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 23rd November 2016.

Present: Prof. E Williamson (*Chair*), Dr L Anderson (*Vice-Chair*), Prof. M Simmonds (2nd *Vice-Chair*), Mr P Anderson, Dr K Helliwell, Dr R Middleton, Mr B Moore, Dr E Reich, Dr M Rowan, Dr K Strohfeldt-Venables, Mr J Sumal and Dr K Zhao. Dr A Gleadle (BP Commission Lay member) also attended the meeting.

Apologies for absence: Prof A Bligh, Ms C Leon, Dr M Pires, Mr C Welham.
Prof S Gibbons did not attend the meeting.

In attendance: Dr P Holland, Dr R A Pask-Hughes, Mr M Whaley, Dr A Gardiner (for item HCM (16)16 only).
Dr C Howard, Dr M Kalantarzadeh, Ms C Gkouva and Mr L Gibson.
Ms F Lee, Ms C Galdino and Mr S Humphries.

534 **Introductory Remarks**

Welcome The Chair welcomed Dr Alison Gleadle, (Lay representative) member of the BP Commission who was attending as an observer. New member Dr Eike Reich was welcomed; he was a member of a number of Ph Eur Groups of Experts. She also welcomed Ms Lee, Ms Galdino and Mr Humphries from the BP Laboratory.

The Chair informed members that this was the last meeting that Dr Helliwell would attend as a member of EAG HCM. She expressed extreme gratitude for Dr Helliwell's extensive and committed help to the work of standard settings for herbal medicines over many years, in particular his commitment and contributions to the work of the BP Commission. He had provided extensive input into the development of BP herbal specifications and, likewise, with his membership of several European Pharmacopoeia Groups of Experts and Working Parties had provided valuable input to the development of Ph Eur standards. The June 2016 meeting of Panel of Experts DNA: Identification Techniques was the last meeting that he had attended as the Chair having likewise now retired from the Panel. Professor Adrian Slater had been appointed as replacement Chair of Panel DNA.

BP Secretariat Members were informed that two staff members would be leaving before the next planned meeting of EAG HCM. The Chair thanked both for their support for the HCM work over many years.

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

Confidentiality The Chair reminded all present of the confidential nature of the papers, discussions and minutes of the meeting.

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

Membership list The contact details of members was circulated so that any changes could be noted.

I MINUTES

535 The minutes of the meeting held on 21 June 2016 were confirmed, subject to the following changes.

Minute 530 Concentrated Peppermint Emulsion Change the last sentence to read 'However, the 2% oil was not expected to be recoverable from the formulation by standard methods due to the emulsifier present.'

EAG HCM Minute numbering Correct the minute numbering by replacing '530 European Pharmacopoeia Reports' by '531 European Pharmacopoeia Reports'. Amend the 2 subsequent minute numbers accordingly.

Panel of Experts DNA Minutes The minutes had been provided to EAG HCM for information since the outcomes were of relevance to the work of HCM.

II MATTERS ARISING FROM THE MINUTES

536 A list of matters arising from the minutes of the meeting of EAG HCM held in June 2016 and on-going matters arising from previous meetings was provided. A copy is appended.

III REPORTS AND CORRESPONDENCE

537 **Public Consultation of Draft Text** HCM (16)16

Responding to stakeholder feedback for opportunity to comment on draft new and revised monographs, four fixed public consultation periods had been agreed for uploading draft new and revised monographs on the updated BP website. The set dates had been aligned with those of public Pharmeuropa consultation times. On the first day of the consultation when the texts are uploaded a news item to alert users is posted on the front page of the BP website and an email is sent to the BP news mailing list. The 2017 schedule is:

1st January – 31st March 2017
1st April – 30th June 2017
1st July – 30th September 2017
1st October – 31st December 2017.

The draft texts are available at https://www.pharmacopoeia.com/draft-text

538 **BP Work Programme** HCM (16)17

Herbal strategy Members were informed that a herbal strategy was under preparation by the Secretariat. This was to better clarify and plan the various strands of work and to allocate resources accordingly. HCM would be consulted at the appropriate time.

Members were informed that a major concern to one of the main UK trades association was the quality of herbal material used by practitioners and the unregulated market place. Approximately 30% of tested samples were of poor quality, many were adulterated as had been demonstrated by some researchers. It was intended that with liaison with academia,

the phytochemistry training might be dovetailed with that of the macro- and microscopic teaching and thus improve the situation. A member considered that if suppliers were aware of the poor quality it would not be supplied. The BP Secretariat would be invited to future BHMA meetings in order to keep informed of the developing situations. It was commented that species of Echinacea (*E. augustifolia, E. purpurea, E. pallida)* and Milk-thistle had been found to contain adulterants.

Work Programme Members recalled that the BP work programme was categorised into three areas; herbal drugs used in Ayurvedic, TCMs and those included in THR products. The aim was to target publication of 5 monographs for herbal drugs for the annual BP publication. The additional laboratory resource in place at NIBSC should enable work to progress at a relatively faster rate.

Prioritisation The following order of prioritisation was noted.
(a) Licensed and registered products in the UK,
(b) Requests from NRAs/NDAs/regional governments where the BP is an inherent part of medicines legislation (mainly Commonwealth countries),
(c) Requests from collaborative partners, including Industry, where additional support is offered by the partner.
Members would be invited to input to the HCM prioritisation process of the candidate monographs.

