BRITISH PHARMACOPOEIA COMMISSION

Expert Advisory Group (EAG): Herbal and Complementary Medicines (HCM)

SUMMARY MINUTES

A meeting of this Expert Advisory Group was held at 151 Buckingham Palace Road, London, SW1W 9SZ on 25th November 2015.

Present: Prof E Williamson (*Chair*), Dr L Anderson (*Vice-Chair*), Mr P Anderson, Dr K Helliwell, Ms C Leon, Dr R Middleton, Mr B Moore, Dr M Rowan, Dr K Strohfeldt-Venables, Mr J Sumal, Mr C Welham and Dr K Zhao.

Apologies for absence: Prof A Bligh, Dr M Pires.
Prof S Gibbons did not attend the meeting.

In attendance: Dr P Holland, Dr R A Pask-Hughes, Mr M Whaley, Dr C Howard, Ms C Lockie-Williams, Mr S Humphries and Miss R Irlam.

494 **Introductory Remarks**

Welcome The Chair welcomed members and extended a particular welcome to Mr S Humphries and Miss R Irlam from the BP Laboratory and also to Dr C Howard and Ms Lockie-Williams from the BP-NIBSC Herbal Laboratory.

Comments had been received from Dr Pires and Dr Krauss (corresponding member – TGA, Australia) and these were taken into consideration during the discussions and decisions of the relevant agenda items.

Declaration of Interests Participants were asked to declare any interest they might have, where appropriate, before the start of the discussion of each paper.

I MINUTES

495 The minutes of the meeting held on the 25th June 2015 were confirmed subject to a minor typographical correction.

II MATTERS ARISING FROM THE MINUTES

496 A list of matters arising from the minutes of the meeting of EAG HCM held in June 2015 and some on-going matters arising from previous meetings was provided. A copy is appended.

III REPORTS AND CORRESPONDENCE

497 **Sample Procurement** HCM (15)18

In response to an e-mail sent to members specifically concerning the number of nutmeg samples available for analysis, it had been suggested that sample requests should be sent routinely to the BHMA and other relevant organisations. The Secretariat had drafted a general form for routine provision by the BHMA and other organisations. It was generally agreed that suppliers should be encouraged to send as much information as possible since it should encourage provision of good quality herbal material for analysis. It was commented that some companies were uncertain as to the reason for such requests and it was therefore important that the BP's intentions were made clear to the UK herbal industry in order to continue to engage with the industry. Members examined the drafted form and certain suggestions were made and agreed.

498 **Laboratory Sample Control Risk Assessment** HCM (15)19

Members were informed that following an incident earlier in the year some of the herbal samples stored at the BP Laboratory had to be discarded due to insect contamination.

Details regarding how the herbal samples should be treated to minimise the chance of such an incident occurring again were considered. Samples received by the NISBC-Herbal Laboratory were all frozen at -80° in order to kill living organisms. Samples received by the BP-Laboratory were not frozen but were carefully inspected on arrival, stored in air-tight boxes with silica gel and were monitored on a regular basis.

499 **Holy Basil Leaf** HCM (15)20

A copy of a report presented at the meeting of the WP DNA in July 2015 was presented for information. Samples of *Ocimum gratissimum* had been analysed using the BP 2016 Appendix XI V DNA Identification method. The results had demonstrated that the current method was capable of separating *Ocimum tenuiflorum* from *O. gratissimum*. A barcode could be published for *O. gratissimum* with no changes to the protocol.

It was noted that the *O. gratissimum* was used in East Africa whereas *O. tenuiflorum* was common in India. In order to assist in determining whether there should be separate specifications for *O. gratissimum* or whether the monograph for *O. tenuiflorum* should be revised, chemical analyses were needed to see if there were any distinct chemical differences between the species, for this more *O. gratissimum* samples were needed and further efforts were being made to procure samples.

500 **BP Work Programme** HCM (15)21

A copy of the BP work programme was received updating members of the developments since June 2014 when the programme was last discussed and the targets for the BP 2017 to BP 2021 were noted. In the future the draft monographs would be made publicly available for comment by stakeholders on the BP website.

Additional Laboratory Resource The BP-NIBSC Herbal Laboratory was expanding and the BP-NIBSC herbal project had been extended.

Draft Strategy for HCM: A draft herbal strategy was under consideration within the Secretariat.

Sample sourcing Difficulties continued with the sourcing of herbal samples for the monograph development work. In the case of the herbal drugs used in Ayurvedic medicines this was being addressed by MHRA senior management and Indian Authorities.

The sourcing problem with European herbal drugs was the identification of suppliers of GMP compliant medicinal herbal drugs and also the purchase of the requisite number of 3 batches of samples from 3 distinct suppliers. Collaborative avenues were continuing to be explored in order to establish partnerships which will enable the Secretariat to source GMP compliant/good quality herbs. Members noted that care was needed when deciding on a monograph to be developed where it was wild harvested, and that it should also be available in the cultivated form, otherwise the plant population might become endangered and might additionally encourage substitution. It was hoped that the ‘sample procurement form’ should help to address this matter.

