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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

Meeting report, 8-9 March 2006

The Committee on Herbal Medicinal Products met for the 10th time at the EMEA offices on 8-9 March 2006.

With a view to appointing an additional co-opted member, the Committee had launched a call for experts in traditional herbal medicinal products among interested parties to the HMPC representing scientific and academic societies in January 2006. The HMPC received a number of CVs from experts submitted by interested parties. Following evaluation of qualifications and any conflicts of interest, the Committee will discuss possible candidates at the meeting scheduled for 11-12 May 2006.

On invitation from the Committee for Medicinal Products for Human Use (CHMP), the HMPC nominated among its members 2 observers to the CHMP Safety Working Party (SWP). The nominated members are Prof. Olavi Pelkonen and Prof. Gert Laekeman, who will attend the SWP meeting on an alternate basis with a view to facilitate coordination between the two scientific committees.

On the second day of the meeting, the HMPC warmly welcomed Prof. Margarida Oliveira, University of Lisbon, who in her capacity as European expert gave a lecture on the production of pharmaceutical proteins in transgenic plants.

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

The first meeting of the permanent HMPC Working Party on Community Monographs and Community List (MLWP) was held on 7-8 March 2006. The MLWP Chairman, Dr Heribert Pittner, informed the HMPC that the meeting was conducted in a very positive and productive atmosphere.

A part of the working party's meeting was dedicated to establish the organisational framework. In this context the HMPC adopted the following documents:

- MLWP Rules of Procedure & Mandate (EMEA/HMPC/379153/2005)
- MLWP Work Programme 2006-2007 (EMEA/HMPC/60552/2006)

The documents are available at on the EMEA website at:

http://www.emea.eu.int/htms/general/contacts/HMPC/HMPC_MLWP.html

The working party also made good progress on the scientific work related to Community herbal monographs and guidance documents. The HMPC adopted for release for public consultation the following documents submitted by the MLWP:

- Barbados aloes (*Aloe barbadensis*) and Cape aloes (*Aloe capensis*)
Draft Community herbal monograph (EMEA/HMPC/76310/2006)
- Frangula bark (*Frangulae cortex*)
Draft Community herbal monograph (EMEA/HMPC/76307/2006)

The draft monographs will be for consultation until the end of June 2006 and can be found on the EMEA website at: <http://www.emea.eu.int/htms/human/hmpc/hmpcmonographs.htm>

The HMPC also adopted the following document submitted by the MLWP:

- Final 'Public statement on chamomilla containing herbal medicinal products'
(EMEA/HMPC/138309/2005)

The document, together with an overview of comments received during the consultation period, is available on the EMEA website at: <http://www.emea.eu.int/htms/human/hmpc/hmpcguide.htm>

The MLWP reviewed the comments received during the external consultation period for the draft Community herbal monographs on Ispaghula husk, Ispaghula seed, Linseed, Psyllium seed and Valerian root as well as draft entries to the Community list for Linseed and Valerian root. Discussions on the final versions of these documents are scheduled to take place during the next MLWP meeting.

In addition, the MLWP made progress on the development of a guidance document on assessment of clinical safety and efficacy in Community herbal monographs and entries to the Community list. Further discussion will take place during the next MLWP meeting.

The next meeting of the MLWP is scheduled for 10-11 May 2006.

Report from the Organisational Matters Drafting Group

The HMPC adopted for release for public consultation the following document submitted by the drafting group:

- Draft 'Guidance on documentation to be provided in support of a Referral by a Member State'
(EMEA/HMPC/431129/2005)

The HMPC adopted the following document submitted by the drafting group:

- Final 'Concept paper on CTD for traditional herbal medicinal products'
(EMEA/HMPC/261344/2005)

The documents can be found on the EMEA website at:

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

In addition, the drafting group held final discussions on the following documents that will be published on the EMEA website after adoption by HMPC through written procedure in March 2006:

- Final 'Procedure for the preparation of Community monographs for traditional herbal medicinal products' (EMEA/HMPC/182320/2005)
- Final 'Procedure for the preparation of Community monographs for herbal medicinal products with well-established medicinal use' (EMEA/HMPC/182352/2005)
- Revised final 'Template for a Community Herbal Monograph' (EMEA/HMPC/384650/2005)

When released, the documents will be available on the EMEA website at:
<http://www.emea.eu.int/htms/general/direct/legislation/legislationherbal.htm>

During their meeting in February 2006, the drafting group held further discussions on the procedure for making a general call for submission of scientific material for use in HMPC assessment work by interested parties. In addition, the group made progress on the development of an assessment report template for use in the assessment work related to establishment of Community herbal monographs and entries to the Community list. Both draft documents are expected to be completed during the drafting group's next meeting, and to be submitted to the HMPC meeting in May 2006 for adoption for release for consultation.

The next meeting of the Organisational Matters Drafting Group is scheduled for 4 April 2006.

Report from the Quality Drafting Group

The HMPC adopted for release for public consultation the following documents submitted by the drafting group:

- Draft 'Guideline on the declaration of herbal substances/preparations in finished herbal medicinal products/traditional herbal medicinal products in the SPC' (EMEA/HMPC/287539/2005)
- Draft 'Concept paper on the quality of combination herbal medicinal products' (EMEA/HMPC/58222/2006)

Prior to publication, the documents will be subject to coordination with other EMEA scientific groups. When released, the documents will be available on the EMEA website at:
<http://www.emea.eu.int/htms/human/hmhc/hmhcguide.htm>

Following a discussion of the drafting group on fumigants and herbal substances, it was agreed that a general HMPC statement on the use of fumigants should be prepared. A first draft is expected for discussion at the group's next meeting.

The next meeting of the Quality Drafting Group is scheduled for 5 April 2006.

Interaction with interested parties

The HMPC reviewed a compiled list of priorities for assessment work as submitted by interested parties during the fourth quarter of 2005. The Committee acknowledged that it is important to take into consideration the cumulated priorities as stated by interested parties to the HMPC, and the Committee will do so when planning forthcoming assessment in relation to Community herbal monographs and entries to the Community list.

It should be noted that the annex to the Meeting Report from the HMPC meeting in November 2005, listing 40 plants identified for commencement of assessment work in 2006, is in principle still valid. No major revision of this list is currently foreseen.

For further information, please contact:

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