

BRITISH PHARMACOPOEIA COMMISSION

Expert Advisory Group: Herbal and Complementary Medicines (HCM)

SUMMARY MINUTES

A meeting of the Expert Advisory Group HCM was held at Market Towers, 1 Nine Elms Lane, London, SW8 5NQ on Tuesday 5 June 2008.

Present: Professor E Williamson, (*Chairman*), Dr L Anderson (*Vice-Chairman*), Professor K Chan, Mr T Chapman, Mr A Charvill, Dr K Helliwell, Ms C Leon, Professor J D Phillipson, and Dr M Pires. Dr E Griffiths attended part of the meeting.

In attendance: Dr P Holland, Dr R A Pask-Hughes, Miss N Thomas, Mr S Young and Mr N Patel. Apologies for absence were received from Dr M Berry, Professor A C Moffat and Mr J Sumal.

Introductory Remarks

Welcome The Chairman welcomed the Chairman of the Herbal Forum; Secretary, British Association of Homoeopathic Manufacturers) and Dr E Griffiths (MHRA Licensing Division) who were attending the meeting.

I MINUTES

109 The minutes of the meeting held on Tuesday 5 June 2007 were confirmed subject to minor technical amendments.

II MATTERS ARISING

110 A list of matters arising from the Minutes of the meeting of EAG: HCM held in November 2007 was circulated together with the papers for the meeting.

III REPORTS AND CORRESPONDENCE

111 **Work Programme** HCM(08)1
European Pharmacopoeia Revised lists of the monographs undergoing preparation were received. The herbal medicines that had been transferred to the TCM work programme were noted. Eclipta herba was on the work programme of the TCM working party; confirmation on the plant part that the Ph Eur monograph was to cover would be sought in order to avoid unnecessary work and overlap with any work towards development of a BP specification.

It was commented that the Test for absence of aristolochic acids I and II should be applied to monographs where aristolochic acid may be present, either from the herbal drug or an adulterant. Likewise, development of tests for known toxic substituents in herbal medicines should be addressed at the time a monograph was being developed.

Future BP monographs Members noted the key times in a cycle of the preparation of new monographs for publication in the BP. The assistance in provision of good quality samples would be drawn to the attention of stakeholders. Information on the benefits of publicly available standards for THMs would be disseminated by the Secretariat.

112 **Guidance notes: Preparation of British Pharmacopoeia Monographs for Traditional Herbal Medicinal products** HCM(08)2
Members received the policy document on 'Development of British Pharmacopoeia Monographs for THMs' together with the draft Practice Guidance Notes on development of BP monographs for THM and processed THMPs and a copy of the Ph. Eur. Guide for the elaboration of monographs on herbal drugs. Revised documents reflecting editorial and technical comments made

by Experts would be prepared at the earliest opportunity and distributed to EAG HCM for confirmation. The resulting documents would be presented to the BP Commission for information.

- 113 **Guidance notes: Preparation of British Pharmacopoeia Monographs for Homoeopathic Medicines** HCM(08)3
Members received a copy of the policy document on ‘Development of British Pharmacopoeia Monographs for Homoeopathic Medicinal Products’ together with a draft Practice Guidance Notes on the development of BP monographs for Homoeopathic preparations. Revised documents reflecting editorial and technical comments made by Experts would be prepared at the earliest opportunity and distributed to EAG HCM for confirmation. The resulting documents would be presented to the BP Commission for information.
- 114 **Placement of herbal monographs in the BP** HCM(08)4
Details of the reorganisation of placement of herbal and complementary medicines monographs in the BP 2009 and the BP 2010 were discussed and noted. For the BP 2010, it was agreed that monographs for substances, the definitions of which were outside those of a Herbal Drug, Herbal Drug Preparation or a Herbal Medicinal Product should be retained in the current positions in Volumes I and II. Monographs affected were Cineole, Eugenol, Honey, Ouabain, Terpeneol, Thymol, Vanillin and Cochineal.
- 115 **Photographs of Herbal Drugs for the BP Website** HCM(08)5
The proposal to include photographs of herbal drugs on the new BP website had been endorsed at the March 2008 meeting of the BPC. It was intended to place photographs for herbal drugs on the BP website (www.pharmacopoeia.gov.uk) at the earliest opportunity.
- 116 **Asparagus Racemosus** HCM(08)6
Asparagus racemosus had been approved for inclusion in the work programme of EAG HCM and was widely used. However, very limited technical information was available. Members agreed that it should remain on the work programme because of its degree of use. The Secretariat and BP Laboratory undertook to investigate further the availability of appropriate methodology and information in order to decide on the feasibility of preparing a monograph.
- 117 **Sandalwood Oil for use in THMP** HCM(08)7
Sandalwood Oil had been approved for inclusion in the work programme of EAG: HCM and the need for a monograph for sandalwood oil had recently been confirmed by stakeholders. The Secretariat would continue to look for a source for genuine Sandalwood oil.
- 118 **Senna Tablets BP** HCM(08)22
Disintegration A request had been received from a UK manufacturer for the relaxation of the disintegration time from 30 minutes to 60 minutes in the monograph for Senna Tablets. The disintegration time of 30 minutes had first been published in the BP 1973 and up to date there had been no adverse reports with compliance. The basis for the request appeared to be a result of variability in the 2007 crop of senna pods.
- It was noted that the test for Loss on drying had been deleted from the monograph by means of the BP 2009. Members agreed that consideration of revision of the test for Disintegration was premature since the request was based solely on results for the 2007 crop of senna pods. The manufacturer would be invited to submit their results for the 2008 crop of senna pods. Other stakeholders would be asked to comment on the acceptability of the disintegration time of 30 minutes.
- 119 **Supplementary Chapter: Traditional Herbal Medicines and Traditional Herbal Medicinal Products** HCM(08)8
The draft chapter would be included in a future BP publication, subject to comments from stakeholders.

