BRITISH PHARMACOPOEIA COMMISSION

EXPERT ADVISORY GROUP: HERBAL AND COMPLEMENTARY MEDICINES (HCM)

SUMMARY MINUTES

A meeting of Expert Advisory Group (EAG): was held virtually on 29th November 2023

Present: Professor M Simmonds (*Chair*), Dr D Middleton (*Vice Chair)*, Dr A Booker, Mr C Welham, Dr K Zhao, Dr E Reich, Professor E Williamson, Ms K Stohfeldt, Mr P Anderson, Mr S Greatorex, Mr N Hope and Dr N Wilson

In attendance: Mr S Young, Mr D Tong, Mrs M Guler and Mrs S Begum

Apologies: Professor A Slater, Mr B Moore, Dr C Leon, Mr J Sumal, Mr C Etheridge and Dr M Rowan

I	**GENERAL MATTERS**	**HCM(23)01**
692	**Opening Remarks**	
692.1	**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 the EAG had not met since 2021 and there were several people attending for the first time.	
692.2	**Membership** The Chair announced several members had stood down from HCM. The Chair announced that following the last recruitment Members can expect reappointment letters from the Committee Services Team to be issued soon. From the recent call for expressions of interest to join BP EAGs, Panels and Working Parties, 2 new members for HCM were identified and approved at the November BPC meeting. The Chair also informed the EAG that MHRA has recently interviewed for some new BP Commission members.	
692.3	**Confidentiality and declaration of interests**	

	Members had all provided a declaration of their interest prior to the meeting and were asked to declare any interests on topics prior to the commencement of discussions; these would be noted in the minutes. The EAG was reminded of the types of interests that should be declared especially those that are personal or specific in relation to the item under discussion. If Experts had any queries relating to interests, they should contact the Committee Services Team.	
692.4	**Fees and Expenses** Members were reminded that any queries regarding expenses should be sent to the Committee Services Team. Members were also reminded that the BP policy on fees and expenses is unchanged. Members must now send all claims directly to Committee Services Team rather than to the BP Secretariat.	
II	**MINUTES**	**HCM(23)02**
693	The minutes and summary minutes of the meeting held on September 2021 were confirmed, with some amendments for accuracy provided by members.	
III	**MATTERS ARISING FROM THE MINUTES**	**HCM(23)03**
694	A list of matters arising from the last meeting was noted.	
	Cyperus rotundus The Secretariat need to update the monograph to exclude the “smaller” rhizomes, following the sub-group discussions, then the monograph should be ready for public consultation.	
	Mint No further action had been taken due to resource constraints. The Secretariat still need to source some “uncut” samples.	
	Squill The Secretariat need to update the monograph with the HPTLC method from a member as per the last meeting then the monograph should be ready for public consultation.	
	Lemon Verbena extract The Secretariat had been unable to source samples as yet. No further action had been taken due to resource constraints.	
	Wormwood Liquid Extract No action had been taken due to resource constraints.	
	Chinese Goldthread extract No action had been taken due to resource constraints.	

