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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

Meeting report, 11-12 March 2009

The HMPC held its 28th meeting at the EMEA on 11-12 March 2009.

The HMPC elected Dr. Werner Knöss as Vice-Chair of the Working Party on Community Monographs and Community List (MLWP).

The HMPC appointed the two nominated experts Dr. M. Brum-Bousquet and Ms A. Kruszewska as members of the Quality Drafting Group (Q DG).

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

- 'Community herbal monograph on *Centaurium erythraea* Rafn, herba'
(EMEA/HMPC/105536/2008)

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 monograph, released for public consultation until 15 July 2009:

- Draft 'Community herbal monograph on *Gentiana lutea* L, radix'
(EMEA/HMPC/578324/2008)

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/hmpcmonographs.htm>

The HMPC adopted a corrigendum for the assessment report on *Harpagophyti radix* and the supporting list of references. They can be found at:

http://www.emea.europa.eu/htms/human/hmpc/monograph/harpagophyti_radix.htm

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

The MLWP held its 19th meeting at the EMEA on 9-11 March 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 *Althaeae radix*. The MLWP also discussed draft monographs on *Valerianae radix* and *Lupuli flos* (combination), *Mate folium*, *Thymi aetheroleum*, *Quercus cortex*, *Rosmarini folium* and *Violae tricoloris herba*, and the preparation of monographs on *Agni casti fructus*, *Orthosiphoni staminei folium*, *Ribis nigri folium*, *Rosmarini aetheroleum* and *Vitis viniferae folium*.

An updated 'Overview of status of HMPC assessment work – March 2009 (EMEA/HMPC/278067/2006)' will be published on the EMEA website at:

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

The MLWP appointed a Rapporteur for the preparation of a Community herbal monograph/Community list entry on Caryophylli flos.

In accordance with the new policy regarding contacts with interested parties announced in January 2009 and upon agreement by the HMPC, the MLWP met representatives from the Association of the European Self-Medication Industry (AESGP) on 10 March in order to discuss a number of general issues related to Community herbal monographs/Community list entries and related documents adopted by the HMPC. Important issues such as access to unpublished data and the conduct of hearings in connection with controversial scientific evaluations were addressed. Once adopted, the report from the meeting will be published at:

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

The next meeting of the MLWP is scheduled for 11-13 May 2009.

Report from the Organisational matters Drafting Group (ORGAM DG)

A meeting of the ORGAM DG was held on 10 February 2009.

The HMPC adopted the revised 'Procedure on management of proposals from interested parties for Community list entries and Community herbal monographs' (EMEA/HMPC/328575/2007 Rev.1) which now requires the submission of a draft monograph/list entry together with comprehensive literature, non-clinical and clinical overviews and Expert Reports. Given the substantial amendments brought to the procedure, this revision is subject to a 3-month public consultation until 15 July 2009.

The HMPC also adopted the revised 'Procedure for the appointment by the HMPC of a Rapporteur for a scientific evaluation or the development of a Community herbal monograph and/or Community list entry' (EMEA/HMPC/108877/2005 Rev.1), and the revised 'Procedure for calls for scientific data for use in HMPC assessment work' (EMEA/HMPC/1004/2006 Rev.1). Both procedures were amended to reflect current practice and remove steps which were not undertaken.

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

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

The ORGAM DG had discussed the pharmacovigilance legal provisions released by the European Commission on 12 December 2008 in order to identify provisions affecting specifically (traditional) herbal medicinal products.

The next meeting of the ORGAM DG is scheduled for 17 June 2009.

Quality Drafting Group (Q DG)

A meeting of the Q DG was held on 11 February 2009.

The HMPC adopted the following document for transmission to the CHMP Safety Working Party and the CHMP/CVMP Quality Working Party for co-ordination. Once agreed, it will be released for three months public consultation: Draft 'Guideline on selection of test materials for genotoxicity testing for traditional herbal medicinal products/herbal medicinal products' (EMEA/HMPC/67644/2009).

The HMPC endorsed the draft programme for a Quality Assessors training to be organised in 2009 aiming at enhancing common interpretation of scientific guidelines by assessors in national competent authorities. The previous Quality Assessors training had led to the publication of a Q&A on quality issues emerging for herbal medicinal products:

<http://www.emea.europa.eu/pdfs/human/hmpc/53130008en.pdf>

The HMPC took note of the EDQM International symposium on herbal drugs & herbal drug preparations organised in September 2009 during which the Chair of the Q DG will give some lectures.

The next meeting of the Q DG is scheduled for 7 April 2009, where the Chairs of European Pharmacopoeia Expert groups 13A & 13B (Phytochemistry) and TCM are invited to discuss ways to strengthen cooperation, as announced in the January 2009 meeting report.

Other relevant information

The HMPC took note of the revised 'Procedure for European Union guidelines and related documents within the pharmaceutical legislative framework' ([EMEA/P/24143/2004 Rev. 1](#)) which integrates a change in policy vis-à-vis transparency on comments received from interested parties on draft guidelines i.e. the identity of the sender will also be made public. The same transparency principles apply to the preparation of Community herbal monographs/Community list entries and related documents. Consequently, templates for the submission/publication of comments by interested parties on these documents have been amended, pointing to the fact that comments and the identity of the sender will be published unless a specific justified objection is received.

This new policy is applied to any new guidelines, guidance documents and monographs/list entries released by the HMPC from this month onwards.

The HMPC took also note of the final agenda for the joint meeting of HMPC and Patients' and Consumers' Organisations (PCO) organised with the EMEA Medical Information Sector on 13 March 2009 to investigate the future involvement of PCO/PCWP in the improvement of HMPC documents intended for the general public. The meeting report will be published at:

<http://www.emea.europa.eu/Patients/PCWP.htm>

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