Members acknowledged that pragmatism was needed in the approach to adopt for the number of samples required for the monograph development work and also types of

suppliers to engage. Members were reminded that BP monographs for herbal drugs used in traditional medicines were elaborated under similar conditions to some *Ph*. *Eur*. traditional monographs for herbal drugs used in traditional medicines. In some cases, commercial samples were used with minimum authentication data.

Confirmation of Botanical identification The collaborative work with the Royal Botanic Gardens, Kew, would continue for confirmation of the botanical identification of herbal drug samples in conjunction with more recently used DNA barcoding data produced at the BP-NIBSC Herbal Laboratory. To date the two distinct data sets had, in general, led to the same conclusions.

Prioritisation The priority for new and revised HCM monographs would be focused on:
(a) herbal drugs used in licensed and registered products in the UK;
(b) requests from NRAs/NDAs/regional governments in areas where the BP is an inherent part of medicines legislation;
(c) requests from collaborative partners, such as the ChP, where additional support was offered.

Additions to the Work Programme
Lists of information on granted THRs had been provided from Licensing that would be examined by the Secretariat with the view to identifying herbal drugs in registered products for which there were no published pharmacopoeial (BP and *Ph. Eur.*) monographs and were not included on either of the work programmes. The new candidates identified would be circulated to members with the view to including them on the current BP work programme, subject to approval by the BP Commission.

Calcium sennosides Addition of the herbal preparation to the work programme was agreed.

Capsicum extracts Since the specifications dated back to BPC 1973, the Secretariat was to check the BPC details with the view to identifying what candidates should be proposed for addition to the work programme.

New Initiatives Members were informed that the Secretariat was open to new initiatives and different ways of working which would support the herbal industry through provision of robust quality standards.

501 **Monographs in Progress** HCM (15)22

A list of monographs in progress was received. The Secretariat was to review the number of samples acquired for the monograph development.

502 **Supplementary Chapter - DNA Barcoding as a tool for botanical Identification of Herbal Drugs** HCM (15)23

HCM members were invited to identify any additional information which should be added to the first draft supplementary chapter entitled ‘DNA Barcoding as a tool for Botanical Identification of Herbal Drugs’ undergoing preparation by the DNA Working Party: Identification Techniques. It was intended as an aid to understanding DNA barcoding and how it was to be applied within the BP. The draft would be presented at the meeting of the Working Party due in July 2015. It was noted that as a Supplementary Chapter, the text was not mandatory and was for guidance only.

IV MONOGRAPHS IN PROGRESS

503 **Vitex Negundo Leaf** HCM (15)24

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

504 **Clivers** HCM (15)25

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

505 **Nutmeg** HCM (15)26

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

506 **Spearmint** HCM (15)27

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

507 **Tribulus Terrestris Fruit** HCM (15)28

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

V NEW MONOGRAPH

508 **Sandalwood Oil** HCM (15)29

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

VI REVISION OF MONOGRAPHS

509 **Liquorice Liquid Extract** HCM (15)30

In view of the problems reported at the previous meeting of EAG HCM the BP Commission had endorsed EAG HCM's recommendation that the monograph for Liquorice Liquid Extract be omitted by means of the BP 2017. A report on the problem would be available for the June 2016 meeting of HCM.

510 **Peppermint Product monographs** HCM (15)31

Gastro-Resistant Peppermint Oil Capsules: **Chromatographic profile** As a result of investigation of the chromatographic profile given in the current *Ph. Eur.* monograph for Peppermint Oil for application to the draft monograph for Peppermint Oral Solution, it had been realised that the limits given in the monograph for Gastro-Resistant Peppermint Oil Capsules had been based on those in the *Ph. Eur.* method in the oil monograph prior to revision of the oil monograph limits. The Secretariat had contacted the manufacturers with a view to revising the limits.

Peppermint Spirit Since the current monograph had no test for identification and there were no chromatographic profile limits on the oil components, the Secretariat had undertaken to contact the producers concerning possible application of the

chromatographic profile test as specified in the *Ph. Eur.* monograph for Peppermint Oil to the Peppermint Spirit monograph.

Concentrated Peppermint Emulsion The BP monograph had been omitted from the BP 2016 as agreed since it did not include any identification, tests or oil analysis. The Secretariat had undertaken to contact the producers to ask if the chromatographic profile test was applicable to the monograph.

Peppermint Oral Solution The Secretariat had discussed the matter internally. It had been agreed that the matter should be 'on hold' until such time that the active ingredient could be assayed with acceptable precision and other analytical issues addressed.

VI EUROPEAN PHARMACOPOEIA

511 Alternatives to HPLC Assay HCM (15)32

Members were informed that the need for inclusion or otherwise of assays in TCM monographs was undergoing consideration. The ongoing discussions had been triggered by concerns being raised by TCM suppliers in Europe who claimed that the implementation of many of the TCM monographs made the correct supply and traditional use of low volume TCMs uneconomic.

512 European Pharmacopoeia Reports HCM (15)33

Members noted that the most recently received reports of the meetings of *Ph. Eur.* expert groups and Working Parties had been circulated to members prior to the meeting.