	Calcium Sennosides The Laboratory work had been completed and both the BP lab and MAH lab data were consistently showing approximately a 20% difference between the UV and LC methods. The Secretariat would discuss any implications of this difference (as simply changing from the UV to the LC method could potentially impact product content) and this would need to be carefully considered.	
	Mr Welham declared interests in one or more agenda items and appropriate action was taken.	
IV	**EAG PCN REFERRAL**	
695	**Change of Titles for herbal infusion monographs** The PCN Secretariat lead attended for this item.	**HCM(23)04**
	The Secretariat reported that during the annual review of monograph titles carried out by EAG PCN, one of the PCN experts had raised a potential issue that two herbal infusion monographs (Compound Gentian Infusion and Orange Peel Infusion) had similar titles to the monographs for injectable infusions. Since the herbal monographs were for oral use this similarity could be confusing for users.	
	The PCN suggestion of "tisane" was not a Standard Term. The Secretariat had also considered some alternatives, such as decoction, herbal tea, maceration but all options considered had their own drawbacks.	
	The Experts discussed the problem and considered that in usual usage, the herbal infusions and parenteral infusions would be unlikely to be used by the same user groups since their indications were so different. On balance therefore the EAG considered the potential risk to be very low. In view of the various drawbacks associated with the alternatives and the low potential risk, the EAG consensus was that the monograph titles should remain unchanged.	
V	**EXTRACT MONOGRAPHS FRAMEWORK DOCUMENT**	
696	Report from the Secretariat The Secretariat presented an updated framework document for extract monographs, based on the feedback received at the previous meeting. The Secretariat noted that the points raised by members about Tinctures on the minutes would need to be included. That the definition should be clear if they covered extracts using only a single solvent or multiple extraction solvents. That the term "Tinctures" should be used rather than "Liquid Extracts" for liquid extracts where the alcohol strengths used were high and the Drug-to-Extract ratio was high (usually minimum 1:3). The term "Liquid Extract"	**HCM(23)05**

	should be used where the alcohol strength was low and the Drug-to-Extract Ratio was 1:1. That the sentence "... for extracts of herbs with a high essential oil content…" should read "... for **dry** extracts of herbs with a high essential oil content…". That the section on naming for Tinctures and Liquid Extracts – should make sure the title correctly defines what the extract is.	
	One member noted that dry extracts (powders/granules) were being used more and more, especially in Western countries. From a practitioner's point of view, when using a dry extract powder they would still prepare the dose based on the amount of raw herb. The definition for dry extracts should therefore include a statement to his effect i.e. "1 g of dry extract is equivalent to X g of raw herb". Another member asked if a tincture would usually contain higher amounts of drug. A member stated that this was a complex issue, since the ratio may differ between manufacturers, and will also vary based on the freshness of the herbs (it could not be assumed that a 7:1 ratio was always better than a 3:1 ratio as the reverse could be true if the 3:1 ratio extract used a fresher herb with higher amounts of constituents in the material than the raw herb used in the 7:1 extract). One member noted that for drug extracts that were granules; this will also be affected by any excipients added and we should refer to the Ph. Eur. "extracts" monograph. In the USP the herbal extract monographs rely on just a single marker; the rest of the materials used are not specified. Another member noted that in Hong Kong they have taken out granules because of complications caused by the excipients. One member supported this point and said that the most important thing is the solvent used and the excipients added. In his own research into TCM extracts on the market, he had found that for cucumber extracts the cucurmin levels were almost zero because they were all aqueous extracts and curcurmin is not water soluble.	
	A member observed that, when looking at the framework document and the draft Juniper and Green Tea monographs together, the question of what the monographs were intending to achieve arose; we have wide varieties of samples obtained from the market and if the monograph limits just reflected the market samples then these would be very wide; we could set tighter limits to define the minimum quality standards but where should the lines be drawn? One member agreed and reiterated the above point. In his view, when it comes to setting limits, we should not be too harsh as this will discourage producers if the limits were too strict. The framework document should define if the monographs covered Quality, Safety and/or Efficacy. Often for herbal materials it was not known exactly what the effective constituents are. The Secretariat noted that BP monographs were Quality standards and did not cover efficacy and safety directly.	
	The member noted that monographs in the BP/Ph. Eur. usually relied on the labelling requirements included in the general monographs. If the	

