



COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

Meeting report, 11-12 May 2006

The Committee on Herbal Medicinal Products met for the 11th time at the EMEA offices on 11-12 May 2006.

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

The 2nd meeting of the permanent HMPC Working Party on Community Monographs and Community List (MLWP) was held on 10-11 May 2006.

A significant part of the working party's meeting was dedicated to discussions on a draft document providing guidance on the assessment of clinical safety and efficacy in Community herbal monographs and entries to the Community list.

The draft document was subsequently adopted by the HMPC for release for public consultation:

- HMPC guideline on the assessment of clinical safety and efficacy in monographs for well-established and monographs/list entries for traditional herbal medicinal products (EMEA/HMPC/104613/2005)

The document is released for consultation until 15 August 2006 and can be found on the EMEA website at: <http://www.emea.eu.int/hums/human/hmpc/hmpcguide.htm>

The MLWP had a detailed discussion on the comments submitted to the draft HMPC '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 Rapporteur will address the comments and it is expected that the document will be finalised at the next meeting.

The MLWP further reviewed and discussed the comments received during the external consultation period for the draft Community herbal monograph and list entry on Valerian Root.

The discussions on the draft Community herbal monographs on Ispaghula husk, Ispaghula seed, Linseed, Psyllium seed as well as draft entry to the Community list on Linseed were postponed to the next MLWP meeting. The reason for this is a general lack of accompanying supporting evidence on suggested claims, additional preparations and other issues raised in the comments received from external parties. The main part of the comments cannot be fully assessed and therefore in principle not be taken into account in the finalisation of the draft documents.

However, as the HMPC and its working party remain committed to maintain a constructive dialogue with interested parties, the MLWP decided to postpone the finalisation of these draft documents, including the draft monograph and list entry for Valerian root. This will allow time for the interested

parties to submit supporting documentation that would substantiate comments made and enable the Rapporteurs to fully assess them.

In addition, the working party had a first discussion on assessment work related to the draft monographs on Fennel and Aniseed. It is expected that the draft monographs will be released for public consultation after the next MLWP meeting.

The next meeting of the MLWP is scheduled for 11-12 July 2006.

Report from the Organisational Matters Drafting Group

A meeting of the Organisational Matters Drafting Group was held on 4 April 2006, where a number of documents were agreed on and submitted to the HMPC meeting held 11-12 May 2006.

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

- HMPC assessment report template for the preparation of Community herbal monographs and for the inclusions of herbal substances, preparations and combinations thereof in the List (EMEA/HMPC/418902/2005)
- Procedure for calls for scientific data for use in HMPC assessment work (EMEA/HMPC/1004/2006)

The documents are released for consultation until 15 August 2006 and can be found on the EMEA website at: <http://www.emea.eu.int/htmls/general/direct/legislation/legislationherbal.htm>

The HMPC adopted the following document for which public consultation ended on 21 April 2005:

- Public statement on HMPC interpretation of 'external use' (EMEA/HMPC/31897/2006)

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

In addition, following the 8-9 March 2006 HMPC meeting, the Committee adopted the following document via written procedure:

- Final 'Template for a Community Herbal Monograph' (EMEA/HMPC/107436/2005 Rev.1)

The document has now been published and can be found on the EMEA website at:
<http://www.emea.eu.int/htmls/general/direct/legislation/legislationherbal.htm>

During the meeting in April 2006, the drafting group furthermore had a preliminary discussion on a procedure for handling third parties' proposals for inclusion of plants on the HMPC's list of priorities for assessment work. The group is expected to further elaborate such a procedure at the next meeting.

The next meeting of the Organisational Matters Drafting Group is scheduled for 14 June 2006.

Report from the Quality Drafting Group

A meeting of the Quality Drafting Group was held on 5 April 2006.

During the meeting a draft public statement on fumigants and herbal substances was discussed. A draft version of the document is expected for transmission to HMPC at the group's next meeting. On a request from the HMPC the group also had a discussion in relation to phospholipids from soya

("lecithins") as active substance in traditional herbal medicinal products. The view of the HMPC in this matter is available in a newly published Q&A document on technical issues (cf. section on 'organisational matters' below).

The following documents adopted at the 8-9 March 2006 HMPC for release for public consultation are for consultation in the joint CHMP/CVMP Quality Working Party meeting scheduled for 22-24 May 2006:

- 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)

The documents will subsequently be subject to coordination with other EMEA scientific groups and when released be available on the EMEA website at:

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

The next meeting of the Quality Drafting Group is scheduled for 13 June 2006.

Pharmacovigilance of herbal medicinal products

On the second day of the HMPC meeting, the Committee welcomed Dr Bob Allkin and Dr Alan Paton from the Kew Royal Botanical Gardens in London who gave a presentation on standardised scientific plant names with a particular focus on the importance for pharmacovigilance and the drug regulatory environment.

Organisational matters

With a view to appointing an additional co-opted member the HMPC had launched a call for experts in traditional herbal medicinal products among interested parties to the Committee representing scientific and academic societies in January 2006. A short list of four candidates had been prepared based on an initial evaluation of qualifications and any possible conflicts of interest in relation to the work of the HMPC.

Three of the short listed experts had accepted an invitation to present their professional career and involvement in the field of herbal medicines. The selected candidates represented expertise in traditional European herbal medicine, Ayurvedic medicine and Anthroposophic medicine. Although all candidates demonstrated excellent skills in each their field of expertise none of them obtained the number of votes necessary for election as co-opted member during the subsequent voting procedure.

The HMPC agreed that this outcome concludes the search for a fifth co-opted member during the current mandate. However, the Committee would like to thank the interested parties that have provided support in relation to identification of possible candidates for co-opted membership in traditional herbal medicines.

On invitation from the Committee for Medicinal Products for Human Use (CHMP), the HMPC nominated among its members an observer to the CHMP Paediatrics Working Party (PEG). The nominated member is Prof. Kurt Widhalm, who will attend forthcoming PEG meetings with a view to facilitate coordination between the two scientific committees.

To further improve transparency in the work of the Committee it was decided to compile in a single document all technical/scientific questions submitted to the HMPC. The document will provide a rolling overview of 'Q&As' and is intended as a means to share information on clarifications provided by HMPC to interested parties. The document is published on the EMEA website and can be found at: <http://www.emea.eu.int/htms/human/hmpc/hmpcguide.htm>

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