VII ANY OTHER BUSINESS

513 Dates of 2016 meetings:

Tuesday 21June
Wednesday 23 November.

MATTERS ARISING FROM PREVIOUS MEETINGS OTHER THAN THOSE MENTIONED ON THE AGENDA

Meeting November 2015

Note from the Secretariat
Given the time elapsed since initiation of some of the items on the list below, members were asked to consider agreeing to re-assessment of the need for the affected monographs. The Secretariat will work with HCM to review the list during 2016.

Minute Reference	Action	Suggested Decision
Minute 335: Chrysanthemum Flower	To be progressed at the earliest opportunity.	The Secretariat will re-assess the need for a monograph before the Spring 2016 meeting
Minute 357.6 Spearmint Oil	The action concerning revision of the oil monograph would be addressed at the earliest opportunity.	Revise the monograph at the same time as the monograph for Spearmint is developed
Minute 358: Adhatoda Vasica Root (Malabar Nut)	To be progressed at the earliest opportunity.	The Secretariat will re-assess the need for a monograph before the Spring 2016 meeting
Minute 359: Cyperus Rotundus	To be progressed at the earliest opportunity.	The Secretariat will re-assess the need for a monograph before the Spring 2016 meeting
HCM meeting December 2013		
Minute 405.3 Opium Tincture	Revision of the monograph would be investigated at the appropriate time.	Review documentation on the request for revision before the Spring 2016 meeting
HCM meeting June 2014		
Minute 435 Burdock Root	Manufacturers of Burdock Root containing products have been contacted.	The action will be initiated before the end of 2015
Minute 437 Golden Cinquefoil	Action to be progressed as part of BP work programme items	The action will be initiated before the end of 2015
Minute 446 Dill Oil	Some samples have been received and work on the assessment of a test for apiole will be considered at the earliest opportunity.	To be progressed
Minute 510 Standardised Senna Leaf Dry Extract	Data is still being sought to support a request for the revision to the test for loss on drying.	Review documentation on the request for revision before the Spring 2016 meeting

Minute 519: **Chloroform-containing preparations**	The revised monographs for Acid Gentian Mixture and Alkali Gentian Mixture to omit reference to the extemporaneous preparations have been included in material for the BP 2016. As agreed the monograph for Concentrated Peppermint Emulsion has been omitted from material for the BP 2016.	To be addressed under AOB at the November 2015 meeting

List of Acronyms/Synonyms

Acronym/Synonym	Name
APhI	Ayurvedic Pharmacopoeia of India
ARTG	Australian Register of Therapeutic Goods
ATA	Ayurvedic Trade Association
BHP	British Herbal Pharmacopoeia
BHomP	British Homoeopathic Pharmacopoeia
BP	British Pharmacopoeia
BP (Vet)	British Pharmacopoeia (Veterinary)
BP Commission	British Pharmacopoeia Commission
BPCx	British Pharmaceutical Codex
BPCRS	British Pharmacopoeia Chemical Reference Substance
BS	British Standard
CMPACC	Chinese Medicinal Plants Authentication and Conservation Centre (Kew)
CEP	Certification Procedure for the European Directorate for the Quality of Medicines
CHM	Commission on Human Medicines
CP	Pharmacopoeia of the People's Republic of China
CRS	Chemical Reference Substance
EAG	Expert Advisory Group
EPC	European Pharmacopoeia Commission
EPCRS	European Pharmacopoeia Chemical Reference Substance
EU	European Union
FDA	Food and Drug Administration
FIP	International Pharmaceutical Federation
FoI	Freedom of Information
GC	Gas chromatography
GMP	Good Manufacturing Practice
HAB	German Homoeopathic Pharmacopoeia
HKCMMS	Hong Kong Chinese Materia Medica Standards
HMPC	Herbal Medicinal Products Committee
ICH	International Conference on Harmonisation
IR	Infrared
ISO	International Organisation for Standardisation
JP	Japanese Pharmacopoeia
LC	Liquid chromatography
LD	Licensing Division

LGC	Laboratory of the Government Chemist, Teddington
LR	BP Laboratory Report
MAIL	Medicines Act Information Leaflet
MHRA	Medicines and Healthcare products Regulatory Agency
MPNS	Medicinal Plant Names Services - Royal Botanic Gardens, Kew
NIBSC	National Institute for Biological Standards and Control
NPA	National Pharmacopoeial Authority
OMCL	Official Medicines Control Laboratory
Ph Eur	European Pharmacopoeia
PMU	Pharmacy Medicines Unit – to be confirmed
QSIMP	Quality Standards of Indian Medicinal Plants
SPC	Special Product Characteristics
TGA	Therapeutic Goods Administration, Australia
THMPD	Traditional Herbal Medicinal Products Directive
TLC	Thin layer chromatography
UK	United Kingdom
UKD	United Kingdom Delegation [to the European Pharmacopoeia]
USP	United States Pharmacopeia
UV	Ultraviolet
WHO	World Health Organization