

**BRITISH PHARMACOPOEIA COMMISSION**  
**Expert Advisory Group: Herbal and Complementary Medicines**  
**SUMMARY MINUTES**

A meeting of this Expert Advisory Group was held at Market Towers, 1 Nine Elms Lane, London, SW8 5NQ on Tuesday, 5 June 2007.

**Present:** Professor A C Moffat (*Chairman*), Dr L Anderson (*Vice-Chairman*), Professor K Chan, Mr A Charvill, Dr K Helliwell, Ms C Leon, Professor J D Phillipson, Dr M Pires, Mr J Sumal and Professor E Williamson.

**In attendance:** Dr P Holland, Dr R A Pask-Hughes, Miss N Thomas, Mr S Young and Mr R Gaur.

An apology for absence was received from Dr M Berry.

**Introductory Remarks**

**Welcome** The Chairman welcomed Professor Chan to his first meeting of EAG: HCM.

**Congratulations** The Chairman congratulated Dr Anderson who had been awarded an honorary fellowship of the School of Pharmacy, University of London and, in his absence, Mr Chapman who had become a fellow of the Royal Pharmaceutical Society of Great Britain.

**I MINUTES**

34 The minutes of the meeting held on Tuesday 14 November 2006 were confirmed subject to minor amendments.

**II MATTERS ARISING FROM THE MINUTES**

35 A list of matters arising from the Minutes of the meeting of EAG: HCM held in November 2006 was circulated together with the papers for the meeting. A copy is attached.

**III REPORTS AND CORRESPONDENCE**

36 **Ownership of Monographs** HCM(07)1  
Members were informed that EAG: MC3 (Medicinal Chemicals) had agreed to take ownership of draft monographs whereby a member would become the expert for a particular monograph. Members considered that this approach would be inappropriate for EAG: HCM as the monographs were closely related and collective experience of all the experts contributed to the development of the monographs.

Members confirmed that they wished to continue receiving hard copies of papers as well as electronically transmitted papers.

37 **British Pharmacopoeia 2008** HCM(07)2  
Members noted that a total of twelve new monographs had been included in material for the BP 2008. Seven of the monographs were for the following traditional herbal medicines 'as is' and processed materials: *angelica sinensis* root, astragalus root, white peony root and processed liquorice root. Five of the monographs were for the following preparations for homoeopathic use: *artemisia cina*, *symphytum officinale* root and *symphytum officinale* root, ethanol decoctum, *toxicodendron quercifolium* and *urtica urens* herb. In addition, the monograph for Liquorice Root for use in THM had been revised and statements relating to traditional herbal medicines and homoeopathic medicines had been included in the General Notices.

- 38 **British Pharmacopoeia Monographs for THMs and THMPS** HCM(07)3

A draft policy document on monographs for Traditional Herbal Medicinal Products had been considered at the March 2007 meeting of the BPC. The document had taken into consideration comments made by EAG: HCM members at earlier meetings. Practice Guidance notes would be drafted.

- 39 **British Pharmacopoeia Monographs for Homoeopathic Preparations: Policy** HCM(07)4

A draft policy document on monographs for Traditional Herbal Medicinal Products had been considered at the March 2007 meeting of the BPC. Practice Guidance notes would be drafted.

- 40 **Work Programme: British Pharmacopoeia Monographs European Pharmacopoeia** Members received a list of the monographs that were undergoing preparation by the EPC Group of Experts No.13A and Group of Experts No. 13B. HCM(07)5

Members noted from the lists that four TCM monographs had been adopted by the EPC, a further four draft monographs had been included in Pharmeuropa 19.1 and that another three monographs had been included in Pharmeuropa 19.3 for comment. A draft Ph Eur monograph for *Paeonia Alba Radix* was undergoing preparation.

Since Piper Longum Fruit was included in the Ph Eur list, the BP draft monograph for Piper Longum Fruit would be forwarded to the Ph Eur Secretariat.

**Ph Eur Groups of Experts 13A and 13B (Phytochemistry)** Members noted that where particular TCMs were common to both the BP and Ph Eur work programmes, work on the BP specifications would not be undertaken.

**Homoeopathic Medicines** The eleven adopted methods of preparation of homoeopathic stocks had been included in Supplement 5.8. The first meeting of the recently formed Working Party on Homoeopathic Manufacturing Methods had been held in April 2007 when a further 12 methods of preparation had been considered for inclusion in the European Pharmacopoeia.

**TCM monographs targeted for the BP 2009** Members noted that the TCM monographs for Sage Root, the development of which were sufficiently progressed to warrant inclusion in the BP prior to inclusion in the Ph Eur, was targeted for inclusion in the BP 2009. Thereafter, the current BP resources would be directed towards development of monographs for the Ayurvedic and Homoeopathic medicines.

**Ayurvedic monographs targeted for the BP 2009** The new monographs for *Terminalia arjuna*, *Terminalia chebula*, *Terminalia bellerica* and *Withania somnifera* had been assigned for inclusion in the BP 2009 (*see also minute 55*).

