



COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

Meeting report, 11-12 November 2009

The HMPC held its 32nd meeting at the EMEA on 11-12 November 2009.

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

- 'Community herbal monograph on *Curcuma longa* L., rhizoma' (EMEA/HMPC/456845/2008)'
- 'Community herbal monograph on *Gentiana lutea* L., radix' (EMEA/HMPC/578324/2008)'
- 'Community herbal monograph on *Hamamelis virginiana* L., cortex' (EMEA/HMPC/114583/2008)
- 'Community herbal monograph on *Hamamelis virginiana* L., folium' (EMEA/HMPC/114586/2008)
- 'Community herbal monograph on *Hamamelis virginiana* L., folium et cortex aut ramunculus destillatum' (EMEA/HMPC/114584/2008)
- 'Community herbal monograph on *Hypericum perforatum* L., herba' (EMEA/HMPC/101304/2008) (well-established medicinal use)
- 'Community herbal monograph on *Hypericum perforatum* L., herba' (EMEA/HMPC/745582/2009) (traditional use)
- 'Community herbal monograph on *Juniperus communis* L., pseudo-fructus' (EMEA/HMPC/441929/2008)
- 'Community herbal monograph on *Salvia officinalis* L., folium' (EMEA/HMPC/331653/2008)
- 'Community herbal monograph on *Taraxacum officinale* Weber ex Wigg, folium' (EMEA/HMPC/579636/2008)
- 'Community herbal monograph on *Taraxacum officinale* Weber ex Wigg., radix cum herba' (EMEA/HMPC/212895/2008)

The final Community herbal monographs as well as the 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>

Upon recommendation from the MLWP, the HMPC adopted the following draft Community herbal monograph and draft Community list entry, to be released for public consultation until 15 April 2010:

- Draft 'Community herbal monograph on *Vitis vinifera* L., folium' (EMEA/HMPC/16635/2009)
- Draft 'Community list entry on *Hamamelis virginiana* L., folium et cortex aut ramunculus destillatum' (EMEA/HMPC/704562/2009)

They will be available on the EMEA website respectively at:

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

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

After assessment of *Salvia officinalis* L., folium, the HMPC considered that it cannot establish a monograph on sage leaf essential oil due to safety concerns (high levels of thujone). The HMPC therefore adopted a draft public statement (EMEA/HMPC/726698/2009), which will be published together with the draft assessment report and the list of references for public consultation until 15 April 2010.

The assessment of *Echinacea angustifolia* DC., radix did not result in the establishment of a draft Community herbal monograph because of insufficient data as regards the period of traditional use. The HMPC adopted a draft public statement (EMEA/HMPC/726698/2009), which will be released together with the draft assessment report and the list of references for public consultation until 15 April 2010.

The assessment of *Euphrasia officinalis* L., *Euphrasia rostkoviana* Hayne, herba concludes on the lack of adequate data on the safe use and plausibility of pharmacological effects for certain preparations for ocular and nasal use. The HMPC adopted a draft public statement (EMEA/HMPC/727465/2009), which will be released together with the draft assessment report and the list of references for public consultation until 15 April 2010.

Public statements and related documents will be available at:

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

The committee looks forward to receiving additional data, if available, to allow the publication of monographs on *Echinacea angustifoliae* radix and *Euphrasiae* herba.

Appointment of Rapporteurs

The HMPC appointed Rapporteurs for the preparation of Community herbal monographs/Community list entries on *Leonuri cardiaca*e herba, *Citri bergamiae* aetheroleum and *Terebinthina* laricina.

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

The MLWP held its 23rd meeting at the EMEA on 9-11 November 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 draft list entries on *Thymi* aetheroleum and *Vitis viniferae* folium and a draft monograph on *Quercus* cortex.

The MLWP also discussed draft monographs on *Arctii* radix, *Cinnamomi* cortex, *Cinnamomi* aetheroleum, *Hederae heli*cis folium, *Millefolii* herba, *Oleae* folium, *Symphyti* radix, *Tanacet*i parthenii herba and *Violae tricoloris* herba cum flore as well as the preparation of monographs on *Matricariae* aetheroleum, *Matricariae* flos and *Visci albi* herba.

An updated 'Overview of status of HMPC assessment work – November 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 11-13 January 2010.

Report from the Organisational matters Drafting Group (ORGAM DG)

A meeting of the ORGAM DG was held on 13 October 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).

The document will be published in due course on the EMEA website at:

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

The HMPC adopted the ORGAM DG mandate, objectives and composition (EMEA/HMPC/644241/2009) and the ORGAM DG work programme for 2010 (EMEA/HMPC/638638/2009).

The documents will be published on the EMEA website at:

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

The next meeting of the ORGAM DG is scheduled for 11 February 2010.

Quality Drafting Group (Q DG)

A meeting of the Q DG was held on 14 October 2009.

The HMPC adopted the 'Guideline on selection of test materials for genotoxicity testing for traditional herbal medicinal products/herbal medicinal products' (EMEA/HMPC/67644/2009). The guideline together with the overview of comments received during public consultation will be published.

The HMPC adopted the revised 'Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products' (EMEA/HMPC/CHMP/CVMP/287539/2005 Rev.1). After adoption by CHMP and CVMP, the guideline together with the overview of comments received during public consultation will be published.

Both guidelines will be available at the EMEA website respectively:

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

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

The Q DG discussed comments received on the draft 'Reflection paper on stability testing of herbal medicinal products and traditional herbal medicinal products' (EMEA/HMPC/3626/2009) and will continue with the generation of a Q&A document to answer specific questions instead of developing a guideline.

The HMPC adopted the Q DG work programme for 2010 (EMEA/HMPC/396307/2009) which will be published on the EMEA website at:

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

The next meeting of the Q DG is scheduled for 15 December 2009.

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