



London, 2 April 2007  
Doc. Ref. EMEA/HMPC/138217/2007

## COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

### **Meeting report, 7-8 March 2007**

The Committee on Herbal Medicinal Products met for the 16<sup>th</sup> time at the EMEA on 7-8 March 2007.

The Chair introduced to the Committee Milan Nagy as the new alternate member from Slovakia and Yasemin Sazak as the new observer from Turkey.

In addition, he welcomed Hans-Georg Eichler, who was recently appointed as senior medical officer at the EMEA and the EMEA Executive Director T. Lönngren, who gave a brief introduction of the rationale for establishing this new position at the EMEA<sup>1</sup>.

### **Report from the Working Party on Community Monographs and Community List (MLWP)**

The 7<sup>th</sup> meeting of the permanent HMPC Working Party on Community Monographs and Community List (MLWP) was held on 5-7 March 2007.

On recommendation of the MLWP, the HMPC adopted the following draft Community herbal monographs, which were released for public consultation until 15 June 2007:

- draft 'Community herbal monograph on *Echinacea purpurea* (L.) Moench., herba'  
(EMEA/HMPC/104945/2006)
- draft 'Community herbal monograph on *Passiflora incarnata* L., herba'  
(EMEA/HMPC/230962/2006)
- draft 'Community herbal monograph on *Primula veris* L., *Primula elatior* (L.) Hill, radix'  
(EMEA/HMPC/143370/2006):
- draft 'Community herbal monograph on *Primula veris* L., *Primula elatior* (L.) Hill, flos'  
(EMEA/HMPC/64684/2007)
- draft 'Community herbal monograph on *Rhamnus purshianus* D.C., cortex'  
(EMEA/HMPC/513579/2006):

The draft Community herbal monographs together with a draft list of bibliographic references used during the assessment can be found at:

<http://www.emea.europa.eu/htms/human/hmpc/hmpcmonographsdraft.htm>

The MLWP made significant progress on the scientific work relating to draft Community herbal monographs and assessment reports for *Eleutherococci radix*, *Menthae piperitae aetheroleum*, *Thymi herba* and *Melissae folium*. Further discussions are scheduled to take place during the May 2007 MLWP meeting on *Betulae folium*, *Lupuli flores* and *Urticae herba*. An updated 'Overview of status of HMPC assessment work March 2007 (EMEA/HMPC/278067/2006)' can be found on the EMEA website at:

<http://www.emea.europa.eu/pdfs/human/hmpc/27806706en.pdf>

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<sup>1</sup> For details on the role of the EMEA senior medical officer see the EMEA press release - [European Medicines Agency appoints Senior Medical Officer \(EMEA/405691/2006\)](#)

## Appointment of rapporteurs

Further appointments of rapporteurs were made for the preparation of draft Community herbal monographs/entries to the Community list for:

- *Polypodii radix*
- *Sambuci flos*
- *Verbasci flos*
- *Salviae folium*

Calls for the submission of scientific data on the first three above-mentioned plants will be prepared in accordance with the '[Procedure for calls for scientific data for use in HMPC assessment work](#)' (data requested by 27 May 2007) and will be available on the EMEA website at:

<http://www.emea.europa.eu/htms/human/hmpc/hmpcdata.htm>

### WEB-PUBLICATION UPDATE

#### Status of publication on the EMEA website of final adopted Community monographs and related documents

All final Community monographs adopted by the HMPC are currently published on the EMEA website at: <http://www.emea.europa.eu/htms/human/hmpc/hmpcmonographsadopt.htm>

In addition, documents relating to the Community herbal monographs (i.e HMPC opinion, assessment report, list of bibliographic references supporting the assessment report, overview of comments received during the consultation period) on linseed, ispaghula seed, ispaghula husk and psyllium seed can be found, at the same webpage, under respective hyperlinks.

Further documents relating to the Community herbal monographs on aloe, frangula bark, senna pods, senna leaf and valerian root will be published in the next weeks.

The EMEA is currently looking at providing a summary of the assessment report written in a manner that is understandable to the public. Once available, the 'Summary of assessment report for the public' for each Community monograph will be translated in all Community languages and published on the EMEA website.

New versions of the following Community monographs have been published as corrigenda:

- 'Community herbal monograph on *Cassia senna* L., fructus and *Cassia angustifolia* Vahl, fructus' (EMEA/HMPC/51871/2006 Corrigendum)
- 'Community herbal monograph on *Cassia senna* L., folium and *Cassia angustifolia* Vahl, folium' (EMEA/HMPC/51869/2006 Corrigendum)
- 'Community herbal monograph on *Rhamnus frangula* L., cortex' (EMEA/HMPC/76307/2006 Corrigendum)
- 'Community herbal monograph on *Aloe barbadensis* Miller and on Aloe (mainly *Aloe ferox* Miller and its hybrids)' (EMEA/HMPC/76310/2006 Corrigendum)

The corrigenda are available at:

<http://www.emea.europa.eu/htms/human/hmpc/hmpcmonographsadopt.htm>

The MLWP/HMPC made significant progress on the development of a 'Guideline on the assessment of genotoxic constituents in herbal substances/preparations' (EMEA/HMPC/104681/2007), addressing the problems raised in the '[Concept paper on the development of a guideline on the assessment of genotoxic constituents in herbal substances/preparations](#)' (EMEA/HMPC/413271/2006)<sup>2</sup>. The draft guideline will be further elaborated in coordination with the Safety Working Party (SWP), taking into account valuable comments already received from the SWP.

