



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

07 July 2014
EMA/HMPC/415092/2014
Committee on Herbal Medicinal Products (HMPC)

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

The 59th HMPC meeting, held on 30 June - 01 July 2014

Final Community herbal monographs

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

- Community herbal monograph on Rosae flos, by majority vote

The final Community herbal monograph as well as the HMPC opinion, assessment report and list of references will be published on the European Medicines Agency's website at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000186.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 October 2014**:

- Community herbal monograph on Capsici fructus
- Community herbal monograph on Eschscholziae herba cum flore
- Community herbal monograph on Matricariae aetheroleum
- Community herbal monograph on Matricariae flos
- Community herbal monograph on Pilosellae herba cum flore

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=menu/medicines/medicines.jsp&mid=WC0b01ac058001fa1d



Draft public statements

Upon recommendation from the MLWP, the HMPC adopted the following draft public statement for public consultation until **31 October 2014**:

- Public statement on *Picrorhizae kurroae* rhizoma

The public statement together with the draft list 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

Uptake of the traditional use registration scheme and implementation of the provisions of Directive 2004/24/EC in EU Member States

The HMPC welcomed the publication of the fourth revision of document EMA/322570/2011 based on data provided by all National Competent Authorities demonstrating the further increase of registrations and authorisations of herbal medicinal products in the EU.

The revised document is published here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000208.jsp&mid=WC0b01ac05800240cf

Drafting Group on Quality (DG Q)

The HMPC heard a report on the DG Q meeting held on 18 June 2014.

The HMPC adopted 3 new Q&As on herbal substances and preparations that do not contain an assay in respective Ph. Eur. monographs and on the declaration of DER and extraction solvent in case of fresh herbal substances. The Q&As will be added to the Questions & answers on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/41500/2010) published here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000365.jsp&mid=WC0b01ac0580029569

The HMPC further agreed to comments drafted by DG Q on fresh herbal drugs for communication to EDQM and noted a progress report on guidance development/revision and other quality related issues.

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

Drafting Group on Organisational matters (DG ORGAM)

The HMPC heard a report on the DG ORGAM meeting held on 13 May 2014.

The Committee heard a report on topics currently under development including the revision of the Guideline on the use of the CTD format in the preparation of a registration application for traditional herbal medicinal products and the revision of monograph and list entry templates.

The next meeting of the DG ORGAM will be held on 9 September 2014.

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

The MLWP held its 50th meeting at the European Medicines Agency on 01 to 03 July 2014.

Revisions

The MLWP endorsed the draft revised monograph on *Echinaceae purpureae herba*. The document together with supporting documents will be finalised by the Rapporteur and transmitted, after peer-review, to the HMPC for possible release for public consultation at the September 2014 meeting.

The MLWP started its work towards the revision of the monograph on *Lini semen*.

Finalisation

The working party re-discussed and endorsed the monograph on *Sisymbrii officinalis herba* after peer review. The documents will be finalised by the Rapporteur and transmitted, to the HMPC for possible final adoption at the September 2014 meeting.

Drafts

The MLWP endorsed the monographs on *Carvi aetheroleum*, *Carvi fructus*, *Crataegi folium cum flore*, *Myrtilli fructus siccus* and *Myrtilli fructus recens* for early peer-review and transmission to the HMPC for possible release in September 2014 for public consultation.

The working party continued its assessment of *Sabalisserrulatae fructus*, *Silybi marianae fructus*, *Uncariae tomentosae cortex* and *Uncariae tomentosae radicis cortex*.

The next meeting of the MLWP is scheduled for 30 September – 2 October 2014.

Contact for further information

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