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## COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

### **Meeting report, 9-10 January 2008**

The HMPC held its 21<sup>st</sup> meeting at the EMEA on 9-10 January 2008.

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

#### Community list entries:

- 'Community list entry on *Pimpinella anisum* L., fructus' (EMEA/HMPC/297757/2006)

Once available in all EU languages, the Community list entry, together with its assessment report and the HMPC opinion, will be transmitted to the European Commission for adoption (Comitology procedure).

#### Draft Community herbal monographs, released for public consultation until 15 April 2008:

- draft 'Community herbal monograph on *Harpagophytum procumbens* D.C. and/or *Harpagophytum zeyheri* Decne, radix' (EMEA/HMPC/251323/2006)

The draft Community herbal monograph 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>

#### **Appointment of Rapporteurs**

The HMPC appointed Rapporteurs for the preparation of draft Community herbal monographs/Community list entries for *Achilleae millefolii flos*, *Agrimoniae herba*, *Agropyri repentis rhizoma*, *Curcubitae semen*, *Fragariae folium*, *Foenugraeci semen*, *Juglandis folium*, *Levistici radix*, *Millefolii herba*, *Myrtilli fructus*, *Orthosiphonis folium*, *Quercus cortex*, *Violae tricoloris herba*.

#### **Referral procedures**

The HMPC received the first notification of a referral under Article 16c(1)(c) of Directive 2001/83/EC, as amended. This referral procedure started at the request of a Member State (Slovak Republic) regarding a traditional use registration application for a fixed combination herbal medicinal product for which the number of ingredients had been reduced during the 30 years of medicinal use. The HMPC was asked to draw up an opinion on the adequacy of the evidence of the long-standing use of the product. The HMPC appointed a Rapporteur and a Co-Rapporteur for the referral procedure who will prepare assessment reports for the Committee. Although the legislation does not provide for a specific timeframe, the HMPC agreed to endeavour to issue a reasoned opinion within 60 days.

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

The MLWP held its 12<sup>th</sup> meeting at the EMEA on 8-9 January 2008.

Upon recommendation from the MLWP, the HMPC introduced a pilot peer-review system for draft Community herbal monographs/Community list entries and related documents, with a view to improving quality and consistency across the documents published on a given herbal substance.

Appointed peer-reviewers will present revised versions of Community herbal monographs/Community list entries and related documents before their final adoption by the Committee and publication on the EMEA website.

In addition to the work that supported the adoption of the above-mentioned documents by the HMPC, the MLWP concluded the scientific work related to *Betulae folium*, *Calendulae flos*, *Echinaceae purpureae herba*, *Eleutherococci radix*; however, the adoption of the respective monographs/list entries and related documents was postponed to the March 2008 HMPC meeting to allow peer review of all documents.

The MLWP also made significant progress on the scientific work relating to draft Community herbal monographs/list entries and assessment reports on *Lupuli flos*, *Urticae folium*, *Boldi folium*, *Cimicifugae rhizoma* and *Polypodii rhizoma*.

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

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

A part of the working party's meeting was dedicated to revise its organisational framework. In this context the HMPC adopted the revised 'Mandate, objectives and rules of procedure for the HMPC Working Party on Community Monographs and Community List (MLWP)' (EMEA/HMPC/379153/2005 Rev.2), which can be found at:

<http://www.emea.europa.eu/pdfs/human/hmpc/mlwp/37915305en.pdf>

In the revised mandate the Committee put particular emphasis on the active contribution of members to the work of the working party, in particular that all members should be Rapporteur for at least one topic per calendar year, such as the establishment and peer review of monographs/list entries, the preparation of guidance on general topics (e.g. ethanol content in herbal medicinal products used in children) thus aiming at increasing the quality and number of monographs/list entries and related documents presented by the MLWP to the HMPC.

The next meeting of the MLWP is scheduled for 3-5 March 2008.

### **Report from the Quality Drafting Group (Quality DG)**

A meeting of the Quality DG was held on 6 December 2007.

The Quality DG presented a final version of the 'Guideline on quality of combination herbal medicinal products/traditional herbal medicinal products' (EMEA/HMPC/CHMP/CVMP/214869/2006) together with the 'Overview of comments received during the consultation period' (EMEA/HMPC/559281/2007). Both documents were adopted by the HMPC on 10 January 2008 and were 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).

The HMPC adopted a draft 'Reflection paper on markers (marker substances) used for quantitative and qualitative analysis of herbal medicinal products and traditional herbal medicinal products' (EMEA/HMPC/253629/2007) which will be released for public consultation until 15 April 2008 and will be available at: <http://www.emea.europa.eu/htms/human/hmpc/hmpcguide.htm>

This reflection paper describes issues related to markers, which are intended for quantitative and qualitative analytical control of herbal medicinal products, and provides possible criteria to be taken into account to select markers.

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

Further to the end of the consultation period, the HMPC adopted a revised version of the 'Guideline on the use of the CTD format in the preparation of a registration application for traditional herbal medicinal products' (EMEA/HMPC/71049/2007).

The revised version of the guideline takes into account comments received during the consultation period, which are presented in the respective 'Overview of comments received during the consultation period' (EMEA/HMPC/539645/2007).

The guideline and the overview of comments will be available on the EMEA website at:

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

### **Legislation and regulatory affairs**

In the context of the proposal launched by the European Commission for a future revision of the legal framework covering changes to the marketing authorisations of medicinal products (Variations Regulations), the HMPC provided comments on the position paper '[Better regulation of pharmaceuticals: towards a simpler, clearer and more flexible framework on Variations](#)', which were presented by the EMEA to the Commission as a part of a general response document. The HMPC will provide specific additional comments later in the process of the revision of the Variations Regulations.

### **Other relevant information**

The HMPC was represented by its Vice-chair, Dr I. Chinou, at the 'Joint forum for discussions between EMEA and its scientific committees and the European Pharmacopoeia' held in London on 17 January 2008.

This Joint Forum was set up in July 2005 to strengthen co-operation between EMEA and European Pharmacopoeia/EDQM, ensure that their activities complement each other and identify in advance potential overlapping areas of interest.

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