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 June 2015.

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

Apologies for absence: Ms C Leon, Dr K Strohfeldt-Venables
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 Mr S Wilson.

474 **Introductory Remarks**

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

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

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

Declaration of Interests Dr K Helliwell, Mr B Moore and Mr C Welham declared interests in one or more agenda items and appropriate action was taken.

I MINUTES

475 The minutes of the meeting held on the 26th November 2014 were confirmed subject to the following.

Minute 468 Tribulus Terrestris: Identification A and B Replace the second sentence by the following.

'Ms Leon said that the physical appearance of Chinese-sourced *Tribulus terrestris* fruits in trade may show considerable variation because the fruits were often threshed to remove their spines. As such, they bear a superficial resemblance to the fruits of some *Atriplex* species and with which they may be adulterated.'

Minute 471 Vitex Negundo Leaf: Authentication Replace the third sentence by the following.

'The supplier names had indicated the samples examined were from India where *Vitex* was wild harvested. With 14 species of *Vitex* growing wild in India there was considerable scope for identification confusion at the point of harvesting.'.

II MATTERS ARISING FROM THE MINUTES

476 A list of matters arising from the minutes of the meeting of EAG HCM held in November 2014 was circulated together with the papers for the meeting. A copy is appended.

III REPORTS AND CORRESPONDENCE

477 Working Party DNA – Summary Minutes HCM (15)01

Members were updated on the progress made by the BP-NIBSC Herbal Laboratory in two distinct areas. The authentication of herbal drugs used for the elaboration of BP monographs and also developing tests and standards to be considered for inclusion in a BP supplementary chapter or in BP monographs where justified.

Members discussed the potential costs of performing the tests that were being developed by the BP-NIBSC Herbal Laboratory and the need for, and availability of, accredited laboratories able to perform molecular method tests specified in BP monographs.

It was noted that laboratory set-up requirements were detailed in the draft Appendix method 'Deoxyribonucleic Acid (DNA)-Based Identification Techniques for Herbal Drugs' to be published in the BP 2016. Also that there were established commercial laboratories in the UK, for instance those involved in the testing of genetically modified crops, which could perform DNA barcoding test.

To a query as to which technologies the BP-NIBSC Herbal Laboratory was using and the benefit of the use of Next Generation Sequencing (NGS) as a means of increasing sample throughput, it was explained that the use of NGS was in early stages of investigation at NIBSC. It was acknowledged that interpretation of the resulting data was complex and time consuming.

The Secretariat encouraged members to help shape the policy statement which would guide the BP Commission on how these methods should be used in the pharmacopoeia.

478 DNA Barcoding HCM(15)02

Members were reminded that at the meeting of EAG HCM held in November 2014 the Secretariat had appraised members of the herbal projects being progressed. One of these was generating DNA barcoding data at the BP-NIBSC herbal Laboratory. The focus of the project was on producing barcode sequence data for commercial herbal drugs used to produce BP monographs. The work aimed to provide a genetic identification of herbal materials and to prove that the material was fit for purpose. The approach had been to analyse several barcode regions and make an assessment as to which was the most useful for the species that was the subject of the monograph.

The Secretariat accepted that the use of DNA barcoding was an innovative method for the pharmacopoeia to be considering. DNA barcoding was a very useful tool for the authentication of the samples used in monograph elaboration and members were assured that, whilst the BP Secretariat were keen to explore ways in which the data generated during the authentication process could be used, DNA identification methods would only be considered for addition to a monograph where justified. The sequences of the 5 bar-code regions (present in all plant species) were being analysed for each target species with the expectation that one of the regions would fulfil the requirements of specificity for each individual situation: target species, close relatives and possible adulterants. In some cases further regions might need analysis. A reference material, applicable to any test that used the *trnH-psbA* region was undergoing preparation for users to demonstrate system

suitability and aid in trouble shooting. The reference material would be designated as a British Pharmacopoeia Nucleic Acid Reference Material (BPNARM). Reference materials for the other 4 bar code regions might also be designed if needed in the near future.

