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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

Meeting report, 7 September 2006

The Committee on Herbal Medicinal Products met for the 13th time at the EMEA offices on 7 September 2006.

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

The 4th meeting of the permanent HMPC Working Party on Community Monographs and Community List (MLWP) was held on 5-6 September 2006.

The Rapporteur presented to the MLWP a consolidated version of the

- 'Guideline on the assessment of clinical safety and efficacy in the preparation of Community herbal monographs for well-established and of Community herbal monographs /entries to the Community lists for traditional herbal medicinal products / substances / preparations' (EMEA/HMPC/104613/2005)

The consolidated version incorporates comments received during the consultation period. The HMPC subsequently adopted the final guideline together with an overview of comments received. Both documents can be found on the EMEA website at:

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

After coordination with the CHMP the following HMPC guideline, adopted in July 2006, is now available on the EMEA website together with an overview of comments received during the consultation period:

- '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/32116/2005)

The documents can be found at: <http://www.emea.europa.eu/htms/human/hmhc/hmhcguide.htm>

The MLWP made significant progress in the area of Community herbal monographs. The following final documents were adopted by the HMPC further to recommendations from the MLWP:

- 'Community herbal monograph on *Cassia senna* L., fructus / *Cassia angustifolia* VAHL, fructus (EMEA/HMPC/51871/2005)
- 'Community herbal monograph on *Cassia senna* L., folium / *Cassia angustifolia* VAHL, folium (EMEA/HMPC/51869/2005)

- 'Community herbal monograph on *Aloe barbadensis* Miller / Community herbal monograph on *Aloe* (various species, mainly *Aloe ferox* Miller and its hybrids) (EMEA/HMPC/76310/2006)
- 'Community herbal monograph on *Rhamnus frangula* L., cortex (EMEA/HMPC/76307/2006)

In addition, the MLWP had a discussion on the responses to general comments received during consultation periods on draft Community herbal monographs and/or entries to the Community list. The following document was adopted by the HMPC, further to recommendations from the MLWP:

- 'Response document to general comments received on draft Community herbal monographs / entries to the Community list (EMEA/HMPC/160937/2006)

It is expected that the document will be continuously updated, reflecting future comments that address general aspects of Community herbal monographs.

The final Community herbal monographs, as well as their respective assessment report and overview of comments received during the consultation period, will be prepared for publication and, when available, published together on the EMEA

On recommendation of the MLWP, the HMPC also adopted the following draft Community herbal monographs for release for public consultation:

- 'Community herbal monograph on *Pimpinella anisum* L., fructus' (EMEA/HMPC/137423/2006)
- 'Community herbal monograph on *Pimpinella anisum* L., aetheroleum' (EMEA/HMPC/263273/2006)

The documents are released for consultation until 15 January 2007 and can be found at: <http://www.emea.eu.int/htms/human/hmpc/hmpcmonographs.htm>

The HMPC decided to attach a draft list of references used for the drafting of the monographs with the view to facilitating comments during public consultation and to avoiding duplications in submission of supporting literature.

Please note, that a template for providing comments to Community herbal monographs is now available at the EMEA website. <http://www.emea.eu.int/htms/human/hmpc/hmpcmonographs.htm>

The next meeting of the MLWP is scheduled for 23-25 October 2006.

Appointment of Rapporteurs

Further Rapporteur appointments were made for the following assessment work relating to establishment of Community herbal monographs / entries to the Community list:

- Hippocastani semen
- Althaeae radix
- Cimicifugae rhizoma

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

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

The document can be found on the EMEA website at:
<http://www.emea.eu.int/hums/human/hmpc/hmpcmonographs.htm>

Report from the Organisational Matters Drafting Group

A meeting of the Organisational Matters Drafting Group was held on 5 September 2006. The following final guidance document was submitted to and subsequently adopted by the HMPC:

- 'Guidance on documentation to be provided by Member States and Applicants/MAHs in support of a Simplified Registration Referral under Articles 16c(1)c and 16c(4) (EMEA/HMPC/431129/2005

The document can be found on the EMEA website at:
<http://www.emea.europa.eu/hums/general/direct/legislation/legislationherbal.htm>

No comments were received on the draft guideline during the consultation period.

The next meeting of the Organisational Matters Drafting Group is scheduled for 3 October 2006.

Legislation and regulatory affairs

The HMPC discussed a draft document with the Committee's contribution to the European Commission's report to the European Parliament and to the Council concerning the application of the provisions of Chapter 2a (specific provisions applicable to herbal medicinal products) of Directive 2001/83/EC as amended. The Committee will further discuss at its next meeting the experience with the Directive since its entry into force.

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