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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

Meeting report, 31 October 2007

The Committee on Herbal Medicinal Products met for the 20th time at the EMEA on 31 October 2007.

This October plenary meeting saw the election of the [Chair and Vice-chair of the Committee](#). Dr K. Keller was re-elected as Chair and Dr I. Chinou as the new vice-Chair, both with a 3-year mandate that started on 31 October 2007.

Upon recommendation from the HMPC Working Party on Community Monographs and Community List (MLWP), the HMPC adopted the following Community herbal monographs and related documents:

Final Community herbal monographs:

- final 'Community herbal monograph on *Melissa officinalis* L., folium' (EMEA/HMPC/5341/2007)
- final 'Community herbal monograph on *Mentha x piperita* L., aetheroleum' (EMEA/HMPC/349466/2006)
- final 'Community herbal monograph on *Thymus vulgaris* L. and *Thymus zygis* L., herba' (EMEA/HMPC/234113/2006)*
- final 'Community herbal monograph on *Rheum palmatum* L. and *Rheum officinale* Baillon, radix' (EMEA/HMPC/189624/2007)

The final Community herbal monographs as well as their respective HMPC opinions, assessment reports and overview of comments received during the consultation period, will be published in due course on the EMEA website at:

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

*The HMPC decided to prepare a separate monograph on Thymi aetheroleum and the essential oil has therefore been removed from the preparations covered by the final monograph on Thymi herba.

Draft Community herbal monographs, released for public consultation until 15 February 2008:

- draft 'Community herbal monograph on *Avena sativa* L., herba' (EMEA/HMPC/202966/2007)
- draft 'Community herbal monograph on *Avena sativa* L., fructus' (EMEA/HMPC/368600/2007)
- draft 'Community herbal monograph on *Solidago virgaurea* L., herba' (EMEA/HMPC/285758/2007)
- draft 'Community herbal monograph on *Equisetum arvense* L., herba' (EMEA/HMPC/394894/2007)
- draft 'Community herbal monograph on *Melilotus officinalis* (L.) LAM., herba' (EMEA/HMPC/354177/2007)
- draft 'Community herbal monograph on *Verbascum* sp., flos' (EMEA/HMPC/395213/2007)

The draft Community herbal monographs together with a draft list of references used during the assessment will be published in due course on the EMEA website at:

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

Appointment of Rapporteurs

The HMPC appointed Rapporteurs for the preparation of draft Community herbal monographs/Community list entries for *Oleae folium* and *Vitis viniferae folium*.

A Rapporteur was also appointed for the assessment of combinations of Valerian and Hops. This represents the second assessment of a fixed combination of two herbal substances, the first being assigned in September 2007 (see meeting report from the [September 2007 HMPC meeting](#)).

Reference documents for the preparation of Community herbal monographs and entries to the community list and related documents

The HMPC adopted a new 'Procedure on management of proposals submitted by interested parties for Community list entries and Community herbal monographs' (EMEA/HMPC/328575/2007) and the related 'Inventory of herbal substances for assessment work' (EMEA/HMPC/494079/2007).

This new document, prepared by ORGAM DG, describes the procedure followed by the HMPC and its secretariat when documentation is submitted by an interested party with a view to including a given herbal substance, preparation or combination in the priority list of herbal substances, preparations and combinations under assessment. In addition, the 'Inventory of herbal substances for assessment work' represents a transparent tool to monitor the progress achieved by the HMPC vis-à-vis its medium- to long-term assessment work.

The procedure will be released for public consultation until 15 February 2008. Both documents will be available at:

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

Scientific guidelines and related documents

Further to coordination with the SWP, the HMPC adopted a draft 'Guideline on the assessment of genotoxic constituents in herbal substances/herbal preparations' (EMEA/HMPC/104681/2007) which will be released for public consultation until 3 March 2008 and will be available at:

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

The guideline describes a general framework and practical approaches on how to test the potential genotoxicity of herbal substances/preparations and how to interpret the results. The stepwise approach described in the guideline represents a pragmatic approach to address both scientific aspects of genotoxicity testing and the special needs of herbal medicinal products within the current regulatory framework applicable for these products.

Further to the end of the consultation period, the HMPC adopted the final 'Reflection paper on the risk associated with furocoumarins contained in preparations of *Angelica archangelica* L.' (EMEA/HMPC/317913/2006). The revised version of the reflection paper takes into account comments received during the consultation period.

The final reflection paper, an overview of the general comments as well as all sets of comments received during the consultation period will be available at:

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

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

The 11th meeting of the MLWP took place on 29-30 October 2007.

In addition to the work that supported the adoption of the above-mentioned documents by the HMPC, the MLWP made significant progress on the scientific work relating to draft Community herbal monographs and assessment reports on *Betulae folium*, *Echinaceae purpureae herba* and *Harpagophyti radix*. An updated 'Overview of status of HMPC assessment work – October 2007' (EMEA/HMPC/278067/2006) will be published on the EMEA website at:

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

The next meeting of the MLWP is scheduled for 8-9 January 2008.

Report from the Quality Drafting Group (Quality DG)

The HMPC endorsed the Q DG proposal to develop guidance on declarations of herbal substances and herbal preparations in (traditional) herbal medicinal products in the package leaflet and labelling, in the form of an annex to the existing 'Guideline on declarations of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products in the SPC' ([EMEA/HMPC/CHMP/CVMP/287539/2005](http://emea.europa.eu/htms/general/direct/legislation/legislationherbal.htm)).

Once finalised, the document will be released for public consultation.

The HMPC adopted the final programme of a 'Training for quality assessors' scheduled for 7 December 2007 at the EMEA premises. The training will focus on emerging quality issues for herbal medicinal products, including control strategies and risk management for contaminants, mycotoxins and microbiological purity, fumigants, heavy metals, pesticides.

Report from the Drafting Group on organisational matters (ORGAM DG)

Further to the end of the consultation period, the HMPC discussed a revised version of the 'Guideline on the use of the CTD format in the preparation of a registration application for traditional herbal medicinal products' (EMEA/HMPC/71049/2007).

The revised version of the guideline takes into account comments made by HMPC members to improve the clarity of the document as to where certain information contained in dossier should be positioned in the CTD modules. Comments received during the consultation period will be addressed as soon as possible by the ORGAM DG.

When finalised, the guideline and an overview of comments will be published on the EMEA website at:

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

Legislation and regulatory affairs

In the context of the proposal launched by the European Commission for a future revision of the Variations Regulations, the HMPC will participate in the preparation of comments that the EMEA will present on the Commission position paper '[Better regulation of pharmaceuticals: towards a simpler, clearer and more flexible framework on Variations](#)'. The HMPC could provide specific additional comments later in the process of the Regulations revision.

Other relevant information

The HMPC accepted a proposal from the Association Européenne des Fabricants de Médicaments utilisés en Thérapeutique Anthroposophique (AEFMUTA) to organise a workshop on Anthroposophic medicine in the margin of the HMPC March 2008 meeting.

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