C Welham declared interests in one or more agenda items and appropriate action was taken.

IV REPORTS AND CORRESPONDENCE

742 EXTRACT MONOGRAPHS FRAMEWORK DOCUMENT HCM(25)19

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.

A member shared with the Secretariats a link to the American Herbal Products Association (AHPA) website to support the development of the Good Agricultural and Collecting Practices (GACP) questionnaire for sourcing samples.

The Secretariat highlighted that samples would still be taken forward even if GACP was not in place; however, the Secretariats would examine the differences between GACP and non-GACP samples in laboratory assessment and monograph development.

A member had submitted two further comments on the document and these had been taken into account, and the EAG endorsed the framework document.

V NEW MONOGRAPHS

743 St. John's Wort Tincture — HCM(25)20

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

744 Tribulus Terrestris Fruit Dry Extract — HCM(25)21

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

745 Prepared Storax — HCM(25)22

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

Removal of reference to Barbados Aloes

The Secretariat sought members' views on whether to delete the reference to Barbados Aloes from the BP Compound Benzoin Tincture monograph immediately, or to wait for formal suppression by the EDQM.

The EAG saw no reason to retain the reference to Barbados Aloes and supported immediate removal.

746 Calcium Sennoside Preparations — HCM(25)23

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

VI REVISED MONOGRAPHS

747 Ispaghula Husk Preparations — HCM(25)24

The Secretariat presented the background and rationale for harmonising the monographs for Ispaghula Husk Granules, Ispaghula Husk

Effervescent Granules, and Ispaghula Husk Oral Powder, with particular focus on the microscopy and TLC/HPTLC identification tests.

Identification

Members agreed that the current microscopic identification tests for each preparation were appropriate and should remain unchanged.

Members also agreed that the TLC identification test for all three preparations should adopt the updated Ph. Eur. HPTLC method, which is now live in Ph. Eur. issue 12.2.

It was noted that Ispaghula Husk contains only trace amounts of mannose, but one expert recommended retaining mannose as a marker in the HPTLC test, as the presence of this band could indicate adulteration. Members endorsed this approach.

The EAG considered whether the presence of Acacia as an excipient in the granules would affect the identification but concluded that the HPTLC pattern for Acacia did not overlap with the bands produced by Ispaghula Husk. Members agreed therefore that Acacia would not interfere with the identification test.

Loss on drying, total ash, disintegration

The Secretariat received no objections to harmonising the loss on drying test across all three monographs.

Members also supported the proposal that the total ash and disintegration tests were fit for their purposes and did not require any changes or harmonisation.

Contaminant Statements in Monographs

A member expressed concern that contaminant controls such as pyrrolizidine alkaloids (PA) and aflatoxins are only referenced in general monographs. He noted a risk that these requirements could be overlooked if following a specific monographs like St. John’s Wort. He suggested that high-risk herbs should include explicit warnings or a cross-reference to the relevant general monograph in their individual monographs to prevent gaps in compliance.

One member acknowledged the challenge of setting a precedent, as including such statements in some monographs but not others could imply that the remaining monographs are free from risk.

The Secretariat highlighted that general notices already state individual monographs should be read in conjunction with the relevant general monographs.

Members noted that the legal restrictions on certain herbal ingredients applied to their supply as medicines, not as food supplements, and that some products may fall between regulatory categories, which underscored the need for clear guidance.

One member suggested that BP could consider developing a general chapter on contaminant risk assessment for herbal drugs, including a table of high-, medium-, and low-risk herbs and contaminants as guidance for producers. He also proposed updating the general monograph on herbal drugs to reference the PA test and recommended that trade associations help disseminate information on contamination risks.

Other members proposed developing a policy or framework to identify high-risk herbs and determine where explicit warnings would be appropriate.

The Secretariat noted that BP already includes UK-specific points at the end of some Ph. Eur. general monographs. The Secretariat agreed to consider these suggestions and bring forward proposals for addressing contaminant statements in BP monographs.

748 Statements on Restricted Herbal Ingredients **HCM(25)25**

The Secretariat presented the background and rationale for including statements in BP monographs that contain restricted herbal ingredients. Members were reminded that the BPC had endorsed this approach in March 2025, which was previously discussed and supported at the last EAG meeting in February 2025.

A selection of revised draft monographs was provided for review. The Secretariat noted that the Prepared Stramonium monograph, which had not been included in the previous paper, was now available for member review.