Success A measure of the value of published BP monographs to the Ph Eur work processes was the degree of consideration and incorporation of the BP methods and specifications into Ph Eur monographs.

539 **Tolu-flavour Solution** HCM (16)18

Tolu-flavour Solution A request had been received from a UK manufacturer for Cinnamic Acid BP to be replaced by “cinnamic acid of commerce” in the BP monograph for Tolu-flavour Solution. This was due to current difficulties in sourcing Cinnamic Acid BP. Members noted that material of commerce could be specified in BP monographs when justified. Such an approach had already been adopted for the storax content in the BP monograph for Compound Benzoin Tincture.

It was agreed that Cinnamic Acid BP should be replaced by “cinnamic acid of commerce” in the statement under ‘Definition’. The material of commerce was used in the food industry and it was noted that Tolu-flavour Solution was only intended to impart flavour to Squill Linctus Opiate.

Cinnamic Acid Members noted that a supplier in the UK had an interest in Cinnamic Acid. The Secretariat undertook to discuss this issue with Panel IGC Secretariat to better understand the quality of material provided by the company. If appropriate, the BP monograph for Cinnamic Acid would be revised at the earliest opportunity.

540 **Phoenix Microwave Furnace** HCM (16)19

With the recent expansion of the BP-NIBSC Herbal Laboratory, the capacity to allow for Loss on Drying (LOD) and Total ash testing had been made possible. A Phoenix microwave furnace had been recently purchased and validated using samples of *Vitex negundo* leaf.

Members discussed the report presented by the BP-NIBSC Herbal Laboratory and made suggestions on further work required to demonstrate the equivalence with the traditional methods and the proposed method. Members would be updated on progress of this work at

the earliest opportunity and before the June 2017 HCM meeting.

IV MONOGRAPHS IN PROGRESS

541 **Galium Aparine (Cleavers; Clivers)** HCM (16)20
The draft monograph would be included in a future publication, subject to comments from manufacturers.

542 **Nutmeg** HCM (16)21
The draft monograph would be included in a future publication, subject to comments from manufacturers.

544 **Indian Sandalwood Oil** HCM (16)23
The draft monograph would be included in a future publication, subject to comments from manufacturers.

545 **Tribulus Terrestris Fruit** HCM (16)24
The draft monograph would be included in a future publication, subject to comments from manufacturers.

546 **Capsicum Oleoresin; Capsicum Tincture** HCM(16)25
The draft monographs would be included in a future publication, subject to comments from manufacturers.

547 **Calcium Sennosides** HCM(16)26
The draft monograph would be included in a future publication, subject to comments from manufacturers.

V NEW MONOGRAPHS

548 **Liquorice Liquid Extract** HCM (16)27
The draft monograph would be included in a future publication, subject to comments from manufacturers.

549 **Glehnia Littoralis Root** HCM (16) 28
The draft monograph would be included in a future publication, subject to comments from manufacturers.

VI REVISION OF MONOGRAPHS

550 **Peppermint Preparations** HCM (16)29

Peppermint Spirit The monograph would be omitted by means of the BP 2018.

Concentrated Peppermint Emulsion Available information indicated this was not supplied in the UK because of restrictions on the use of chloroform in formulated preparations. In view of the lack of a formulation not containing chloroform, work on the monograph was not

advocated.

Peppermint Oil Enema At the June 2016 HCM meeting, members had discussed the need for a monograph for peppermint oil enema. The information received following the meeting showed there was a low degree of use in hospitals. Members agreed that a monograph should not be progressed at this time.

VI EUROPEAN PHARMACOPOEIA

551 **European Pharmacopoeia Reports** HCM (16)30

Informal reports for EDQM Groups of Experts and a Working Party were discussed.

552 **Toxicodendron Quercifolium for Homoeopathic Preparations** HCM (16)31

A monograph for Toxicodendron Quercifolium for Homoeopathic Preparations was currently under consideration by the HOM Working Party.

VII ANY OTHER BUSINESS

553 **Programme of Meetings in 2017**

Thursday, 22nd of June
Thursday, 23rd of November.

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

Minute 335: Chrysanthemum Flower
To be progressed at the earliest opportunity.

Minute 357.6: Spearmint Oil
The action concerning revision of the oil monograph would be addressed at the earliest opportunity.

Minute 358: Adhatoda Vasica Root (Malabar Nut)
Group 13A at the EDQM are in the process of elaborating a monograph for Adhatoda Vasica Leaf.

Minute 359: Cyperus Rotundus
To be progressed at the earliest opportunity.

Minute 446 Dill Oil
To be progressed at the earliest opportunity.

Minute 487: Phyllanthus Amarus
To be progressed at the earliest opportunity.
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Minute 520: Aristolochic Acids in Herbal Drugs
As agreed at the meeting in June 2016 the Secretariat provided the paper "LC-MS- and 1H NMR-Based Metabolomic Analysis and *in Vitro* Toxicological Assessment of 43 Aristolochia Species." to the EDQM for consideration. Members agreed that revision to the published Ph Eur appendix method was not necessary at this time as the use of herbal drugs containing AAs (aristolochic acids) is banned in Europe, (see EMA public statement http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2010/04/WC500089957.pdf;

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
GC-FID	Gas chromatography – Flame Ionization Detector
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
Panel IGC	Panel IGC: Inorganic and General Chemicals
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