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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

**Meeting report, 12-13 July 2006**

The Committee on Herbal Medicinal Products met for the 12<sup>th</sup> time at the EMEA offices on 12-13 July 2006.

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

The 3<sup>rd</sup> meeting of the permanent HMPC Working Party on Community Monographs and Community List (MLWP) was held on 11-12 July 2006.

The Rapporteur presented to the MLWP a consolidated draft version of the '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), incorporating comments received during the consultation period.

The HMPC subsequently adopted the document:

- final '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)

To ensure co-ordination with the CHMP, the adopted guideline will be distributed to the Safety Working Party (SWP) and to the CHMP prior to publication.

When available, the guideline and an overview of comments received during the consultation period will be published on the EMEA website at:

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

The MLWP also made significant progress on the scientific work related to Community herbal monographs. The following final documents were adopted by the HMPC, further to recommendations from the MLWP:

- final 'Community herbal monograph on *Valeriana officinalis* L., radix (valerian root)' (EMEA/HMPC/340719/2005)
- final 'Community herbal monograph on *Linum usitatissimum* L., semen (linseed)' (EMEA/HMPC/340849/2005)
- final 'Community herbal monograph on *Plantago ovata* Forssk., seminis tegumentum (ispaghula husk)' (EMEA/HMPC/340857/2005)
- final 'Community herbal monograph on *Plantago ovata* Forssk., semen (ispaghula seed)' (EMEA/HMPC/340861/2005)
- final 'Community herbal monograph on *Plantago afra* L., and *Plantago indica* L., semen (psyllium seed)' (EMEA/HMPC/340865/2005)

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 website at:

<http://www.emea.eu.int/hums/human/hmpc/hmpcmonographs.htm>

The MLWP held further discussions on the draft entries to the 'list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products' (List entries) for *Valeriana officinalis* L., radix (Valerian root) and *Linum usitatissimum* L., semen. The working party identified issues concerning availability and quality of genotoxicity data for these and other herbal substances. The HMPC will at forthcoming meetings further reflect on how to resolve these issues.

In the context of the organisational framework of the MLWP, the HMPC adopted the following document:

- MLWP Work Programme 2007 (EMEA/HMPC/152126/2006)

The document can be found on the EMEA website at:

<http://www.emea.eu.int/pdfs/human/hmpc/mlwp/15212606en.pdf>

The MLWP faces challenges with available resources and time constraints to carry out its tasks, which are expected to enhance European harmonisation for well-established and traditional herbal medicinal products and to facilitate access of such products to the market. In order to overcome these difficulties it was proposed to prolong the duration of the MLWP meeting by a further half-day. The HMPC endorsed the working party proposal.

A revised MLWP meeting schedule will be agreed in the context of the EMEA budget for 2007 and, when available, published on the EMEA website at:

<http://www.emea.eu.int/hums/human/hmpc/hmpcmeet.htm>

The next meeting of the MLWP is scheduled for 5-6 September 2006.

### **Appointment of Rapporteurs and assessment of priorities**

Further Rapporteur appointments were made for the preparation of draft monographs/List entries for *Avena sativa*, *Cynarae folium*, *Echinaceae angustifoliae radix*, *Echinaceae pallidae radix*, *Echinaceae purpureae radix*, *Equiseti herba*, *Primulae veris flos* and *Rusci aculeati rhizoma*.

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

- 'Status of scheduled HMPC assessment work July 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>

### **MLWP meeting with interested parties held on 11 July 2006**

A meeting with interested parties was held on 11 July 2006 with representatives from AESGP<sup>1</sup> and ESCOP<sup>2</sup>, some of the main contributors to the MLWP work. The purpose of the meeting was for the MLWP and HMPC to continue to update interested parties regarding key achievements. In addition, the interested parties were invited to express their views on the Committee's work and their expectations for the Committee's deliverables in the future. There was a good exchange of views and information as well as discussion on the current priorities of the HMPC and potential copyright issues related to bibliographic references used as supportive information for the assessment work. Both the

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<sup>1</sup> Association of the European Self-Medication Industry (AESGP)

<sup>2</sup> European Scientific Co-operative on Phytotherapy (ESCOP)

Committee and the participants expressed their appreciation for this opportunity to exchange information and viewpoints.

