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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

**Meeting report, 7 September 2007**

The Committee on Herbal Medicinal Products met for the 19<sup>th</sup> time at the EMEA on 7 September 2007.

Upon recommendation from the HMPC working party on Community monographs and Community list (MLWP), the HMPC adopted the following Community list entries and related documents:

- 'Community list entry on *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare*, fructus' (EMEA/HMPC/428817/2006)
- 'Community list entry on *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung, fructus' (EMEA/HMPC/428963/2006)

These represent the first Community list entries adopted by the Committee. List entries are essential tools to enhance European harmonisation since they serve as a basis for simplified registration applications and mutual recognition provisions will apply for registrations granted upon assessment of applications based on the content of list entries. These list entries, in all official EU languages, together with the supporting assessment report (in English) and the HMPC opinions will be transmitted to the European Commission for adoption according to Article 121(2) of Directive 2001/83/EC as amended.

The following final Community herbal monographs were adopted by the HMPC, further to recommendations from the MLWP:

- final 'Community herbal monograph on *Passiflora incarnata* L., herba' (EMEA/HMPC/230962/2006)
- final 'Community herbal monograph on *Primula veris* L. and *Primula elatior* (L.) Hill, radix' (EMEA/HMPC/143370/2006)
- final Community herbal monograph on *Primula veris* L. and *Primula elatior* (L.) Hill, flos (EMEA/HMPC/64684/2007)
- final Community herbal monograph on *Rhamnus purshianus* D.C., cortex (EMEA/HMPC/513579/2006)

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/hmhc/hmhcmonographsadopt.htm>

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

- draft 'Community herbal monograph on *Ruscus aculeatus* L. rhizoma' (EMEA/HMPC/261938/2007)
- draft 'Community herbal monograph on *Salix* cortex' (EMEA/HMPC/295338/2007)
- draft 'Community herbal monograph on *Sambucus nigra* L., flos' (EMEA/HMPC/283166/2007)

- draft 'Community herbal monograph on *Urtica dioica* L. and *Urtica urens* L., herba (EMEA/HMPC/168377/2006)

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>

### **Appointment of Rapporteurs**

The HMPC appointed Rapporteurs for the preparation of draft Community herbal monographs/Community list entries for:

Agni casti fructus, Allii sativi bulbus, Arnicae flos, Cardui mariae fructus, Eucalypti aetheroleum, Eucalypti folium, Gentianae radix, Ginkgo folium, Ginseng radix, Hederae helices folium, Mate folium, Marrubii herba, Matricariae flos, Matricariae aetheroleum, Plantaginis lanceolatae folium, Rosmarini folium, Serenoae repentis fructus, Taraxaci radix cum herba.

A Rapporteur was also appointed for the assessment of combinations of Primula and Thyme. This represents the first assessment of a fixed combination of two herbal substances.

A call for the submission of scientific data for use in HMPC assessment work was published for Althaeae radix and for Taraxaci radix cum herba.

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

Data should be submitted by 30 November 2007.

The HMPC adopted a revised version of the 'Procedure for calls for scientific data for use in HMPC assessment work' (EMEA/HMPC/1004/2006 Rev.1) that can be found at:

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

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

The 10<sup>th</sup> meeting of the permanent HMPC Working Party on Community Monographs and Community List (MLWP) took place on 5-6 September 2007.

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 and assessment reports on Avenae herba, Avenae fructus, Equiseti herba, Meliloti herba, Solidaginis virgaureae herba, and Verbasci flos. An updated 'Overview of status of HMPC assessment work – September 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 29-30 October 2007.

### **Report from the Quality Drafting Group (Quality DG)**

Meeting dates in 2008 for the Quality DG were adopted together with the group's work plan that will be reflected in the EMEA 2008 Work Programme. In 2008, the Quality DG aims at finalising the guideline on the quality of combination (traditional) herbal medicinal products and releasing draft guidance on the declaration of herbal substances and preparations in (traditional) herbal medicinal products in the labelling, on marker substances and on contaminants.

The HMPC adopted a training programme for quality assessors scheduled for December 2007 on emerging quality issues for herbal medicinal products, including control strategies and risk management for contaminants, mycotoxins and microbiological purity, heavy metals, pesticides.

The Committee raised preliminary comments on a number of documents prepared by the CHMP Quality Working Party that will be further discussed by the Quality DG at its next meeting on 4 October 2007. Means to strengthen co-operation between the HMPC and the CHMP QWP on quality matters are being investigated.

## **Report from the Drafting Group on organisational matters (ORGAM DG)**

The Committee discussed briefly different options in relation to documents under preparation at the ORGAM DG level to streamline the procedure for the revision of final monographs/list entries and the procedure for the management of proposals from interested parties for monographs and list entries. Once finalised, the documents will be released for public consultation.

### **Legislation and regulatory affairs**

In August 2007, comments raised by the Committee on the draft "[Report to the Council and the European Parliament on the experience acquired as a result of the application of the provisions of Chapter 2a of Directive 2001/83/EC \(introduced by Directive 2004/24/EC\)](#)" were sent to the European Commission as part of the public consultation that took place on the document.

The HMPC status report (EMEA/HMPC/187219/2006) presenting the Committee's experience with Directive 2004/24/EC since its entry into force was published in August 2007. The status report can be found at:

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

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