A member highlighted what they considered to be the main difficulties in the application of DNA barcoding to the analysis of formulated herbal products, the main one being that it would be difficult to detect the DNA of the herbal substance in the formulated product manufactured using a herbal drug extract. It would be unlikely that a DNA-based method would be approved for inclusion in a licence application for a dosage form. The Secretariat acknowledged that different presentations of herbal material might produce further challenges. The current focus was analyses of herbal drugs and this had been proven to be successful in identifying the species. Any work on analyses of herbal products would be planned and performed using a scientific and evidence based approach. If it was shown that DNA could not be detected in the vast majority of products, manufactured using herbal drug extracts, then this would be a valid finding of the project.

The Chair of Working Party (DNA): Identification Techniques, informed EAG HCM that the Working Party (DNA) had started work on applying DNA barcoding to herbal drugs and the next logical step would be to investigate the applicability of the methods to herbal drug preparations. The Working Party acknowledged that the next step for the herbal project would be challenging. Development of tests methods to herbal drug products was not yet scheduled as part of the project but it will need to be considered in the long term as part of the project considerations. It was his opinion that the work investigating the applicability of the methods to herbal drug preparations was of industrial and regulatory relevance because the supply chain for some herbal extracts which were being produced outside of Europe could not always be guaranteed.

A member expressed concern with any approach which would seek to identify the herbal starting material at the mid or end–point of the supply chain. He considered work investigating the application of DNA-based methodology to herbal drug preparations to be counter to GMP principles which should seek to assure the quality of the manufacturing chain from the very start of the process.

The Secretariat confirmed that the project would deal with herbal drugs, herbal drug preparations and herbal drug products in turn and once again encouraged EAG HCM to help ensure that DNA barcoding was used appropriately and effectively within BP monographs.

479 **Guidelines on the use of DNA Barcoding as an Identification Method in BP Monographs** **HCM(15)03**

A first draft of the ‘Guidelines on DNA barcoding as identification method in a BP Monograph’ had been discussed by the BP Commission’s Working Party (DNA): Identification Techniques at its meeting held in January 2015. It had been agreed that DNA barcoding was highly sensitive and capable of distinguishing between the monograph subject and adulterants, substitutes and contaminants. It provided unequivocal information on the botanical identification of the material. It was also agreed that it was not necessary to develop a DNA barcoding test method to distinguish between the monograph subject and material of animal origin.

A revised document taking into consideration comments made by the Working Party (DNA) was presented. Members’ attention was drawn to the intention to use DNA barcoding routinely as part of a package to confirm identification of herbal drugs used for the development of BP monographs.

Attention was also drawn to two instances where bar coding information would be included in the BP. These were as detailed below.

(a) When there was evidence to demonstrate that it added value to determining the quality of the herbal drug. In this case a purposefully designed identification test method would be developed in consultation with the WP (DNA) with advice and contributions from EAG HCM.

(b) The data generated to demonstrate botanical identification of the herbal drug would included in a dedicated supplementary chapter on barcoding of herbal drugs. It was intended to publish a supplementary chapter in the BP 2017 subject to the BP Commission's approval. A draft text would be made available to both HCM and the Working Party (DNA) for comment before or at the autumn 2015 HCM meeting.

480 **Quillaia Bark** **HCM(15)04**

At the previous meeting of HCM, members agreed that the newly adopted *Ph. Eur.* monograph for Quillaia Bark was not a direct replacement for the BP monograph for Quillaia Bark since the monographs were used for different purposes. Material complying with the *Ph. Eur.* monograph was used as a vaccine adjuvant and material complying with the BP monograph did not need to be controlled in such a way for its intended use in herbal drug preparations. It was agreed that the BP monograph should be revised to indicate the different intended use and to include, if appropriate, the *Ph. Eur.* TLC identification test in the BP monograph.

A member undertook to contact supplier(s) of Quillaia Bark in order to acquire samples that could be used to assess the suitability of the *Ph. Eur.* TLC method for inclusion in a revised BP monograph.

