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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

Meeting report, 5-6 March 2008

The HMPC held its 22nd meeting at the EMEA on 5-6 March 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 *Calendula officinalis* L., flos' (EMEA/HMPC/179283/2007)

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.

Final Community herbal monographs

- 'Community herbal monograph on *Calendula officinalis* L., flos' (EMEA/HMPC/179281/2007)
- 'Community herbal monograph on *Echinacea purpurea* (L.) Moench., herba' (EMEA/HMPC/104945/2006)

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>

Appointment of Rapporteurs

The HMPC appointed Rapporteurs for the preparation of draft Community herbal monographs/Community list entries for *Capsella bursa-pastoris* herba, *Filipendulae ulmariae* herba, *Filipendulae ulmariae* flos, *Juniperi fructus*, *Myrrha* (*Commiphora molmol*), *Taraxaci folium* and *Solanum dulcamara*.

Reference documents for the preparation of Community herbal monographs and Community list entries and related documents

The HMPC adopted a revised version of the following documents underpinning the preparation of Community herbal monographs and Community list entries:

- Community list entry template (EMEA/HMPC/439705/2006 Rev.3)
- Community herbal monograph template (EMEA/HMPC/107436/2005 Rev.3).

Both documents had been revised by the Working Party on Community Monographs and Community List (MLWP) to reflect the current practice in the MLWP in the preparation of draft Community herbal monographs and Community list entries, to facilitate the future translation of Community list entries adopted by the Committee as well as to improve consistency between the two templates.

Referral procedures

The HMPC concluded the first referral procedure under Article 16c(1)(c) of the Community code on human medicinal products (Directive 2001/83/EC, as amended) by consensus. This referral procedure started in January 2008 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.

In its scientific assessment, the HMPC concluded that the evidence of the long-standing use of the herbal medicinal product was adequate.

The HMPC opinion and the supporting assessment report for this referral procedure will be available on the EMEA website when the registration procedure will be concluded at national level.

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

The MLWP held its 13th meeting at the EMEA on 3-5 March 2008.

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 *Lupuli flos*, *Menthae piperitae folium*, *Verbasci flos*, *Sambuci flos* and *Urticae herba*; however, the adoption of the respective monographs/list entries and related documents was postponed to the May 2008 HMPC meeting to allow peer review of all documents.

The MLWP made significant progress on the scientific work relating to draft Community herbal monographs/list entries and assessment reports on *Althaeae radix*, *Boldi folium*, *Centaurii herba*, *Cimicifugae rhizoma*, *Hyperici herba* and *Polypodii rhizoma*.

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

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

The next meeting of the MLWP is scheduled for 5-7 May 2008.

Report from the Quality Drafting Group (Quality DG)

A meeting of the Quality DG was held on 7 February 2008.

A part of the Quality DG's meeting was dedicated to revise its organisational framework. In this context the HMPC adopted the revised 'Quality DG work plan 2008' which included additional guidance documents to be drafted by the Quality DG such as guidelines on stability testing for herbal products/preparations or on comparability of herbal substances/preparations (e.g. extracts using different solvents).

Report from the Organisational Matters Drafting Group (ORGAM DG)

A teleconference of the ORGAM DG was held on 12 February 2008.

The HMPC adopted the following document for release for public consultation until 30 June 2008:

- 'Reflection paper on the reasons and timelines for revision of final Community herbal monographs and Community list entries' (EMEA/HMPC/326440/2007).

This reflection paper aims to identify the criteria/reasons to trigger the revision of Community herbal monographs and/or Community list entries and the associated timelines.

The reflection paper will be available on the EMEA website at:

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

Other relevant information

HMPC members attended an 'information session' on Anthroposophic medicine on 6 March 2008, organised in cooperation with the Association Européenne des Fabricants de Médicaments utilisés en Thérapeutique Anthroposophique (AEFMUTA). A report from the event will be published on the EMEA website at a later stage.

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