BRITISH PHARMACOPOEIA COMMISSION

Expert Advisory Group: 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 Wednesday 25th June 2014.

Present: Prof E Williamson (*Chair*), Dr L Anderson (*Vice-Chair*), Mr T Chapman, Mr A Charvill, Dr K Helliwell, Ms C Leon, Prof A C Moffat, Dr M Pires, Dr M Rowan, Dr K Strohfeldt-Venables, Mr J Sumal, Ms P Viner, Dr C Wright and Dr K Zhao.

In attendance: Dr P Holland, Dr R A Pask-Hughes, Mr M Whaley, Mr P Crowley, Mr M Coxon and Mr A Aktar.
Mr Paul Anderson attended as an observer.
An apology for absence was received from Prof P Hylands.

426 **Introductory Remarks**

Welcome The Chair welcomed everybody to the meeting. In particular Dr C Howard and Mrs C Lockie-Williams, from NIBSC, who were working on the joint project for molecular characterisation of herbs, were welcomed as observers. Mr M Coxon and Mr A Aktar, from the BP Laboratory, were also welcomed together with Mr P Crowley from the BP Secretariat, who was attending for training purposes.

Comments from Corresponding Members The Chair highlighted that comments had been received from Dr Krauss that would be taken into consideration during the decision-making process of the relevant agenda items.

Declaration of interests Members and observers were reminded to declare any interest they might have, where appropriate, before the start of the discussion of each paper.

I MINUTES

427 The minutes of the meeting held on the 3rd December 2013 were confirmed.

II MATTERS ARISING FROM THE MINUTES

428 A list of matters arising from the minutes of the meeting of EAG HCM held in December 2013 was circulated together with the papers for the meeting. A copy is appended.

III REPORTS AND CORRESPONDENCE

429 **BP Work Programme** HCM(14)01

Criteria for Prioritisation of Work Programme Experts were invited to discuss effective ways in which the work programme of the group could be prioritised given the limited resources of the BP Laboratory. Prioritisation of monograph work to take into account any possible supply issues was suggested and was noted.

Prioritisation of Ayurvedic Work Programme The primary and secondary priority lists that made up the Ayurvedic work programme were examined and discussed. It was

commented that the majority of items on the two Ayurvedic work programmes were used in an unregulated market and the true volume of use of the items in the UK was not known.

Prioritisation of Herbal Ingredients in THR Products Work Programme The work programme had been amended to include details of the numbers of THR holders. It was agreed that to facilitate decision-making of members, future versions of the BP work programme should include details of the composition and proportion of the components in the respective herbal products. Members discussed the need to elaborate BP monographs for herbs which were only present in very small amounts in multicomponent products, especially in cases where herbal practitioners could substitute the herbs with other related herbs.

Members suggested that because it was unlikely that TCM or Ayurvedic medicine would become fully regulated in the near future there was an argument for focussing purely on herbal ingredients in THR products or on established herbs for which monographs had previously been published in the British Herbal Pharmacopoeia (BHP). Also that available resources could be used to elaborate and revise monographs for herbs in which the UK had a particular interest, as for instance Squill.

Squill Monographs Six THR products on the work programme contained squill as an ingredient. A proposal to invite THR holders to provide a specification for the herbal drug used to formulate their products in order to assess whether the existing pharmacopoeial monographs for squill were appropriate was endorsed.

430 **Structure and content of BP and *Ph. Eur.* Monographs for Herbs used in Traditional Herbal Medicines** HCM(14)02

Members discussed concerns that had been raised by the herbal industry on the practicality of complying with published pharmacopoeial monographs for herbs used in traditional medicines.

It was noted that the BP was not looking to overburden industry with unnecessary analytical requirements in published BP monographs. The current BP policy was to include specific assays in herbal monographs whenever possible. Previously 'Extractive tests' had been deemed not specific enough for use as an assay, however it was noted that some limits in specific HPLC assays recently included in global pharmacopoeia had very low specified assay contents and the suitability of such assays for traditional herbal drugs had been questioned by some suppliers.

Members acknowledged that assays served an important purpose in the GMP of herbal medicinal products and that there were legal requirements to quantify markers in registered products. However it was also agreed that in the majority of cases where the BP was elaborating monographs it was the identification section and microbial quality of the item that were absolutely critical. A comment that, unless there was a compelling need, it was unnecessary to include an assay in a new monograph for a herb used in traditional medicines was noted. It was accepted that if deemed necessary at a later date, published monographs could be revised to include an assay method.

431 **Chloroform** HCM(14)03

A report was received for information concerning decisions taken by the Commission on Human Medicines concerning chloroform-containing preparations.

The BP Commission had confirmed that the CHM decisions should be considered for application to all oral preparations included in the British Pharmacopoeia and, in particular, to extemporaneous preparations.

Members noted that the published BP monographs for Acid Gentian Mixture, Alkaline Gentian Mixture and Concentrated Peppermint Emulsion included chloroform in the extemporaneous preparations. It was acknowledged that a possibility would be to delete the extemporaneous preparation section in each of the monographs in order that chloroform was not specified. It was also noted that chloroform was used as a reagent in 14 HCM published monographs and that alternatives were to be considered by the BP Laboratory.

432 **Standardised Senna Leaf Dry Extract** HCM(14)04

An issue had been reported with the test for loss on drying in the *Ph. Eur*. monograph for Standardised Senna Leaf Dry Extract. Samples of the dry extract had been tested and failed to meet the loss on drying limit of 'maximum 5.0 per cent' whilst the material had appeared to be significantly altered by the heating process. It was suggested that a semi-micro determination of water should be used instead.