481 **BPCRS – Coumarin** **HCM(15)05**

The BP Laboratory had investigated provision of the new BPCRS Coumarin using the TLC method given in the monograph for Medicago Sativa for Homoeopathic Preparations. A discrepancy had been identified between the results obtained and the description of the coumarin spot in the monograph. Supplementary work had confirmed the discrepancy.

The Laboratory had recommended an amendment to the description of the coumarin spot before spraying from '*fluorescent turquoise' to 'indigo blue'.* Members acknowledged that the description needed amendment but agreed that the spot would be better described as '*blue*'. In addition reference to fluorescence of the coumarin spot before and after spraying was not appropriate.

482 Squill **HCM(15)06**

At the meeting of the WP (DNA): Identification Techniques in January 2015, it was reported that species other than *Drimia maritima* (L.) Stearn was being sold on the market as white squill. This in particular had occurred when there were shortages (twice in the last 20 years) of *Drimia maritima* (L.) Stearn, the species specified in the published BP monograph. The comment on the presence of cardiac glycosides in Squill was discussed and it was noted that the levels were very low. An appropriate HPTLC method providing control of such glycosides would be sought.

The BP-NIBSC Herbal Laboratory had been provided with 14 samples of Squill. These will be analysed once the method for DNA amplification for the species had been optimised. Some of the samples had also been forwarded to Dr Reich for hptlc analyses at CAMAG. It was anticipated that botanically verified samples would be provided by Dr Hawkins from the University of Reading Herbarium for analysis at the BP-NIBSC herbal Laboratory. Analysis

of the herbarium samples should aid identification of the commercial samples to be analysed.

A comment that the Definition statement in the monograph for Squill needed revision to reflect the true harvesting period during dormancy was accepted by members. It was agreed that once the outcomes from the work on the DNA analyses and also investigation of HPTLC procedures were known, general revision of the BP monographs for Squill, Squill Liquid Extract and Squill Oxymel should be considered to modernise the degree of control provided within the monographs.

483 HPTLC Methods in the BP **HCM(15)07**

British Pharmacopoeia Monographs At the December 2013 meeting of EAG HCM a new approach to the development of HPTLC identification methods in the BP had been discussed. The aim of the approach had been to develop identification methods using harmonised chromatographic systems suitable for the analysis of particular classes of compounds and to use and document standardised conditions, wherever possible, in order to maximise the reproducibility of BP methods. Members were reminded that since that time EAG HCM had been responsible for publishing three monographs containing HPTLC methods using the new approach (Phellodendron Chinense Bark, Phellodendron Amurense Bark and Holy Basil Leaf) and were in the process of developing a further eight.

European Pharmacopoeia A new draft general chapter had been published for comment in Pharmeuropa 27.1 detailing the use of high-performance thin-layer chromatography in herbal drugs and herbal drug preparations. A number of draft revisions to monographs had also been included in Pharmeuropa 27.1 in order to illustrate the changes introduced by this proposed general chapter. The main proposed changes to the approach included the use of standard sample application and plate layout details; the provision of standard tank preparation and plate development details; matching of colour descriptions and the introduction of intensity markers to the pharmacopoeia to facilitate the evaluation of the zones of the chromatogram; the routine inclusion of system suitability criteria. Mr Humphries, commenting on the impact the proposed *Ph. Eur.* chapter would have on work at the BP Laboratory said he considered that the proposed draft *Ph. Eur.* chapter was consistent with the BP Laboratory HPTLC SOP. He commented that the proposal still permitted the use of non HPTLC plates and the use of these plates may in practice lead to compromised chromatography.

Experts supported the proposals of the *Ph. Eur.* and agreed that the progress at the *Ph. Eur*. level should be monitored in order to ensure that the BP approach remained in line with the developments by the EDQM.

It was noted that the BP Laboratories HPTLC SOP included the herbal drug specific detail as an annex. It was suggested that the HPTLC analysis of herbal drugs might be better detailed in a “stand-alone” SOP and might encourage further improvement of the HPTLC work of the BP Laboratory. The BP Laboratory believed that one of the immediate ways the work of the BP Laboratory could be improved was by upgrading the camera of the HPTLC system.

