



London, 20 November 2008
Doc. Ref. EMEA/HMPC/610485/2008

COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

Meeting report, 5-6 November 2008

The HMPC held its 26th meeting at the EMEA on 5-6 November 2008.

Upon recommendation from the MLWP, the HMPC adopted the following Community herbal monographs/Community list entries and related documents:

Final Community herbal monographs

- 'Community herbal monograph on *Harpagophytum procumbens* D.C. and/or *Harpagophytum zeyheri* Decne, radix' (EMEA/HMPC/251323/2006)
- 'Community herbal monograph on *Polypodium vulgare* L., rhizoma' (EMEA/HMPC/600668/2007)

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/hmpcmonographs.htm>

Final Community list entries

- 'Community list entry on *Mentha x piperita* L., aetheroleum' (EMEA/HMPC/189245/2008)

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.

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

- Draft 'Community herbal monograph on *Hypericum perforatum* L., herba' (EMEA/HMPC/101304/2008)

The HMPC decided to release during the consultation period the preliminary draft assessment report supporting the draft Community herbal monograph on *Hypericum perforatum* L., herba. This represents an exceptional case justified by the complexity of the assessment and the advanced stage of preparation of the assessment report.

- Draft 'Community herbal monograph on *Artemisia absinthium* L., herba' (EMEA/HMPC/234463/2008)
- Draft 'Community herbal monograph on *Hamamelis virginiana* L., cortex' (EMEA/HMPC/114583/2008)
- Draft 'Community herbal monograph on *Hamamelis virginiana* L., folium et cortex and *Hamamelis virginiana* L., ramunculus' (EMEA/HMPC/114584/2008)
- Draft 'Community herbal monograph on *Curcuma longa* L., rhizoma' (EMEA/HMPC/456845/2008)

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>

Upon recommendation from the MLWP, the HMPC adopted the draft 'Reflection paper on ethanol content in herbal medicinal products and traditional herbal medicinal products used in children' (EMEA/HMPC/85114/2008), which was developed in coordination with the CHMP and PDCO. The document is released for public consultation until 15 February 2009 and can be found at:

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

Referral procedures

The HMPC concluded in March 2008 the first referral procedure under Article 16c(1)(c) of the Community code on human medicinal products (Directive 2001/83/EC, as amended). 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 (Doppelherz Energovital Tonik) for which the number of ingredients had been reduced during the 30 years of medicinal use. The HMPC concluded in March 2008 that the evidence of the long-standing use of the herbal medicinal product was adequate. The referring Member State followed the conclusions of the HMPC and Doppelherz Energovital Tonik K was registered as a traditional herbal medicinal product by the Slovak Republic on 24 September 2008.

The background information on the HMPC opinion and the supporting assessment report for this referral procedure will be published on the EMEA website at:

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

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

The MLWP held its 17th meeting at the EMEA on 4-5 November 2008.

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 draft Community herbal monographs/list entries and assessment reports on Boldi folium and Urticae folium. The MLWP also discussed draft monographs on Salviae folium, Taraxaci radix cum herba, Juniperi pseudo-fructus and Urticae radix.

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

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

The MLWP welcomed and is considering the first proposal for a draft Community herbal monograph on Lavandulae aetheroleum submitted by an interested party in accordance with the 'Procedure on management of proposals submitted by interested parties for Community list entries or Community herbal monographs' (EMEA/HMPC/328575/2007).

With a view to initiating assessment work on several herbal substances, calls for the submission of scientific data have been published. They can be found at:

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

Upon recommendation from the MLPW, the HMPC adopted a 'Template for list of references supporting HMPC assessment report' (EMEA/HMPC/574496/2008).

This template is a reference document for use by HMPC Rapporteurs and can be found at

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

The HMPC adopted the MLWP Work programme for 2009 (EMEA/HMPC/535085/2008) which can be found at:

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

The next meeting of the MLWP is scheduled for 13-14 January 2009.

Report from the Organisational matters Drafting Group (ORGAM DG)

A meeting of the ORGAM DG was held on 8 October 2008.

The HMPC adopted templates prepared by the ORGAM DG for opinions of the HMPC pursuant to referrals for traditional herbal medicinal products under Article 29, Article 30 and Article 31 of Directive 2001/83/EC, as amended.

The HMPC adopted a revised version of the HMPC 'Assessment report template for the development of Community monographs and for inclusion of herbal substance(s), preparation(s) or combinations thereof in the List' (EMEA/HMPC/418902/2005) which was amended to improve its readability and the presentation of data related to the traditional use(s) of herbal substances/herbal preparations and to add considerations on benefit-risk assessment.

This template will be published in due course on the EMEA website at:

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

The next meeting of the ORGAM DG is scheduled for 10 February 2009.

Quality Drafting Group (Q DG)

A meeting of the Q DG was held on 9 October 2008.

The HMPC adopted the following document for release for public consultation until 15 February 2009:

- Draft 'Reflection paper on level of purification of extracts to be considered as herbal preparations' (EMEA/HMPC/186645/2008).

This reflection paper aims to generate discussion on establishing criteria to distinguish the borderline between what may be considered as a herbal preparation and what might be classified as an isolated herbal constituent.

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

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

The HMPC adopted a 'Questions & answers document on quality issues related to herbal medicinal products' (EMEA/HMPC/531300/2008) prepared by the Q DG as a follow-up activity to the training for HMPC assessors on quality emerging issues for herbal medicinal products held at the EMEA on 7 December 2007.

The Q&A document will be available on the EMEA website at:

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

The next meeting of the Q DG is scheduled for 11 December 2008.

Other relevant information

The HMPC continued to provide input on the definition of requirements for ISO Standards for the nomenclature related to herbal medicinal products. This activity is part of the objectives of the ICH M5 topic to develop harmonised electronic transmission standards that build on the regulatory and technical processes currently established in the three ICH regions and observer countries.

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