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## COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

### **Meeting report, 3-4 September 2008**

The HMPC held its 25th meeting at the EMEA on 3-4 September 2008. The HMPC welcomed Prof. G. Calapai as co-opted member with expertise in clinical pharmacology. The Committee also welcomed Ms Oyku Mumcu Arisan as a new observer from Turkey.

During the plenary meeting the HMPC renewed the three-year term of Prof. Gert Laekeman, co-opted member with expertise in experimental/non-clinical pharmacology.

The HMPC appointed Dr. Maria Helena Pinto Ferreira as co-opted member to broaden medical practice with herbal medicinal products in the HMPC.

The updated composition of the Committee can be found at:

[http://www.emea.europa.eu/htms/general/contacts/HMPC/HMPC\\_members.html](http://www.emea.europa.eu/htms/general/contacts/HMPC/HMPC_members.html)

The HMPC appointed Dr D. Csupor as a member of the Working Party on Community Monographs and Community List (MLWP). The composition of the MLWP can be found 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)

Upon recommendation from the MLWP, the HMPC adopted the following Community herbal monographs and related documents:

#### Final Community herbal monographs

- 'Community herbal monograph on *Avena sativa* L., fructus' (EMEA/HMPC/368600/2007)
- 'Community herbal monograph on *Avena sativa* L., herba' (EMEA/HMPC/202966/2007)
- 'Community herbal monograph on *Mentha x piperita* L., folium' (EMEA/HMPC/193909/2007)
- 'Community herbal monograph on *Ruscus aculeatus* L., rhizoma' (EMEA/HMPC/261938/2007)
- 'Community herbal monograph on *Solidago virgaurea* L., herba' (EMEA/HMPC/285758/2007)

The final Community herbal monographs as well as their respective HMPC opinions, assessment reports and overview of comments received during the consultation period, will be published in due course on the EMEA website at:

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

The HMPC adopted a revised version of the 'Overview of comments received on Community herbal monograph on *Equisetum arvense* L., herba' (EMEA/HMPC/230479/2008) including comments received from AESGP. The HMPC did not identify the need to modify the 'Community herbal monograph on *Equisetum arvense* L., herba' (EMEA/HMPC/394894/2007) and the supporting assessment report adopted in July 2008 as a result of the assessment of the comments from AESGP.

The HMPC adopted the following draft Community herbal monographs, released for public consultation until 15 January 2009:

- Draft 'Community herbal monograph on *Aesculus hippocastanum* L., semen' (EMEA/HMPC/225319/2008)
- Draft 'Community herbal monograph on *Hamamelis virginiana* L., folium' (EMEA/HMPC/114586/2008)

- Draft 'Community herbal monograph on *Echinacea pallida* Nutt., radix' (EMEA/HMPC/332350/2008)

The draft Community herbal monographs, together with a draft list of references used during the assessment, will be published in due course on the EMEA website at:

<http://www.emea.europa.eu/htms/human/hmhc/hmhcmonographsdraft.htm>

The HMPC had a first discussion on a draft monograph on *Hyperici herba*. The Committee advised the MLWP on further development of the draft that is expected to be re-presented to HMPC in November.

Upon recommendation from the MLPW, the HMPC adopted a draft 'Concept paper on the development of a guideline on preparation of herbal teas' (EMEA/HMPC/451978/2008) which will be released for public consultation until 15 January 2009 and will be available at:

<http://www.emea.europa.eu/htms/human/hmhc/hmhcguide.htm>

The guideline will aim at providing instructions for the preparation of herbal teas and standardise terminology used in Community herbal monographs, Community list entries and related documents

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

The MLWP held its 16<sup>th</sup> meeting at the EMEA on 1- 3 September 2008.

In addition to the work that supported the adoption of the above-mentioned documents by the HMPC, the MLWP made significant progress on the scientific work relating to draft Community herbal monographs/list entries and assessment reports on *Absinthii herba*, *Hamamelis cortex/distillate*, *Harphagophyti radix* and *Salicis cortex*. The MLWP also discussed draft monographs on *Salviae folium*, *Taraxaci radix cum herba*, *Curcumae longae rhizoma*, *Juniperi fructus* and *Urtica radix*.

An updated 'Overview of status of HMPC assessment work – September 2008

(EMEA/HMPC/278067/2006)' will be published on the EMEA website at:

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

With a view to initiating assessment work on several herbal substances, calls for the submission of scientific data have been published. They can be found at:

<http://www.emea.europa.eu/htms/human/hmhc/hmhcdata.htm>

The next meeting of the MLWP is scheduled for 4-5 November 2008.

### **Report from the Organisational matters Drafting Group (ORGAM DG)**

A meeting of the ORGAM DG was held on 27 August 2008.

The HMPC adopted the final 'Reflection paper on the reasons and timelines for revision of final Community herbal monographs and Community list entries' (EMEA/HMPC/326440/2007). The final version of the reflection paper takes into account comments received during the consultation period, which are addressed in the 'Overview of comments received on draft reflection paper on the reasons and timelines for revision of final Community herbal monographs and Community list entries' (EMEA/HMPC/370642/2008).

Both documents will be published in due course on the EMEA website at:

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

The ORGAM DG discussed proposals for the revision of the HMPC 'Assessment report template for the development of Community monographs and for inclusion of herbal substance(s), preparation(s) or combinations thereof in the List' (EMEA/HMPC/418902/2005) in order to improve its readability and the presentation of data related to the traditional use(s) of herbal substances/herbal preparations. A revised version of the assessment report template, including input received from the MLWP, will be presented to the HMPC in November 2008.

The next meeting of the ORGAM DG is scheduled for 8 October 2008.

### **Quality Drafting Group (Q DG)**

The next meeting of the Q DG is scheduled for 9 October 2008 in preparation of the HMPC November 2008 meeting.

The HMPC adopted the 'Mandate, objectives and composition for the HMPC quality drafting group (Q DG)' (EMEA/HMPC/410043/2008) which describes the mandate, objectives, composition, rules of participation and meeting frequency of the drafting group.

This document can be found at:

[http://www.emea.europa.eu/htms/general/contacts/HMPC/HMPC\\_QDG.html](http://www.emea.europa.eu/htms/general/contacts/HMPC/HMPC_QDG.html)

### **Other relevant information**

The HMPC initiated a dialogue with the European Commission DG Enterprise and Industry on classification issues related to borderline products between herbal medicinal products and medical devices. The Committee was informed about procedures in place involving Commission services, Member States and/or stakeholders to discuss borderline and classification cases.

The HMPC provided input on the definition of requirements for ISO Standards for the nomenclature related to herbal medicinal products. This activity is part of the objectives of the ICH M5 topic to develop harmonised electronic transmission standards that build on the regulatory and technical processes currently established in the three ICH regions and observer countries.

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