**Homoeopathic monographs targeted for the BP 2009** A further five monographs from the BHomP had been targeted for the BP 2009 (*Apomorphinum muriaticum*, *Calcium phosphoricum*, *Ferrum phosphoricum* (ferric phosphate), *Ferrum phosphoricum* (ferroso-ferric phosphate) and *Hepar sulphuris calcareum*; *see also minute 56 to minute 60*).

- 41 **Placement of Herbal and Complementary monographs** HCM(07)6

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Members were informed that a proposal to group the monographs for herbal and complementary medicines in the Pharmacopoeia had been accepted at the BPC meeting held in March 2007. The grouping would bring together all the relevant monographs currently present in volumes I, II and III into a new single section in the BP 2009.

It was agreed that the assignment of the preparations containing crude drugs, as for instance Calamine Lotion, to HCM would be reviewed.

### 42 **Monograph Titles** HCM(07)7

Members were informed that subsequent to the discussions on the need for BP Approved Synonyms for the Ph Eur Coneflower monographs an internal meeting had been held to agree common names. The resulting proposals to adopt the following Echinacea-type names were agreed by the BPC in March 2007. The titles for the monographs had been amended for inclusion in the BP 2008 and would also be listed in Appendix XXI B as follows.

<b>Ph Eur Monograph Title</b>	<b>Approved Synonym for publication in the BP 2008</b>
Pale Coneflower Root	Echinacea Pallida Root
Narrow-leaved Coneflower Root	Echinacea Augustifolia Root
Purple Coneflower Herb	Echinacea Purpurea Herb
Purple Coneflower Root	Echinacea Purpurea Root

### 43 **Pin Yin** HCM(07)8

Members noted that it had been previously agreed that Pin Yin names should not be placed in the mandatory sections of the BP monographs. Members supported the proposal that the names were placed together in a BP Supplementary chapter.

### 44 **Ash: Appendix XI J: BP and Ph Eur Methods** HCM(07)9

Attention was drawn to the difference between Method I (BP) where a temperature of not more than 450° is used and Method II (Ph Eur) where a temperature of 600° was used. Since the levels of alkali chlorides would be very low, members agreed that the Ph Eur method could be applied to all herbal monographs.

### 45 **Calamine Lotion** HCM(07)10

Attention was drawn to the instruction of the analyst under Identification A (silver mirror test) where there was no requirement to heat the sample. Gentle heating was sometimes required for the reaction to proceed. Members accepted the proposal to amend the test to include the heating process.

### 46 **Senna Tablets** HCM(07) 31

A request for the revision of the limit in the test for Loss on drying was considered.

It was agreed that a recommendation for omission of the test from the monograph should be made.

## IV **NEW MONOGRAPHS FOR TRADITIONAL HERBAL MEDICINES**

### 47 **General Monograph: Processed Herbal Drugs** HCM(07)11

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

48 **Ayurvedic monographs: General**

It was noted that, as with many Ayurvedic medicines, the ‘as is’ material was used in Ayurvedic medicines.

**BP Policy** In line with BPC policy, no common traditional names, action and use statements or dose statements had been included in the draft BP monographs for Ayurvedic medicines.

**Title** Members agreed that ‘THM’ should be amended to ‘THMP’ since the ‘as is’ drug was usually used in the final product.

**Water-soluble extractive** The test from the Ayurvedic Pharmacopoeia of India (APhI) Appendix 2.2.7 was included in all the draft monographs. It was agreed that the test should be accommodated in the Appendices with cross references in the specific monographs.

49 **Emblica Offinalis Fruit, Dried**

HCM(07)12

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

50 **Tinospora Cordifolia**

HCM(07)13

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

51 **Bacopa Monnieri**

HCM(07)14

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

52 **Azadirachta Indica Leaf**

HCM(07)15

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

**V MONOGRAPHS IN PROGRESS FOR TRADITIONAL HERBAL MEDICINES**

53 **Red Sage Root for use in THM**

HCM(07)16

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

54 **Processed Red Sage Root for use in THMP**

HCM(07)16

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

55 ***Terminalia belerica, Terminalia chebula and Terminalia arjuna***

HCM(07)17

The draft monographs would be included in a future BP publication, subject to comments from stakeholders.

## VI NEW MONOGRAPHS FOR HOMOEOPATHIC PREPARATIONS

- 56 **Apomorphinum Muriaticum for Homoeopathic Preparation** HCM(07)18

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

- 57 **Calcium Phosphoricum for Homoeopathic Preparations** HCM(07)19

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

- 58 **Ferric Phosphate for Homoeopathic Preparations** HCM(07)20

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

- 59 **Ferroso-ferric Phosphate for Homoeopathic Preparations** HCM(07)21

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

- 60 **Hepar Sulphuris Calcareum for Homoeopathic Preparations** HCM(07)22

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

## VII MONGORAPH REVISIONS

- 61 **Toxicodendron Quercifolium for Homoeopathic Preparations** HCM(07)23

Subsequent to inclusion of the monograph for Toxicodendron Quercifolium for Homoeopathic Preparations in the BP 2008 responses had been received on the draft monograph sent out to stakeholders. The comments received were noted and certain points agreed.

