



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

08 April 2014
EMA/HMPC/171245/2014
Committee on Herbal Medicinal Products (HMPC)

HMPC meeting report on Community herbal monographs, guidelines and other activities

The 57th HMPC meeting, held on 24-25 March 2014

New nominations: Maria Stavrou as new member for Cyprus, Erika Svedlund as new alternate member for Sweden. The full composition of the HMPC can be found at:

http://www.ema.europa.eu/ema/index.jsp?curl=/pages/contacts/2010/02/people_listing_000006.jsp&mid=WC0b01ac0580028e7e

Final Community herbal monographs

Upon recommendation from the MLWP as a result of its January 2014 meeting, the HMPC adopted the following final Community herbal monographs and related documents:

- Community herbal monograph on Eucalypti aetheroleum, by consensus,
- Community herbal monograph on Ginseng radix, by majority vote,
- Community herbal monograph on Ononidis radix, by consensus.

The final Community herbal monographs as well as the HMPC opinion, assessment report and overview of comments received during the consultation period, will be published on the European Medicines Agency's website at:

http://www.ema.europa.eu/ema/index.jsp?curl=/pages/medicines/landing/herbal_search.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001fa1d

Revised Community herbal monographs

As a result of the 5-year systematic review, the HMPC adopted the following revised final Community herbal monographs and related documents:

- Community herbal monograph on Eleutherococci radix, by majority vote,
- Community herbal monograph on Passiflorae herba, by consensus.

Given the minor changes to the monographs, a public consultation was not considered necessary after careful assessment of new scientific data. The revised final Community herbal monographs as well as the HMPC opinion, modified assessment reports and lists of references will be published on the European Medicines Agency's website at:



http://www.ema.europa.eu/ema/index.jsp?curl=/pages/medicines/landing/herbal_search.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001fa1d

Other

Cancellation of assessment work

The HMPC endorsed the MLWP recommendation to cancel the assessment work for *Crataegi fructus* upon identification by the Rapporteur that there are no products on the market containing *Crataegi fructus* or preparations thereof as single active substance allowing to establish a monograph.

Drafting Group on Quality (DG Q)

The HMPC heard a report on the DG Q meeting held on 12-13 February 2014.

The group had continued its work on guidance as regards benzene in extracts and a mock-up module 3 as second appendix to the 'Guideline on the use of the CTD format in the preparation of a registration application for THMP' (EMA/HMPC/71049/2007). In addition to topics at the work programme the HMPC endorsed the work on a Q&A for herbal substances or preparations, which are covered by a Ph. Eur. monograph, but the monograph does not contain an assay.

The next meeting of the DG Q will be held on 10 April 2014.

Drafting Group on Organisational matters (DG ORGAM)

The HMPC heard a report on the DG ORGAM meeting held on 10 February 2014. The group had particularly focused on the finalisation of an improved template for the HMPC assessment report and a Questions & Answer document pointing to sources of (regulatory) guidance for traditional herbal medicinal products that could be particularly useful for applicants who are not familiar with the European framework such as for products from a 'non-European tradition'.

The HMPC adopted the 'Q & A on the EU framework for (traditional) herbal medicinal products, including those from a non-European tradition' (EMA/HMPC/402684/2013).

The question and answer document will be published at the EMA website at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000355.jsp&mid=WC0b01ac0580118a1d

The HMPC adopted a revision of the 'Template for Assessment report for the development of Community herbal monographs and Community list entries' (EMA/HMPC/814902/2005 Rev.4).

The HMPC adopted a revision of the 'Template for information exchange for the preparation of the assessment report supporting the establishment of Community monographs and Community list entries' (EMA/HMPC/137093/2006 Rev.1).

The documents will be available at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000212.jsp&mid=WC0b01ac058003380a#section5

The next meeting of the DG ORGAM is scheduled for 8 April 2014.

Report from the March 2014 Working Party on Community Monographs and Community List (MLWP)

The MLWP held its 48th meeting at the European Medicines Agency on 25 to 27 March 2014.

Revisions

The MLWP continued its work towards the revision of the monograph and/or list entry (and supporting documents) on Echinaceae purpureae herba, Menthae piperitae aetheroleum and Lupuli flos. The latter was transmitted for possible adoption by the HMPC in May, while the others were scheduled for another round of MLWP discussion.

Finalisation

The MLWP reviewed the comments received during the public consultation on the draft monographs on Arnicae flos, Fucus vesiculosus and Melaleucaea alternifoliae aetheroleum (M/LE). The documents for Arnicae flos and Fucus vesiculosus will be transmitted, after peer-review, to the HMPC for possible final adoption at the May 2014 meeting.

Drafts

The MLWP endorsed the monographs on Agrimoniae herba, Capsici fructus, Lichen islandicus, Matricariae flos & M. aetheroleum, and Pilosellae herba cum flore for early peer-review and transmission to the HMPC for possible release in May 2014 for public consultation. The working party continued its assessment of Allii sativi bulbus, Crataegi folium cum flore, Eschscholziae herba cum flore, and Sabalis serrulatae fructus. Rapporteurs for Glycine max and Picrorhizae kurroae rhizoma received input from the MLWP on specific questions at the start of the scientific assessment taking into account regulatory aspects and available market information.

The next meeting of the MLWP is scheduled for 6-8 May 2014.

Contact for further information

Anthony Humphreys
Head of Scientific Committee Support Department
Tel.: +44 (0)20 7418 8583
Fax: +44 (0)20 7523 7051
E-mail: hmpc.secretariat@ema.europa.eu