433 **Gastro-resistant Peppermint Oil Capsules** HCM(14)05

Chromatographic profile Whilst considering the results in Laboratory Report No 5590 for Peppermint Oral Solution, where the oil components had been investigated by GC, the Secretariat had noted that the limits specified in the monograph for Gastro-Resistant Peppermint Oil Capsules were different to those in the published monograph for Peppermint Oil. Reference to past records indicated that the limits in the monograph for Peppermint Oil Capsules had been based on those given in the published BP 1998 monograph for Peppermint Oil which had since been revised. It was agreed that manufacturers should be contacted with a view to revising limits given for the composition of the peppermint oil in the monograph for Gastro-Resistant Peppermint Oil Capsules.

434 **Peppermint Spirit** HCM(14)06

Members noted that the current monograph had no test for identification and there were no chromatographic profile limits on the oil components. However the oil content was specified as 9.0 to 11.0%. The Secretariat undertook 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. If applicable the test would be a means to confirming the correct oil had been used in the formulation and also provide a test for identification. It was acknowledged that BP laboratory input might be necessary.

Concentrated Peppermint Emulsion

If the monograph was to be retained in the BP and since no identification tests or oil analysis were included in the monograph, the Secretariat undertook to contact the producers concerning possible application of the chromatographic profile test as specified in the *Ph. Eur.* monograph for Peppermint Oil to the Concentrated Peppermint Emulsion published monograph.

IV MONOGRAPHS IN PROGRESS

435 **Burdock Root** HCM(14)07

It was agreed that work on the BP monograph should cease since Burdock Root had been included on the *Ph. Eur.* work programme**.**

436 **Clivers** HCM(13)08

The draft monograph would be included in a future BP publication subject to comments from stakeholders and to resolution of any outstanding points.

437 **Golden Cinquefoil** HCM(14)09

It was agreed that a request should be made for inclusion of Golden Cinquefoil on the *Ph. Eur.* work programme**.**

438 **Holy Basil Leaf** HCM(14)10

The draft monograph would be included in a future BP publication subject to comments from stakeholders and to resolution of any outstanding points.

439 **Phyllanthus Amarus** HCM(14)11

The draft monograph would be included in a future BP publication subject to comments from stakeholders and to resolution of any outstanding points.

440 **Phellodendron Chinense Bark** HCM(14)12
Phellodendron Amurense Bark

The draft monographs would be included in a future BP publication subject to comments from stakeholders and to resolution of any outstanding points.

441 **Ophiopogonis Japonicus Root** HCM(14)13

Work on the draft monograph would be suspended since enquiries were to be made as to the *Ph. Eur.* intentions.

442 **Peppermint Oral Solution** HCM(14)14; Annexes 1 to 4; LR 5590

The draft monograph would be included in a future BP publication subject to comments from stakeholders and to resolution of any outstanding points.

443 **Tinospora Cordifolia Stem** HCM(14)15

The draft monograph would be included in a future BP publication subject to comments from stakeholders and to resolution of any outstanding points.

444 **Vitex Negundo Leaf** HCM(14)16

The draft monograph would be included in a future BP publication subject to comments from stakeholders and to resolution of any outstanding points.

445 **Mentha Spicata** HCM(14)17

The draft monograph would be included in a future BP publication subject to comments from stakeholders and to resolution of any outstanding points.

Spearmint Oil The characteristics section and test for Optical rotation would be considered for revision.

V REVISION OF MONOGRAPHS

446 **Dill Oil** HCM(14)18

At the previous meeting of EAG HCM, members had agreed with the proposal that, because the Dill Oil monograph did not exclude Indian Dill, the BP Laboratory should be asked to look at the suitability of the TLC identification method, as published in the BP monograph for Anethum Graveolens Sowa, as a means of ensuring exclusion of Indian Dill from Dill Oil.

VI EUROPEAN PHARMACOPOEIA

447 **Groups 13A, 13B, TCM and Homoeopathic Working Parties HMM and HOM**
A table giving Latin, English, Pinyin and Sinogram names of herbal drugs used in Traditional Chinese Medicine included in *Ph. Eur*. Supplement 8.2 was received for information.

VII ANY OTHER BUSINESS

448 None.

449 **Date of next meeting**
Tuesday, 25 November 2014

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)	To be progressed at the earliest opportunity.
Minute 359: Cyperus Rotundus	To be progressed at the earliest opportunity.
Minute 362: Myristica Fragrans	In view of the results from Kew further samples are being sought for laboratory analysis.
Minute 368: Himalayan Cedar	The macro-morphological authentication of four samples which were sent to Kew was not possible. The samples had been sent for chemical authentication. The Laboratory has been asked to carry out the necessary practical work to progress the monograph.
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Minute 405.3 Opium Tincture	Revision of the monograph would be investigated at the earliest opportunity.
Minute 405.4: *Tribulus Terrestris Fruit*	Work on the monograph was to be restarted at the earliest opportunity and the European fruit would continue to be sought.
Minute 406: Homoeopathics paper for BP Commission	The BP Commission accepted the paper and confirmed that work on the following monographs should be suspended until a sufficient number of samples from different batches were available for meaningful practical work: Chamomilla Recutita Dried Root for Ethanol Decoction for Homoeopathic Preparations Lysimachia Nummularia Herb for Ethanol Decoction for Homoeopathic Preparations Tamus Communis for Homoeopathic Preparations.
Minute 411: HPTLC – New approach	The BP Laboratory continues to use the new standardised conditions for herbal HPTLC work. The BP Lab standard conditions will be compared against the draft Ph. Eur. HPTLC text when available.

List of Acronyms/Synonyms

Acronym/Synonym	**Name**
APhI	Ayurvedic Pharmacopoeia of India
ATA	Ayurvedic Trade Association
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