- 62 **Artemisia Cina for Homoeopathic Preparations** HCM(07)24

Subsequent to inclusion of the monograph for Artemisia Cina for Homoeopathic Preparations in the BP 2008 responses had been received on the draft monograph sent out to stakeholders. The comments received were noted and certain points agreed.

- 63 **Urtica Urens Herb for Homoeopathic Preparations** HCM(07)25

Subsequent to inclusion of the monograph for Urtica Urens Herb for Homoeopathic Preparations in the BP 2008, responses had been received on the draft monograph sent out to stakeholders. The comments received were noted and certain points agreed.

- 64 **Symphytum Officinale Root for Homoeopathic Preparations  
Symphytum Officinale Root, Ethanol. Decoctum  
for Homoeopathic Preparations** HCM(07)26

Subsequent to inclusion of the monograph for Symphytum Officinale Root for Homoeopathic Preparations and Symphytum Officinale Root, Ethanol. Decoctum for

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Homoeopathic Preparations in the BP 2008, responses had been received on the draft monographs sent out to stakeholders. The comments received were noted and certain points agreed.

### VIII EUROPEAN PHARMACOPOEIA

- 65 **Comments from the BP Commission** HCM(07)27  
**Pharmeuropa: Vol.18, No 3, Vol 18, No 4 and Vol.19, No 1**  
The comments, that had been sent to the European Pharmacopoeia Commission and were the responsibility of EAG: HCM, had been sent to members for information.
- 66 **Comments requested on the Ph. Eur. draft monographs** HCM(07)28  
**Pharmeuropa Vol.19, No 2** Members had been invited to comment on relevant draft texts.
- 67 **Texts adopted at the 126<sup>th</sup> Session** HCM(07)29  
A list of the texts that related to the work of the EAG that had been adopted at the 126<sup>th</sup> Session of the EPC had been sent to members for information.
- 68 **Formal Reports of meetings of European Pharmacopoeia** HCM(07)30  
**Commission Groups of Experts 13A, 13B and 13H**  
Reports from the meetings of Group of Experts 13A (held April 2007), Group of Experts 13B (held April 2007), Group of Experts 13H (held April 2007) and Working Party HMM (held April 2007) were received for information. The Summaries of the September 2006 meetings of the same Groups were also received.

### ANY OTHER BUSINESS

ORAL

- 69 **Date of the next meeting**  
The date of the next meeting of EAG: HCM was scheduled for Tuesday, 20 November 2007.

**Matters arising from the Minutes**  
(other than those appearing on the Agenda)

<b>Matters arising from the Minutes of meeting held 3 May 2006</b>	
<b>Minute 979.1: Honey (antibacterial) for topical use</b>	Advice has been received that the proposed antibacterial activity test in the submission for a monograph received from Capilano Honey was not appropriate. Capilano has been informed and guidance on the type of test that would be acceptable has been provided.
<b>Matters arising from the Minutes of meeting held 14 November 2006</b>	
<b>Minutes 14 and 15: Liquorice Root and Processed Liquorice Root for use in Traditional Chinese Medicines</b>	Further comments have been received on the draft texts and proposals for revision will be brought to the attention of the EAG at the November meeting.
<b>Minutes 16 and 17: Angelica Root and Processed Angelica Root for use in Traditional Chinese Medicines</b>	Further comments have been received on the draft texts and proposals for revision will be brought to the attention of the EAG at the November meeting.
<b>Minutes 18 and 19: White Peony Root and Processed White Peony Root for use in Traditional Chinese Medicines</b>	Further comments have been received on the draft texts and proposals for revision will be brought to the attention of the EAG at the November meeting.
<b>Minute 11.6: Ayurvedic monographs targeted for BP 2009</b>	<i>Withania somnifera</i> : The BP Laboratory work is ongoing and a Laboratory Report should be available for the November meeting.

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### List of Acronyms/Synonyms

Acronym/Synonym	Name
APhI	Ayurvedic Pharmacopoeia of India
BHomP	British Homoeopathic Pharmacopoeia
BP	British Pharmacopoeia
BP (Vet)	British Pharmacopoeia (Veterinary)
BPC	British Pharmacopoeia Commission
BPCRS	British Pharmacopoeia Chemical Reference Substance
BS	British Standard
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
HAB	German Homoeopathic Pharmacopoeia
HKCMMS	Hong Kong Chinese Materia Medica Standards
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
NIBSC	National Institute for Biological Standards and Control
NPA	National Pharmacopoeial Authority
OMCL	Official Medicines Control Laboratory
Ph. Eur.	European Pharmacopoeia
TGA	Therapeutic Goods Administration, Australia
TLC	Thin layer chromatography
UK	United Kingdom
UKD	United Kingdom Delegation [to the European Pharmacopoeia]
USP	United States Pharmacopoeia
UV	Ultraviolet
WHO	World Health Organisation