



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 May 2014
EMA/HMPC/292352/2014
Committee on Herbal Medicinal Products (HMPC)

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

The 58th HMPC meeting, held on 05-06 May 2014

The Committee re-elected Dr Marisa Delbò (IT) as the vice-Chair of the Monograph and List Working Party (MLWP), for a second 3-year mandate.

Final Community herbal monographs

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

- Community herbal monograph on Arnicae flos, by consensus
- Community herbal monograph on Fucus vesiculosus, by majority vote

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 monograph and related documents:

- Community herbal monograph on Lupuli flos, by majority vote

Given the minor changes to the monograph, a public consultation was not considered necessary after careful assessment. The revised final Community herbal monograph as well as the HMPC opinion and modified assessment report 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



Draft Community herbal monographs

Upon recommendation from the MLWP, the HMPC adopted the following draft Community herbal monograph for public consultation until 31 August 2014:

- Community herbal monograph on Agrimoniae herba, by consensus
- Community herbal monograph on Lichen islandicus, by consensus

The monographs together with the draft supporting documents 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

Public statement on herbal substances for which currently no detailed assessment will be performed

The HMPC adopted a Public statement on herbal substances containing constituents associated with safety concerns (EMA/HMPC/682247/2013) listing non-exhaustively some herbal substances that have been proposed but are currently not considered a priority for detailed assessments because it is foreseeable that a Community herbal monograph cannot be established.

The Public statement will be published here (Assessment - proposals, prioritisation and status):

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

Drafting Group on Quality (DG Q)

The HMPC heard a report on the DG Q meeting held on 10 April 2014. The next meeting of the DG Q will be held on 18 June 2014.

Drafting Group on Organisational matters (DG ORGAM)

The DG ORGAM meeting 08 April 2014 had been postponed to 13 May 2014.

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

The MLWP held its 49th meeting at the European Medicines Agency on 06 to 08 May 2014.

Revisions

The MLWP continued its work towards the revision of the monograph (and supporting documents) on Echinaceae purpureae herba.

Finalisation

No comments have been received on draft monographs for Sisymbrii officinalis herba and Rosae flos. The documents will be finalised by the Rapporteurs and transmitted, after peer-review, to the HMPC for possible final adoption at the July 2014 meeting.

Drafts

The MLWP endorsed the monographs on *Pilosellae herba cum flore* (re-discussed upon request by the HMPC) and *Eschscholziae herba cum flore* for early peer-review and transmission to the HMPC for possible release in July 2014 for public consultation. The working party further agreed on a draft public statement on *Picrorhizae kurroae rhizoma* to stimulate submission of data that may allow further assessment towards a monograph.

The working party continued its assessment of *Carvi aetheroleum*, *Carvi fructus*, *Crataegi folium cum flore*, *Myrtilli fructus*, *Pruni africanae cortex*, *Sabalis serrulatae fructus* and *Silybi marianae fructus*. A first presentation/discussion took place for *Uncariae tomentosae cortex*.

The next meeting of the MLWP is scheduled for 1-3 July 2014.

Hearing with association representing the self-medication industry

The MLWP held a hearing with representatives from AESGP on 06 May. AESGP welcomed the further improved transparency via publication of agendas and minutes as very useful for industry. Several topics related to the establishment of Community herbal monographs including the extent of information given in some sections of traditional use monographs or the revision procedure. Furthermore ongoing issues as regards data availability (use in paediatric population, genotoxicity) were discussed as well as topics potentially related to the use of Community monographs and HMPC assessments such as information on MRP/DCP procedures for herbal products in the EU, developments in the food sector regarding health claims for food supplements, and tasks performed by the Agency for herbal substances in accordance with the pharmacovigilance legislation.

A more detailed report on the matters raised at the hearing will be available at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000223.jsp&mid=WC0b01ac058003529f

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