<sup>2</sup> <http://www.emea.europa.eu/pdfs/human/hmpc/41327106en.pdf>

The HMPC adopted also the revised 'MLWP Mandate, Objectives and Rules of Procedure' (EMEA/HMPC/358825/2005), which will be available on the EMEA website at: [http://www.emea.europa.eu/htms/general/contacts/HMPC/HMPC\\_MLWP.html](http://www.emea.europa.eu/htms/general/contacts/HMPC/HMPC_MLWP.html)

The next meeting of the MLWP is scheduled for 7 May 2007.

### **Report from the Organisational Matters Drafting Group**

During the meeting on 14 February 2006, the Organisational Matters Drafting Group agreed on the following documents, underpinning the preparation of Community herbal monographs and entries to the Community list:

- Draft 'Procedure for the preparation of an entry to the Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products' (EMEA/HMPC/57137/2007).<sup>3</sup>
- Draft 'Timetable for the establishment of a Community list entry and/or a Community herbal monograph' (EMEA/HMPC/126542/2005 Rev. 1)

The new procedure and the timetable were drafted and revised respectively to take account of current practice in the MLWP in the preparation of draft monographs/list entries as well as to achieve consistency with other HMPC templates and guidelines.

Subsequently the two documents were discussed by the MLWP and adopted by the HMPC. The new procedure is released for three months public consultation until 15 June 2007. Both documents are available on the EMEA website at:

<http://www.emea.europa.eu/htms/general/direct/legislation/legislationherbal.htm>

### **Report from the Quality Drafting Group**

A meeting of the Quality Drafting Group was held on 15 February 2007.

The Quality Drafting Group presented a revised version of the draft 'Guideline on quality of combination herbal medicinal products/traditional herbal medicinal products' (EMEA/HMPC/214869/2006). The revision addresses comments made by the HMPC in January 2007. [see also [HMPC meeting report 11 January 2007 \(EMEA/HMPC/138217/2007\)](http://www.emea.europa.eu/htms/general/direct/legislation/legislationherbal.htm)].

The HMPC subsequently endorsed the revised draft guideline, which will be distributed to the Quality Working Party (QWP) for comments, to ensure co-ordination with the Committee for Medicinal Products for Human Use (CHMP) and the Committee for Medicinal Products for Veterinary Use (CVMP) prior to its release for public consultation.

Coordination is ongoing between the *ad hoc* GMP Inspection Services Group and the HMPC on the revision of the Annex 7 to the good manufacturing practice (GMP) guide: 'Manufacture of herbal medicinal products' initiated by the European Commission in March 2006 with a public consultation<sup>4</sup> on a new draft Annex 7.

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<sup>3</sup> The procedure, once finalised at the end of the consultation period, will replace the document: 'Structure of the list of herbal substances, preparations and combinations thereof' (EMEA/HMPC/100824/2005 Rev.1)

<sup>4</sup> [http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2006/05\\_2006/2006\\_03\\_annex\\_7.pdf](http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2006/05_2006/2006_03_annex_7.pdf)

## Meeting with interested parties to the HMPC

On 7 March 2007, the HMPC held a meeting with representatives from scientific associations (ESCOP<sup>5</sup>) healthcare professionals' organisations & patients' organisations (EFCAM<sup>6</sup>, EHPA<sup>7</sup>, IVAA<sup>8</sup>) and from industry associations (AEFMUTA<sup>9</sup>, AESGP<sup>10</sup>, EFPIA<sup>11</sup>, EHGA-EUROPAM<sup>12</sup>, EHPM<sup>13</sup>).

The Committee addressed specific questions received from the interested parties on the Community herbal monographs established by the HMPC. In particular, the interested parties expressed the desire for an increased level of transparency in the different stages of the development of monographs.

In response to a query from EFCAM, the Committee expressed itself open to receive from interested parties data on the use of fennel in traditions other than the European (e.g. traditional Chinese medicine (TCM)), provided that they are relevant to the indications accepted under the European tradition. These data would be assessed and integrated in the on-going elaboration of the Community monographs on fennel.

In addition, the HMPC will further reflect upon the offer from AEFMUTA to hold an information session on anthroposophic medicine.

In addition, a number of interested parties provided the HMPC with their view on the Committee's work to date and their expectations for the future.

The HMPC Chair also presented the recent Committee's achievements and the challenges identified by the HMPC in the preparation of Community monographs/list entries.

Both the Committee and the participants expressed their appreciation for this opportunity to exchange information and viewpoints.

For further information, please contact:

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<sup>5</sup> European Scientific Cooperative on Phytotherapy

<sup>6</sup> European Forum for Complementary and Alternative Medicine

<sup>7</sup> European Herbal Practitioners Association

<sup>8</sup> International Federation of Anthroposophical Medical Associations

<sup>9</sup> European Association of Manufacturers of Medicines for Anthroposophic Therapy

<sup>10</sup> The Association of the European Self-Medication Industry

<sup>11</sup> European Federation of Pharmaceutical Industries and Associations

<sup>12</sup> European Herb Growers Association

<sup>13</sup> European Federation of Associations of Health Product Manufacturers