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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

Meeting report, 13-14 May 2009

The HMPC held its 29th meeting at the EMEA on 13-14 May 2009.

The HMPC welcomed Mrs F. Handan Öztunca as a new observer from Turkey.

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

- 'Community herbal monograph on *Althaea officinalis* L., radix (EMEA/HMPC/98717/2008)

The final Community herbal monograph as well as the HMPC opinion, assessment report 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/hmpcmonographs.htm>

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

- Draft 'Community herbal monograph on *Valerian officinalis* L., radix and *Humulus lupulus* L., flos (EMEA/HMPC/585558/2007). The committee agreed to publish additionally the draft assessment report in order to facilitate comments on the assessment of the multiple combinations of preparations from these herbal substances.
- Draft 'Community herbal monograph on *Thymus vulgaris* L.; *Thymus zygis* L., aetheroleum (EMEA/HMPC/131901/2009). The HMPC could not adopt a draft list entry on *Thymus vulgaris* L.; *Thymus zygis* L., aetheroleum for release for public consultation because of insufficient supporting genotoxicity data according to the [Guideline on the assessment of genotoxicity of herbal substances/preparations \(EMEA/HMPC/107079/07\)](#)

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/hmpcmonographs.htm>

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

The MLWP held its 20th meeting at the EMEA on 11-13 May 2009.

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 the draft Community herbal monograph and assessment report on Echinaceae pallidae radix and Absinthii herba. The MLWP discussed the monographs on Hyperici herba, Hippocastani semen, Hamamelidis cortex, Hamamelidis folium, Hamamelidis folium et cortex aut ramunculus destillatum and the respective comments received during the public consultation period; further discussion is scheduled at the July 2009 meeting.

The MLWP also discussed draft monographs on *Mate folium*, *Agni casti fructus*, *Echinaceae angustifoliae radix*, *Echinaceae purpureae radix*, *Ribis nigri folium*, *Rosmarini folium*, *Rosmarini aetheroleum*, *Orthosiphoni staminei folium*, *Hederae helioides folium* and the preparation of monographs on *Centellae asiaticae herba*, *Arctii radix*, *Arctii folium*, *Cinnamomi cortex*, *Euphrasiae herba tota*, *Visci albi herba* and *Oenotherae biennis oleum*.

An updated 'Overview of status of HMPC assessment work – May 2009 (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 13-15 July 2009.

Quality Drafting Group (Q DG)

A meeting of the Q DG was held on 7 April 2009 which the Chairs of European Pharmacopoeia Expert groups 13A & 13B (Phytochemistry) and TCM attended, as part of the initiatives to strengthen cooperation with the EDQM. Presentations on the status of work and examples of current issues were given for the three expert groups. Main points for discussion were markers, classification of extracts, refined extracts and levels of purification, family monographs, heavy metals, and the certification procedure for herbal substances.

Participants were pleased with the satisfactory match of work programmes between quality monographs of the Ph. Eur. and safety/efficacy monographs of the HMPC for covering the important European herbal substances and it was agreed to continue the fruitful collaboration between HMPC and relevant groups within EDQM through regular update on state of work, mutual observership and such meetings on an annual basis.

The next meeting of the Q DG is scheduled for 18 June 2009. As previously announced, a Quality Assessors training on applying established and new requirements for the quality assessment of herbal medicinal products will be held at the EMEA on 19 June 2009.

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