The Secretariat also mentioned that these statements are considered editorial amendments, as they do not introduce any technical changes. Accordingly, the revised monographs will be published in BP 2027 without public consultation.

Members endorsed the draft monographs for publication. No objections or further comments were raised.

It was also noted that the Ph. Eur. belladonna monographs were undergoing revision.

749 DNA Sequence Review **HCM(25)26**

The Secretariat presented the background and rationale for correcting errors in the published DNA sequences in the BP supplementary chapters and appendices. Members were reminded that, following identification by one of the EAG experts, the DNA sequence for *Ocimum tenuiflorum* had been corrected and published in BP 2026.

A review of other reference DNA sequences in Supplementary Chapter VII D and Appendix XI V was conducted. The Secretariat reported that errors were identified in the sequences for *Galium aparine* and *Glehnia littoralis* in Supplementary Chapter VII D. The revised sequences were presented for member endorsement.

The Secretariat confirmed that these amendments are considered editorial corrections, as they address errors in the published sequences and do not introduce any technical changes. Accordingly, the revised sequences will be published in BP 2027 without public consultation.

Members endorsed the proposed corrections. No objections or further comments were raised.

750 Senna Tablets **HCM(25)27**

The Secretariat presented the ongoing investigation into assay methods for Senna Tablets, focusing on the comparison between the UV and LC methods.

The Laboratory had completed further work on the LC assay method and assessed the disintegration method in the current monograph. The disintegration method was found to be satisfactory for all samples except one that was long expired; no changes were proposed to the method or the 60-minute disintegration time limit.

Assay Investigation

The LC gradient method (based on the senna pods method) was found suitable for analysis of senna tablets, while the isocratic LC method (from the granules monograph) was not suitable. Comparison of Sennoside B EPCRS and Alexandrian Senna Fruit BPCRS as reference standards did not show significant differences for the pods method, but differences were seen with the granules method.

Available data on Senna Tablets and BPCRS using the UV method was limited data , but the available data for tablets showed poor agreement between duplicate UV results and lower values than LC data, but the BPCRS results showed good precision for the UV method.

Review of Broader Data and Regulatory Context

The Secretariat had also reviewed other available information and regulatory reports on senna dosage. Data comparing LC and UV methods for senna leaves and pods showed no systematic bias; in some cases, LC results were higher, in others, lower. Most results fell within 85–115% (the current assay limits for Senna Tablets), but some were outside this range.

The Secretariat noted that the established dosage range for senna products is based on long-standing use rather than formal dose-finding studies, and that the wide effective range may reduce the risk of significant patient impact from changes in assay measurement.

Discussion and Next Steps

Members discussed the significance of differences between assay methods and the potential regulatory and clinical impact. It was noted that the UV method is currently required for batch-specific content determination in finished products, but is complex, time-consuming, and subject to variability. The LC method is preferred for specificity and accuracy and is already adopted for senna pods and leaves.

Members agreed that further laboratory work was needed to investigate the variability of the UV method for senna tablets, including multiple determinations, different analysts, and concurrent comparison with LC data. Suggestions included reviewing the initial extraction steps, comparing extraction solvents, and engaging with external QC labs for additional data.

VII EUROPEAN PHARMACOPOEIA — Verbal Update

The Secretariat provided an update on European Pharmacopoeia and Pharmeuropa activities. Members were thanked for submitting comments

on Pharmeuropa 37.3 texts and were reminded that Pharmeuropa 37.4 texts had been circulated on 16 October 2025. Experts were invited to submit any further comments before the deadline of 31 December 2025.

The EAG noted that currently the UK only had a representative on Group 13B. The Secretariat was considering nominating one of the BP Secretariat for one of group 13A or TCM and invited members to volunteer or suggest other potential UK experts.

Members discussed the value of having UK representation, as this expertise and critical review are still valuable contributions to the groups.

VIII ANY OTHER BUSINESS **Verbal Update**

A member had submitted a proposal for a standardised HPTLC approach to herbs, extracts, and tinctures. The Secretariat will discuss this further with him, and he will present the concept at the next meeting for discussion.

A member has conducted follow-up work on the previous Juniper Berry revision discussions. He had sent samples to Kew for LC/MS analysis to try and identify the bands, and this data had been sent to the Secretariat before this meeting.

IX NEXT MEETNG **Verbal Update**

753 The provisional date for the next meeting date would be in spring 2026. The date would be confirmed by the Secretariat soon.