



London, 21 May 2007
Doc. Ref. EMEA/HMPC/216295/2007

COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

Meeting report, 8 May 2007

The Committee on Herbal Medicinal Products met for the 17th time at the EMEA on 8 May 2007.

The Committee adopted revised rules of procedure, which can be found at:

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

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

The 8th meeting of the permanent HMPC Working Party on Community Monographs and Community List (MLWP) took place on 7 May 2007.

On recommendation of the MLWP, the HMPC adopted the following draft Community herbal monographs, which are released for public consultation until 15 August 2007:

- draft 'Community herbal monograph on *Betula pendula* Roth and *Betula pubescens* Ehrh., folium' (EMEA/HMPC/260019/2006)
- draft 'Community herbal monograph on *Melissa officinalis* L., folium' (EMEA/HMPC/5341/2007)
- draft 'Community herbal monograph on *Mentha x piperita* L., aetheroleum' (EMEA/HMPC/349466/2006)
- draft 'Community herbal monograph on *Thymus vulgaris* L. and *Thymus zygis* L., herba' (EMEA/HMPC/234113/2006)

The draft Community herbal monographs together with a draft list of references used during the assessment can be found at:

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

Furthermore the Committee adopted a draft 'Community list entry on *Echinacea purpurea* (L.) Moench., herba' for release for consultation until 15 June 2007, which can be found at:

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

The MLWP made significant progress on the scientific work relating to draft Community herbal monographs and assessment reports on Calendulae flos, Eleutherococci radix, Lupuli flores, Menthae piperitae folium and Rhei radix. An updated 'Overview of status of HMPC assessment work – May 2007' (EMEA/HMPC/278067/2006) can be found on the EMEA website at:

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

The next meeting of the MLWP is scheduled for 2-4 July 2007.

Report from the Organisational Matters Drafting Group

During its meeting on 11 April 2007, the Organisational Matters Drafting Group agreed on a proposal for amendment of Chapter 3 'Community referral' of the Volume 2A of the Notice to Applicants to include referrals made to the HMPC under Article 16(c) of the Community code. The Committee

discussed and adopted the proposal, which will be forwarded to the Group on Notice to Applicants at the European Commission.

The HMPC also adopted a draft guideline, prepared by the Organisational Matters Drafting Group, on the use of the Common Technical Document (CTD) format in the preparation of a registration application for traditional herbal medicinal products (EMEA/HMPC/1049/2007); the guideline is released for public consultation until 15 August 2007 and can be found at:

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

Report from the Quality Drafting Group

A meeting of the Quality Drafting Group was held on 12 April 2007.

The Quality Drafting Group presented a final version of the 'Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products in the SPC' (EMEA/HMPC/CHMP/CVMP/287539/2005) together with the 'Overview of comments received during the consultation period' (EMEA/HMPC/230249/2006). Both documents were adopted by the HMPC on 8 May 2007 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).

Other relevant information

The Committee adopted a draft 'Guideline on the assessment of genotoxic constituents in herbal substances/herbal preparations' (EMEA/HMPC/104681/2007), which was transmitted to the CHMP Safety Working Party for comments.

The Committee was informed about recent developments concerning the involvement of healthcare professionals in the work of the Agency. The report on the first meeting of the EMEA/CHMP Working Group with Healthcare professionals' organisations (HCPWG) can be found here: <http://www.emea.europa.eu/pdfs/human/hcpwg/47054606en.pdf>

The HMPC will reflect on the areas where the HCPWG's future work is relevant to the Committee's competence so as to contribute to projects identified so far to meet the Agency's objective to strengthen interactions with healthcare professionals.

The Committee discussed the recommendations and proposals that emerged from the first meeting held in March 2007 between representatives of the HMPC and of the European Food Safety Authority and its Scientific Committee. EMEA and EFSA will work to establish a framework for cooperation between the two committees as part of the Agency's initiatives for the implementation of Article 59 of Regulation (EC) No 726/2004. A major area of common interest is safety and risk assessment and the objectives of the committees' cooperation include exchange of requirements for safety assessment and practical cases of the application of such requirements in relation to botanicals/herbal substances and their preparations.

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