IV MONOGRAPHS IN PROGRESS FOR TRADITIONAL HERBAL MEDICINES

- 120 **General Monograph: Processed Herbal Drugs** HCM(08)9
The draft general monograph would be included in a future BP publication, subject to comments from stakeholders.
- 121 **Emblica Officinalis Fruit for use in THM** HCM(08)10
The draft monograph would be included in a future BP publication, subject to comments from stakeholders.

V NEW MONOGRAPHS TRADITIONAL HERBAL MEDICINES

- 122 **Eclipta Alba for use in THMP** HCM(08)11
The draft monograph would be included in a future BP publication, subject to comments from stakeholders.
- 123 **Tribulus Terrestris Root for use in THMP** HCM(08)12
The draft monograph would be included in a future BP publication, subject to comments from stakeholders.
- 124 **Tribulus Terrestris Fruit for use in THMP** HCM(08)13
The draft monograph would be included in a future BP publication, subject to comments from stakeholders.

HOMOEOPATHIC MONOGRAPHS

- 125 **Causticum Hahnemanni for Homoeopathic Preparations** HCM(08)14
The draft monograph would be included in a future BP publication, subject to comments from stakeholders.
- 126 **Cineraria Maritima for Homoeopathic Preparations** HCM(08)15
The draft monograph would be included in a future BP publication, subject to comments from stakeholders.
- 127 **Citrullus Colocynthis for Homoeopathic Preparations** HCM(08)16
The draft monograph would be included in a future BP publication, subject to comments from stakeholders.
- 128 **Cydonia Oblonga for Homoeopathic Preparations** HCM(08)17
The draft monograph would be included in a future BP publication, subject to comments from stakeholders.

VI EUROPEAN PHARMACOPOEIA

- 129 **Definition of Potentisation** HCM(08)18
A request from the UKD for inclusion of a definition of potentisation in the Ph Eur Glossary had been considered at the May 2008 meeting of the Ph Eur Working Party on Homoeopathic Raw Materials and Stocks. The Working Party had considered that the definition as given in the Ph. Eur. monograph for Homoeopathic Preparations was complete and that inclusion of a homoeopathic definition in a general part of the European Pharmacopoeia such as the Glossary was not appropriate. The Chairman undertook to bring this to the attention of the BPC.
- 130 **Comments from the BP Commission** HCM(08)19

Pharmeuropa: Vol.19, No 3 Comments had been submitted on draft Ph Eur monographs that were the responsibility of EAG HCM using the Document Review Tool.

Pharmeuropa: Vol.19, No 4 Comments had been submitted on draft Ph Eur monographs that were the responsibility of EAG HCM using the Document Review Tool.

- 131 **Comments requested on the Ph. Eur. draft monographs** HCM(08)20
Pharmeuropa Vol.20, No 1 Comments were being prepared on draft Ph Eur monographs that were the responsibility of EAG: HCM for submission using the Document Review Tool.
Pharmeuropa Vol.20, No 2 Members were invited to comment on relevant draft Ph Eur monographs that were the responsibility of EAG: HCM by 30 June 2008.

- 132 **Texts adopted at the 127th Session** HCM(08)21
A list of the texts that related to the work of EAG: HCM that had been adopted at the 127th Session of the EPC was received for information.

- 133 **Formal Reports of meetings of European Pharmacopoeia Commission Groups of Experts 13A, 13B, 13H and Working Parties TCM and HOM** HCM(08)23
Reports from the meetings of Group of Experts 13A, 13B, 13H were received for information. Also received for information were the report of the first meeting of the TCM Working Party and that of the first meeting of the HOM Working Party.

ANY OTHER BUSINESS

- 134 **Heavy metal limit** ORAL
The need for limiting heavy metals in herbal medicines was discussed. It was agreed that this should be drawn to the attention of the relevant advisory committee.

- 135 **Ambra grisea**
A draft monograph for Ambra grisea had been discussed at the May 2008 meeting of the Ph Eur Working Party on Homoeopathic Stocks and Raw Materials. Homoeopathic texts reported the source of Ambra grisea to be 'most probably a morbid product found in the sperm whale or floating in the sea'. Dr Pask-Hughes sought advice from HCM Experts, reminding members that the UK did not accept inclusion of methods of preparation for nosodes (material originating from a diseased or pathological animal/organ/source). Since the whales were wild there was no traceability on the health of the animals.

Members supported the suggestion that the monograph requirements concerning the health of the source animals, with adequate measures to minimise the risk of agents of infection (such as transmissible spongiform encephalopathies) should be made transparent. Direct reference to the controls should be given in the monograph for Homoeopathic Preparations. The Chairman undertook to bring the recommendation to the attention of the BPC.

- 136 **Dr Paul Bremner**
Members noted that with Dr Helliwell's appointment as Chairman to Group of Experts 13B, Dr Bremner had been elected the UK member of Group 13B. It was hoped that he would attend the November 2008 meeting as a new member of EAG: HCM.

- 137 **Pin Yin names**
It was noted that a proposal to include Pin Yin names in Ph Eur monographs had been made to the EP Commission.

- 138 **Date of the next meeting** 24th November 2008.

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 Pharmacopeia
UV	Ultraviolet
WHO	World Health Organisation