

SUMMARY BRITISH PHARMACOPOEIA COMMISSION

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 27th June 2024.

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

Online attendees: Dr S Greatorex (LGC), Mr D Crowe (LGC), Dr A Booker, Professor A Slater, Professor K Strohfeldt-Venables

In attendance: Mr S Young, Dr D Tong

Apologies: Mr P Anderson

I	GENERAL MATTERS	HCM(24)01
709	Opening Remarks	
709.1	Welcome The Chair welcomed members to the meeting of the Expert Advisory Group (EAG) on Herbal and Complementary Medicines. The Chair asked everyone to introduce themselves as there were some new members.	
709.2	Membership The Chair noted that Dr Rowan and Ms Leon had both stood down from HCM due to retirement. The Chair recognised both their valuable contributions to the work of the EAG and noted that they would both be receiving letters of thanks. The Chair congratulated Dr Thanacoody and Dr Wilson on their appointments to the EAG.	
709.3	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. Mr Moore had noted one interest related to the Framework Document item, Mr Welham had noted an interest relating to the Capsicum Tincture and Squill items and Mr Middleton, Dr Booker, Prof Williamson and Dr Etheridge had sent in nil returns. Members were	

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	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 should contact the Committee Services Team at MHRA.	
709.4	Fees and Expenses Members were reminded that any queries regarding expenses should be sent to the Committee Services Team at MHRA. The BP policy on fees and expenses is unchanged and available to all experts. Members must now send all claims directly to the Committee Services Team rather than to the BP Secretariat.	
709.5	Organisational update Mr Young provided some organisational updates. The MHRA had been through an organisational restructure over the last couple of years and this was now well established. The Agency continued to operate across all functions. There had also been several new appointments to the BP Commission. Two lay members and three technical experts would be joining the BPC meeting in July and this would be the Commission back close to replacing the members who previously had reached the end of their terms. Dr Anna-Maria Brady was reappointed as Chair and Mr Rob Lowe was the vice-Chair of the new Commission. The Chair reported that she had agreed with Dr Brady that it was opportune to update the Commission about the ongoing HCM work, since it had been some time since the HCM work had been discussed with the Commission.	
II	MINUTES	HCM(24)02
710	The minutes and summary minutes of the meeting held on 29 th November 2023 were confirmed, with some amendments for accuracy provided by Professor Williamson.	
III	MATTERS ARISING FROM THE MINUTES	HCM(24)03
711	A list of matters arising from the last meeting was noted.	
711.1	Mint No further action had been taken due to resource constraints. The Secretariat need to source some “uncut” samples.	
711.2	Lemon Verbena extract No further action had been taken due to resource constraints. The Secretariat need to source samples.	
711.3	Wormwood Liquid Extract	

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	No further action had been taken due to resource constraints. The Secretariat need to source samples.	
711.4	Chinese Goldthread extract No further action had been taken due to resource constraints. The Secretariat need to source samples.	
711.5	Titles of herbal infusions EAG PCN had been informed of the EAG's view that the herbal infusion titles should remain unchanged.	
711.6	Juniper Tincture Secretariat had received some lab results from CAMAG and added in Supplementary Papers on the forum. A paper and an updated draft will be presented in the next EAG meeting. Mr Young asked if the EAG agreed that, since the work has been done by CAMAG, there was no need to ask the BP lab to verify the method and the EAG agreed this was not necessary.	
711.7	Bacopa Monnieri No further action had been taken due to resource constraints. The Secretariat had to update the Related Substances method to harmonise with the Ph. Eur.	
712	BP2025 HCM monographs	HCM(24)04
712.1	The Secretariat provided members with an update on the changes made to HCM monographs for the BP 2025.	
IV	EXTRACT MONOGRAPHS FRAMEWORK DOCUMENT <i>Mr B Moore declared an interest and took part in the discussion.</i>	
713	Report from the Secretariat The Secretariat presented an updated framework document for extract monographs, based on the feedback received at the previous meeting.	HCM(24)05
	The EAG agreed that the extract monographs should be targeted at the at the producers not the practitioners, and the document should make this clear.	
	The EAG agreed that the monograph titles should cross refer to the herbal drug extracts general monograph for defining different drug:extract ratios and the individual monographs should include the drug: extract ratio.	
	The EAG agreed to add the words 'where appropriate' to assay and identification tests to clarify that herbal drug assays were not always appropriate to the extracts.	
	The EAG agreed that the loss on drying test for dry extracts should aim for a standard limit of around 5% unless justified.	