### **Report from the Organisational Matters Drafting Group**

A meeting of the Organisational Matters Drafting Group was held on 14 June 2006, where a number of documents were agreed on and submitted to the HMPC meeting held 12-13 July 2006.

The HMPC adopted revised versions of the following documents submitted by the drafting group:

- 'Structure of the List of herbal substances, preparations and combinations thereof' (EMEA/HMPC/100824/2005 Rev.1)
- 'Template for a Community herbal monograph' (EMEA/HMPC/107436/2005 Rev.2)
- 'Procedure for the preparation of Community monographs for traditional herbal medicinal products' (EMEA/HMPC/182320/2005 Rev.1)
- 'Procedure for the preparation of Community monographs for herbal medicinal products with well-established medicinal use' (EMEA/HMPC/182352/2005 Rev.1)

The revised documents can be found on the EMEA website at:

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

The Organisational Matters Drafting Group made progress in the establishment of a framework for the performance of the following tasks arising from Article 16c(1) and (4) of Directive 2001/83/EC as amended:

- The duty to provide Member States upon request with opinions on the adequacy of the evidence of the long-standing use of a traditional herbal medicinal product.
- The preparation of opinions on products, which have been used in the Community for less than 15 years but are otherwise eligible for traditional use registration and are referred to the Committee by a Member State.

Further to a request for clarification to the European Commission on the procedure to follow when referring to these provisions and moreover, further to the HMPC proposal to the Notice to Applicants Group, a revised version of Chapter 3 of Volume 2A of the Notice to Applicants will be released by the European Commission.

During the meeting in June 2006, the drafting group furthermore had a preliminary discussion on a guideline on how to present the application for a traditional herbal medicinal product in the Common Technical Document (CTD) format; the current structure and content of Modules 2, 4, 5 were discussed regarding their applicability in the context of dossier content for herbal medicinal products. The group is expected to further elaborate such a guideline at the next meeting.

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

### **Report from the Quality Drafting Group**

A meeting of the Quality Drafting Group was held on 13 June 2006.

The HMPC adopted for release for public consultation until the 1<sup>st</sup> October 2006:

- draft 'Reflection paper on the use of fumigants' (EMEA/HMPC/125562/2006)

The draft document can be found on the EMEA website at:

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

In addition, the Quality Drafting Group had a preliminary discussion on the draft 'Guideline on quality of combination herbal medicinal products/traditional herbal medicinal products' (EMEA/HMPC/214869/2006). A revised draft version of the document, taking into account comments received, is expected for transmission to the HMPC at the group's next meeting.

The next meeting of the Quality Drafting Group is scheduled for 4 October 2006.

### **Pharmacovigilance of herbal medicinal products**

The HMPC discussed and adopted the 'Assessment of case reports connected to herbal medicinal products containing *Cimicifugae racemosae* rhizoma (Black Cohosh, root)', which was published on 18 July 2006 as an annex to the 'EMEA public statement on herbal medicinal products containing *Cimicifugae racemosae* rhizoma (Black Cohosh, root)' (EMEA/269259/2006).

The public statement can be found on the EMEA website at:  
<http://www.emea.eu.int/pdfs/human/hmpc/26925906en.pdf>

In addition, the Committee discussed a draft version of the HMPC assessment report on safety evaluation of *Angelica archangelica* L., which will be further reviewed at the next meeting. The HMPC endorsed the proposal to prepare a concept paper on the assessment of genotoxic constituents in herbal preparations.

### **Legislation and regulatory affairs**

The Committee discussed a number of legal and regulatory topics, in particular the provision of Article 16i of Directive 2004/24/EC regarding the European Commission 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 HMPC is expected to contribute to the above-mentioned document, reporting to the Commission the Committee's experience with the Directive since its entry into force.

In accordance with Article 16i of the Directive, the report shall be submitted by the European Commission to the European Parliament and to the Council before 30 April 2007.

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