	extract monographs were targeted at a different user group, we should consider including a labelling statement for extracts that were intended to be administered directly to patients, rather than being used as an ingredient in a product.	
V	**NEW MONOGRAPHS**	
697	**Juniper Tincture**	**HCM(23)06**
	The draft monograph would be included in a future BP publication, subject to amendments and comments from manufacturers.	
698	**Green Tea Extract**	**HCM(23)07**
	The draft monograph would be included in a future BP publication, subject to amendments and comments from manufacturers.	
VI	**REVISED MONOGRAPHS**	
699	**Podophyllum Resin, Compound Podophyllin Paint**	**HCM(23)08**
	Following the discussions at the last meeting, the Secretariat had updated both the resin and paint monographs to include the use of both *Podophyllum hexandrum* Royle (*P. emodi* Wall) and *Podophyllum peltatum* L. species. For the paint monograph, the calculations for total solids had also been updated with a variable strength approach. Both monographs had been published for public comment in the October - December 2023 consultation window.	
	One member pointed out that the use of silica GF TLC plates in the identification test is outdated and he recommended the use of HPTLC plates instead. He also pointed out the use of chloroform in the mobile phase should be avoided. The Secretariat reminded the group the intention of this revision is to update the definition to allow the use of both species, and then to remove the use of *Podophyllum hexandrum* in a subsequent revision. The group agreed to update the definition and to replace silica gel GF plates with HPTLC plates for BP 2025, followed by updating the TLC method to remove the use of chloroform when the use of *P. hexandrum* species is removed entirely.	
700	**Ispaghula Husk Granules, Effervescent Granules**	**HCM(23)09**
	The Secretariat presented updated monographs for Ispaghula granules and effervescent granules, in line with the decisions taken by the EAG at the previous meeting. The TLC identification test had been harmonised across the monographs. The two draft monographs were published on the BP website for the September to December public consultation window.	
	One member noted that the Ph. Eur. was in the process of updating the HPTLC methods used to determine carbohydrates in the ispaghula husk	

	and similar monographs (e.g. acacia gums, psyllium husk etc...) to avoid the use of TFA in the sample preparation following a request for revision in October 2023. The EAG agreed that the BP monographs should be updated in line with any changes in the Ph. Eur. Ispaghula Husk monograph once any revision was completed.	
	One member asked if there were any UK MAHs. The Secretariat confirmed that there were and that MAHs had been informed that the consultation was live.	
	The EAG endorsed the inclusion of the revised monographs in the next edition of the BP, subject to any significant comments received during the public consultation.	
701	**Eclipta prostrata whole plant – omission**	**HCM(23)10**
	The Secretariat reported that the European Pharmacopoeia had included a new monograph for Eclipta Herb with Root supplement 11.3 (effective date 1 January 2024). This new monograph would supersede the existing BP monograph for Eclipta prostrata whole plant. In terms of tests and limits the Ph. Eur. and BP monographs were entirely similar. The EAG endorsed that the monograph be omitted from the next edition of the BP.	
702	**Capsicum Tincture query**	**HCM(23)11**
	The Secretariat had received a query pointing out the difficulties in calculating the assay using the formula provided in the monograph. One member commented on the calculation in the draft monograph and agreed to share a detailed calculation with the Secretariat after the meeting.	
702	**Bacopa Monnieri query**	**HCM(23)12**
	The Secretariat had received a query pointing out the difficulties in identifying the peak for bacopaside I with the RRT provided in the assay. One member mentioned that the EDQM has elaborated the monograph on Bacopa Monnieri, and the monograph will be published once the EPHRS has been established. The member also reminded the Secretariat that the USP is using powdered bacopa dry extract RS and bacopaside A_3 as reference materials. Therefore, it would be worth adopting the most recent Ph. Eur. method as adding the use of EPHRS is the only thing to change once EDQM has published their monograph.	
VII	**EUROPEAN PHARMACOPOEIA**	**HCM(23)13**

703	The Secretariat thanked members for their contributions to the Pharmeuropa review. The EAG were reminded that the draft texts for Pharmeuropa 35.4 were still open for comments and, if they had any comments to send them by 31st December.	
VIII	**ANY OTHER BUSINESS**	
707	None	
IX	**NEXT MEETINGS**	
708	The next meeting date was planned for June (26th/27th) 2024 and the date would be confirmed by Committee Services soon. It was intended that this would be a face-to-face meeting.	