IV MONOGRAPHS IN PROGRESS

484 Clivers (Cleavers) **HCM(15)08**

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

485 Holy Basil Leaf **HCM(15)09**

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

486 Nutmeg **HCM(15)10**

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

487 Phyllanthus Amarus **HCM(15)11**

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

488 Tribulus Terrestris Fruit **HCM(15)12**

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

489 Vitex Negundo Leaf **HCM(15)13**

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

490 Spearmint **HCM(15)14**

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

V REVISION OF MONOGRAPHS

491 Liquorice Liquid Extract **HCM(15)15**

It was reported that the production of Liquorice Liquid Extract by the method currently indicated in the BP was very time consuming and required prolonged settling/standing stages.

Prior to the early 1980s the major production of the extract was at Bush Boake & Allen (BBA; UK). The BBA production had been lengthy, being based on the monograph procedure with the final settling stage of 3 to 4 months, with 50,000 litres of the liquid extract in process at any one time. However BBA had ceased production of the extract. Since then the Liquorice Liquid Extract available in the UK, although in compliance with the analytical requirements of the pharmacopoeial monograph, was not in line with the definition, extemporaneous preparation and method of production. Less than 50% of the dried residue was derived from liquorice and the starting liquorice herb was unlikely to be of pharmacopoeial quality. A significant proportion of the Liquorice Liquid Extract used in the medicinal products was known to have a content of 0.5% m/v or less of 18β-glycyrrhizic acid, this acid was not currently controlled in the BP monograph. The content of 18β-glycyrrhizic acid given in the *Ph. Eur.* monograph for Liquorice was a minimum of 4.0% of the dried material.

In view of the manufacturing time required to produce the extract in accordance with the current BP monograph, it was considered that it was unlikely that any company would undertake large scale manufacture of the product. Since Liquorice Liquid Extract was present in a significant number of UK medicinal products as either an active ingredient or

excipient, members agreed that revision of the monograph was necessary. In the interim period the product monograph should be omitted from the BP.

After discussion, members agreed that the method of production should be investigated further using Liquorice in compliance with the *Ph. Eur*. monograph for Liquorice, a drug extract ratio of 1:1 and a slightly modified method from that given in the BP. The addition of excipients such as glucose, glycerol and sorbitol should also be taken into account. Once the method of production had been agreed, analytical aspects such as inclusion of limits for 18β-glycyrrhizic acid, as advocated by Dr Krauss, would be considered.

VI EUROPEAN PHARMACOPOEIA

492 Alternatives to HPLC Assay HCM(15)16

Mr Whaley reported on discussions at the EDQM's TCM Working Party on alternative approaches to elaborating herbal drug monographs.

493 European Pharmacopoeia Reports HCM(15)17

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

Date of next meeting

Wednesday, 25 November 2015

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.

HCM meeting December 2013

Minute 405.3 Opium Tincture	Revision of the monograph would be investigated at the appropriate time.

HCM meeting June 2014

Minute 429 BP Work programme	Actions to be progressed
Minute 435 Burdock Root	Manufacturers of Burdock Root containing products have been contacted.
Minute 437 Golden Cinquefoil	Action to be progressed as part of BP work programme items
Minute 445 Mentha Spicata	Samples are still being sought (one received to date)
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.

HCM meeting November 2014

Minute 466 Himalayan Cedar	To be progressed at the earliest opportunity.
Minute 469 Tinospora Cordifolia	To be progressed at the earliest opportunity.
Minute 509 Peppermint Preparations	The Secretariat to contact producers at the earliest opportunity concerning application of the chromatographic profile test as specified in the current *Ph. Eur*. monograph for Peppermint Oil to the monographs for Gastro-Resistant Peppermint Oil Capsules, Peppermint Spirit and Concentrated Peppermint Emulsion.
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.
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.

Acronym/Synonym	Name
APhI	Ayurvedic Pharmacopoeia of India
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

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