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	The EAG agreed that sufficient information should be included on the labelling to ensure that any adverse reactions could be properly followed up.	
	The EAG agreed that, for HPTLC identification tests, the framework document should cross refer to <i>Ph. Eur.</i> method 2.8.25 as this chapter covers all considerations.	
	The EAG agreed that the terms used in the title and the content sections should be clarified to ensure they were not contradictory.	
V	NEW MONOGRAPHS	
714	Cyperus rotundus	HCM(24)06
	The draft monograph would be included in a future publication subject to public consultation and resolution of any outstanding points.	
715	Manufacturer request – <i>Tagetes erecta</i>	HCM(24)07
	Members were informed that a manufacturer had asked that a monograph for marigold (<i>Tagetes erecta</i>) extract be included in the BP. The consensus of the EAG was that this item should not be added to the work programme since it was a purified rather than a coarse botanical extract.	
VI	REVISED MONOGRAPHS	
716	Capsicum Tincture <i>Mr Welham declared an interest and took part in the discussion.</i>	HCM(24)08
	The EAG discussed several questions that had been raised during the final monograph review.	
	The EAG agreed that there was no need to put such additional labelling information in the monograph as this was covered by the corresponding section in the herbal drug extracts general monograph.	
	The EAG agreed that there was no need to include an Action and Use statement as these were included in API monographs but not for other monographs like tinctures.	
	The EAG agreed that the current draft gave the same range of the total capsaicinoids contents as the <i>Ph. Eur.</i> Standardised Capsicum Tincture monograph, so it did not require further revision.	
	The EAG agreed the reference to industrial methylated spirits (IMS) should be removed because IMS was that it was badly defined in industry and could represent a toxicity risk if misused.	
	The EAG also provided additional comments on the HPTLC method of this monograph.	

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717	Ispaghula Husk Effervescent Granules	HCM(24)09
	The EAG discussed a question that had been raised during the final monograph review. During the BPC Document Review Tool stage, Commission members raised a question concerning whether the microscopic identification test A in Ispaghula Husk Granules also applies to the effervescent granules.	
	The EAG agreed not to include the microscopic identification test in the effervescent granules monograph, because the effervescent ingredients , might interfere with the observation.	
718	Squill <i>Mr Welham declared an interest and took part in the discussion.</i>	HCM(24)10
	The Secretariat presented a draft monograph to the EAG, which was based on a validation report for an updated HPTLC method.	
	The EAG made some minor comments and agreed the draft monograph should be put out for public consultation.	
719	Senna monographs review	HCM(24)11
	The Secretariat provided an overview of the current monographs for Senna-containing products in the BP.	
	The EAG agreed that the Senna Liquid Extract monograph should be omitted, subject to the usual consultation process.	
	The EAG agreed that the Senna Granules monograph should be omitted, subject to the usual consultation process.	
	The EAG agreed that the definition of the Senna Tablets monograph should be updated to read “Senna tablets contain the powdered pericarp of Senna Pods.” to reflect the change in definition in the single Senna Pods monograph (<i>Ph. Eur. monograph 0207</i>).	
	Finally, the EAG agreed that a new monograph for Calcium Sennosides Oral Solution should be added to the work programme, since there were two licensed products (Senokot Syrup and SenEase Oral Liquid) but the BP currently did not contain a monograph for Senna Oral Solution.	
720	Calcium Sennosides API and Products	HCM(24)12
	The draft monographs would be included in a future publication subject to public consultation and resolution of any outstanding points.	
VII	EUROPEAN PHARMACOPOEIA	HCM(24)13
721	The Secretariat thanked members for their contributions to the Pharmedropa 36.1 and 36.2 review. The Secretariat also confirmed that	

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	five texts in the Pharmeuropa 36.2 review had been assigned to HCM, with a deadline at the end of June.	
VIII	ANY OTHER BUSINESS	
722	The following items were discussed	
	Juniper Tincture HPTLC The draft monograph would be included in a future publication subject to public consultation and resolution of any outstanding points.	
	New concepts for HPTLC The EAG agreed to adopt the concepts of the Universal HPTLC Mixture (UHM) and the Complementary Developing Solvent (CDS) protocol in future monographs that included HPTLC methods, since this could potentially replace the need for multiple specific SSTs and solvents.	
	Diagnostic DNA sequence for the <i>Ocimum tenuiflorum</i> monograph The EAG noted that the DNA identification sequence relating to related to the monograph for Holy Basil (<i>Ocimum tenuiflorum</i>) contained a different sequence from the original published sequence. This would be corrected in the next edition (BP2026) and the Secretariat would review the other sequences for accuracy.	
IX	NEXT MEETING	
723	The provisional date for the next meeting date would be in November or December 2024. The date would be confirmed by the Secretariat soon.	