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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

Meeting report, 4-5 July 2007

The Committee on Herbal Medicinal Products met for the 18th time at the EMEA on 4-5 July 2007.

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

The 9th meeting of the permanent HMPC Working Party on Community Monographs and Community List (MLWP) took place on 2-4 July 2007.

The MLWP made significant progress on the scientific work related to Community herbal Monographs and Community list entries.

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

- final 'Community herbal monograph on *Pimpinella anisum* L., fructus' (EMEA/HMPC/137423/2006)
- final 'Community herbal monograph on *Pimpinella anisum* L., aetheroleum' (EMEA/HMPC/263273/2006)
- final 'Community herbal monograph on *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare*, fructus' (EMEA/HMPC/137428/2006)
- final 'Community herbal monograph on *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare*, aetheroleum' (EMEA/HMPC/263292/2006)
- final 'Community herbal monograph on *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung., fructus' (EMEA/HMPC/263293/2006)

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 prepared for publication and published in due course on the EMEA website at:

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

The MLWP also finalised the scientific work related to content and wording of the following proposed Community list entries which were subsequently endorsed by the HMPC:

- '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. *vulgare*, fructus' (EMEA/HMPC/428817/2006)

The Community list entries, together with their respective updated assessment reports will be transmitted to the European Commission for adoption (Comitology procedure), further to their formal adoption by the HMPC in September 2007.

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

- draft 'Community herbal monograph on *Eleutherococcus senticosus* (Rupr. et Maxim.) Maxim., radix' (EMEA/HMPC/244569/2006)

- draft 'Community list entry on *Eleutherococcus senticosus* (Rupr. et Maxim.) Maxim., radix' (EMEA/HMPC/83756/2007)
- draft 'Community herbal monograph on *Calendula officinalis* L., flos' (EMEA/HMPC/179281/2007)
- draft 'Community list entry on *Calendula officinalis* L., flos' (EMEA/HMPC/179283/2007)
- draft 'Community herbal monograph on *Humulus lupulus* L., flos' (EMEA/HMPC/513617/2006)
- draft 'Community herbal monograph on *Mentha x piperita* L., folium' (EMEA/HMPC/193909/2007)
- draft 'Community herbal monograph on *Rheum palmatum* L.; *Rheum officinale* Baillon, radix' (EMEA/HMPC/189624/2007)
- draft 'Community list entry on *Pimpinella anisum* L., fructus' (EMEA/HMPC/297757/2007)

The draft Community herbal monographs and draft Community list entries 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>

Further to the discussion on the scientific assessment of *Eleutherococcus senticosus*, the HMPC adopted the draft 'Reflection paper on the adaptogenic concept' (EMEA/HMPC/99116/2007) submitted by the Working Party: The draft reflection paper intends to clarify the term 'adaptogen' which is attributed to different herbal medicinal products, among them preparations deriving from *Eleutherococcus senticosus*. The HMPC presents also in this document its position on how to approach the assessment of adaptogenic herbal medicinal products.

The reflection paper has been released for public consultation until 15 October 2007 and can be found on the EMEA website at:

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

The MLWP made also significant progress on the scientific work relating to draft Community herbal monographs and assessment reports on *Urticae herba*, *Avenae herba*, *Rusci aculeati rhizoma*, *Sambuci flos*, *Salicis cortex* and *Solidaginis virgaureae herba*. An updated 'Overview of status of HMPC assessment work – July 2007' (EMEA/HMPC/278067/2006) can be found on the EMEA website at:

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

Appointment of rapporteurs

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

- *Crataegi fructus*
- *Crataegi folium cum flore*.

The next meeting of the MLWP is scheduled for 5-6 September 2007.

The HMPC adopted revised versions of the following reference documents for the preparation of entries to the Community list and related documents:

- Template for a Community list entry (EMEA/HMPC/439705/2006 Rev. 2)
- Final Procedure for the preparation of an entry to the Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products' (EMEA/HMPC/57137/2007)
- Guideline on the documentation to be submitted for inclusion into the 'Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products' (EMEA/HMPC/107399/2005 Rev.1)

The templates, procedure and guideline 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 13 June 2007.

The Committee was informed about the adoption of the following tripartite guidelines by the Committee for Medicinal Products for Human Use (CHMP) and the Committee for Medicinal Products for Veterinary Use (CVMP):

- final '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)

The final guideline together with an overview of comments received during the consultation period will be available on the EMEA website at:

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

The draft 'Guideline on quality of combination herbal medicinal products/traditional herbal medicinal products' (EMEA/HMPC/214869/2006), adopted by the HMPC at its 8 May 2007 meeting, was adopted by the joint CHMP/CVMP Quality Working Party and subsequently by the CHMP and the CVMP.

The draft guideline will be prepared for publication and will be released for public consultation until 15 October 2007 on the EMEA website at:

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

Legislation and regulatory affairs

The Committee noted 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 \(introduced by Directive 2004/24/EC\)](#)" which has been released by the European Commission for public consultation until 10 August 2007.

The report was prepared by the European Commission taking into account the contribution provided by the HMPC in its status report of 31 October 2006 (EMEA/HMPC/187219/2006), in which the Committee's experience with Directive 2004/24/EC since its entry into force was presented (for background information see [HMPC meeting report October 2006](#)).

Other relevant information

In the context of the co-ordination with the CHMP, the Committee nominated Steffen Bager (HMPC member from Denmark) as the HMPC permanent observer to the EMEA/CHMP Working Group with Healthcare professionals' organisations (HCPWG).

The HMPC observer will report on and contribute to the areas where the HCPWG's future work is relevant to the Committee's remit.

For further information, please contact:

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