



London, 15 July 2008
Doc. Ref. EMEA/HMPC/369359/2008

COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

Meeting report, 2-3 July 2008

The HMPC held its 24th meeting at the EMEA on 2-3 July 2008. The HMPC welcomed the following new alternate HMPC members: V. Gulevska from Latvia, V. Halldorsdottir from Iceland and the following observers from Turkey: H. Ozbek and M. Varel.

During the plenary meeting the HMPC elected Prof. G. Calapai as co-opted member with expertise in clinical pharmacology. The HMPC will further discuss in September 2008 the appointment of a co-opted member with expertise in herbal traditional medicine and the renewal of the three-year membership of G. Laekeman, co-opted member with expertise in experimental/non-clinical pharmacology.

The updated composition of the Committee can be found at:

http://www.emea.europa.eu/htms/general/contacts/HMPC/HMPC_members.html

Upon recommendation from the HMPC Working Party on Community Monographs and Community List (MLWP), the HMPC adopted the following Community herbal monographs and related documents:

Final Community herbal monographs

- 'Community herbal monograph on *Equisetum arvense* L., herba' (EMEA/HMPC/394894/2007)
- 'Community herbal monograph on *Melilotus officinalis* (L.) Lam., herba' (EMEA/HMPC/354177/2007)
- 'Community herbal monograph on *Sambucus nigra* L., flos' (EMEA/HMPC/283166/2007)
- 'Community herbal monograph on *Urtica dioica* L. and *Urtica urens* L., herba' (EMEA/HMPC/170261/2006)
- 'Community herbal monograph on *Verbascum thapsus* L., *V. densiflorum* Bertol. and *V. phlomoides* L., flos' (EMEA/HMPC/395213/2007)

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 the following draft Community herbal monographs, released for public consultation until 15 November 2008:

- Draft 'Community herbal monograph on *Althaea officinalis* L., radix' (EMEA/HMPC/98717/2008)
- Draft 'Community herbal monograph on *Centaurium erythraea* Rafn., herba' (EMEA/HMPC/105536/2008)

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/hmpc/hmpcmonographsdraft.htm>

The Committee was informed about the progress at the European Commission towards the establishment of the 'list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products' having regard to several opinions of the EMEA formulated by the HMPC. Publication on the first Commission decisions is expected in the autumn 2008.

Appointment of Rapporteurs

The HMPC appointed Rapporteurs for the preparation of draft Community herbal monographs/Community list entries for *Tormentillae rhizoma* and *Liquiritiae radix*.

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

The MLWP held its 15th meeting at the EMEA on 30 June- 2 July 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 *Hyperici herba*, *Absinthii herba*, *Hamamelis cortex/folium/distillate* and *Hippocastani semen*. The MLWP also discussed draft monographs on *Echinaceae pallidae radix* and *Salviae folium*.

An updated 'Overview of status of HMPC assessment work – July 2008 (EMEA/HMPC/278067/2006)' will be published on the EMEA website at:

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

The next meeting of the MLWP is scheduled for 1-3 September 2008.

Report from the Quality Drafting Group (Quality DG)

A meeting of the Quality DG was held on 19 June 2008.

The Quality DG presented the revised 'Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products' (EMEA/HMPC/CHMP/CVMP/287539/2005 Rev. 1). The revised guideline includes an annex with recommendations for applicants on the declaration of herbal substances and herbal preparations in the package leaflet and labelling of herbal medicinal products.

This document was adopted by the HMPC on 3 July 2008 and was transmitted to the Quality Working Party (QWP) for agreement before adoption by the Committee for Medicinal Products for Human Use (CHMP) and the Committee for Medicinal Products for Veterinary Use (CVMP) for 3-month public consultation on the content of the annex and the revised sections of the guideline.

The HMPC adopted a draft 'Concept paper on selection of test materials for genotoxicity testing for traditional herbal medicinal products/herbal medicinal products' (EMEA/HMPC/315413/2008) which will be released for public consultation until 15 October 2008 and will be available at:

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

This concept paper foresees the development of further guidance on a standard range of test materials to be used in genotoxicity testing for the herbal substances/preparations. It will be presented as an annex to the recently adopted HMPC 'Guideline on the assessment of genotoxicity of herbal substances/preparations' (EMEA/HMPC/107079/2007).

The HMPC adopted the final 'Reflection paper on markers used for quantitative and qualitative analysis of herbal medicinal products and traditional herbal medicinal products' (EMEA/HMPC/253629/2007). The final version of the reflection paper takes into account comments received during the consultation period which are addressed in the 'Overview of comments on the reflection paper on markers used for quantitative and qualitative analysis of herbal medicinal products and traditional herbal medicinal products' (EMEA/HMPC/297843/2008).

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

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

The next meeting of the Quality DG is scheduled for 9 October 2008.

Organisational Matters Drafting Group (ORGAM DG)

The next meeting of the ORGAM DG is scheduled for 27 August 2008 in preparation of the HMPC September 2008 meeting.

Other relevant information

The HMPC continued to discuss various aspects of the borderline between therapeutic indications and health claims for herbal ingredients which are described in a summary document proposing to establish a cooperation with the European Food Safety Authority panel on dietary products, nutrition and allergies (NDA panel), with the view to exchanging scientific views on common areas of interest. It also highlights the need to involve the European Commission in this dialogue. The HMPC document will be presented to the EMEA Executive Director for further actions.

The HMPC adopted a report from the AESGP hearing during the MLWP meeting on 6 May. Major issues had been highlighted in the May 2008 meeting report. The hearing report will be published on the EMEA website at:

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

The Committee noted the outcome of a Transatlantic Administrative Simplification Workshop co-chaired by the European Commission and the United States Food and Drug Administration (FDA) and organised in collaboration with the EMEA and the Heads of the EU National Medicines Agencies. In particular, exchange of information on herbal medicines will take place in the form of provision of the Community herbal monographs established by the HMPC (final and draft) to the FDA. The Action Plan from the workshop can be found at:

http://ec.europa.eu/enterprise/pharmaceuticals/international/doc/eu_fda_action_plan_200806.pdf

The HMPC discussed recent development in the area of documentation and protection of traditional knowledge as well as access to traditional resources. The Committee would like to reflect on the pertinence of some orientations vis-à-vis its competence as laid down in Directive 2001/83/EC as amended.

For further information, please contact:

Tony Humphreys
Head of Regulatory Affairs and Organisational Support Sector
Tel.: (44-20) 7418 8583
Fax: (44-20) 7523 7051
hmpc.secretariat@emea.europa.eu