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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

Meeting report, 25-26 October 2006

The Committee on Herbal Medicinal Products met for the 14th time at the EMEA offices on 25-26 October 2006.

The HMPC welcomed the following new observers to the Committee: Josipa Kvek from Croatia, Meral Gündogan and Mehtap Varel from Turkey.

On invitation from the EMEA Human Scientific Committees Working Party with patients' and consumers' Organisation (PCWP), the HMPC nominated Thorbjorg Kjartansdottir as its representative to the Working Party. On behalf of the HMPC, Thorbjorg Kjartansdottir will attend the meetings of the PCWP on a regular basis, the first one taking place on 8 December 2006.

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

The 5th meeting of the permanent HMPC Working Party on Community Monographs and Community List (MLWP) was held on 23-25 October 2006.

The HMPC adopted the following document submitted by the Working Party:

- draft 'Concept paper on the development of a guideline on the assessment of genotoxic constituents in herbal substances/preparations' (EMEA/HMPC/413271/2006).

The draft concept paper identifies the need to develop, in addition to the existing guideline¹, a more specific document for the practical interpretation and implementation of genotoxicity testing, hazard identification and risk assessment of herbal medicinal products.

The draft concept paper is released for public consultation until 28 February 2007 and can be found on the EMEA website at:

<http://www.emea.europa.eu/pdfs/human/hmpc/41327106en.pdf>

The HMPC endorsed the following draft Community herbal monographs and draft entries to the 'list of herbal substances, preparations and combination thereof for use in traditional herbal medicinal products', which are released for public consultation until 28 February 2007:

- draft 'Community herbal monograph on *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare*, fructus' (EMEA/HMPC/137428/2006)
- draft 'Community herbal monograph on *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare*, aetheroleum' (EMEA/HMPC/263292/2006)
- draft 'Community herbal monograph on *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce*, fructus' (EMEA/HMPC/263293/2006)

¹ Guideline on Non-Clinical Documentation for Herbal Medicinal Products in Applications for Marketing Authorisation (Bibliographical and Mixed Applications) and in Applications for Simplified Registration (EMEA/HMPC/32116/05): adopted by HMPC in July 2006

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

The draft Community herbal monographs and Community list entries together with a draft list of bibliographic references used during the assessment can be found respectively at:

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

and

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

The MLWP also made significant progress on the scientific work related to draft Community herbal monographs and assessment reports for *Echinacea purpureae* herba, *Primulae radix*, *Thymi herba*, *Passiflorae herba*, *Harpagophyti radix* and *Eleutherococci radix*. Further discussions are scheduled to take place during the January 2007 MLWP meeting.

The next meeting of the MLWP is scheduled for 9-10 January 2007.

Appointment of Rapporteurs

A further Rapporteur appointment was made for the preparation of draft monographs/list entries for *Hyperici herba*.

An updated overview of the status of HMPC assessment work is provided in the document:

- 'Status of scheduled HMPC assessment work October 2006' (EMEA/HMPC/278067/2006)

The document can be found on the EMEA website at:

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

Report from the Organisational Matters Drafting Group

A meeting of the Organisational Matters Drafting Group was held on 3 October 2006, where, further to end of the consultation period, the following document was agreed on, submitted to and subsequently adopted by the HMPC:

- final 'Procedure for calls for scientific data for use in HMPC assessment work' (EMEA/HMPC/1004/2006)

The final document as well as an overview of comments received during the consultation period can be found on the EMEA website at:

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

Following to the end of the consultation period the HMPC held further discussions on the 'Assessment report template for the development of Community monographs and for inclusion of herbal substance(s), preparation(s) and combinations thereof in the list' (EMEA/HMPC/41892/2005). The HMPC identified the need to further modify the template to address comments received, also taking into account the experience gained so far by Rapporteurs in using the template. A new draft document is expected to be completed during the drafting group's next meeting and to be submitted for adoption to the HMPC in January 2007.

The next meeting of the Organisational Matters Drafting Group is scheduled for 5 December 2006.

Report from the Quality Drafting Group

A meeting of the Quality Drafting Group was held on 4 October 2006.

Further to the end of the consultation period, the following final document was submitted to and subsequently adopted by the HMPC:

- final 'Reflection paper on the use of fumigants' (EMEA/HMPC/125562/2005)

The document can be found on the EMEA website at:

<http://www.emea.europa.eu/pdfs/human/hmhc/12556205en.pdf>

No comments were received on the draft reflection paper during the consultation period.

During the meeting on 4 October 2006 the drafting group made significant progress on the development of the draft 'Guideline on quality of combination herbal medicinal products/traditional herbal medicinal products'. The HMPC endorsed the general criteria used by the drafting group to develop the guideline and requested the group to further elaborate such a guideline at the next meeting.

The next meeting of the Quality Drafting Group is scheduled for 6 December 2006.

Legislation and regulatory affairs

A discussion was held on a draft report presenting the Committee's experience with Directive 2004/24/EC since its entry into force. The draft report, which will be presented to the EMEA Management Board in December 2006, is the Committee's contribution to the European Commission report on the application of the provisions of Chapter 2a (specific provisions applicable to herbal medicinal products) of Directive 2001/83/EC as amended by Directive 2004/24/EC as regards traditional herbal medicinal products.

Other relevant information

In the context of a safety evaluation of products containing *Angelica archangelica* (see HMPC meeting report July 2006) the Committee drafted and adopted the following document for release for public consultation until 28 February 2007:

- Draft 'reflection paper on the risk associated with furocoumarins contained in preparations of *Angelica archangelica* L.' (EMEA/HMPC/317913/2006)

To ensure co-ordination with the CHMP, the draft reflection paper will be distributed to the Safety Working Party (SWP) prior to publication.

When available the document will be published on the EMEA website at:

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

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