



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 July 2015
EMA/HMPC/473270/2015
Committee on Herbal Medicinal Products (HMPC)

HMPC meeting report on European Union herbal monographs, guidelines and other activities

The 65th HMPC meeting, held on 06-07 July 2015

The Vice-Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 65th meeting of the Committee.

Final European Union herbal monographs

Upon recommendation from the MLWP, the HMPC adopted the following final EU herbal monographs and supporting documents:

- European Union herbal monograph on Carvi fructus, by consensus
- European Union herbal monograph on Carvi aetheroleum, by majority vote
- European Union herbal monograph on Matricariae flos, by majority vote
- European Union herbal monograph on Matricariae aetheroleum, by majority vote

The monographs together with the supporting documents including the Overview of comments received during public consultation, if any, 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&mid=WC0b01ac058001fa1d

Revised European Union herbal monographs

Upon recommendation from the MLWP as a result of its May 2015 meeting, the HMPC adopted the following draft revised European Union herbal monographs and supporting documents for 3 months public consultation **until 31 October 2015**:

- Revised European Union herbal monograph on Equiseti herba
- Revised European Union herbal monograph on Valerianae radix
- Revised European Union herbal monograph on Valerianae aetheroleum

These revisions had been triggered by new data available to the HMPC following the systematic review of monographs older than 5 years. Because of major changes to the monographs, Interested parties are given the opportunity to comment before finalisation of the revision.



The draft revised monographs together with the 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&mid=WC0b01ac058001fa1d

Draft European Union herbal monographs and list entries

Upon recommendation from the MLWP, the HMPC adopted the following draft EU herbal monographs and list entries for public consultation until **31 October 2015**:

- Draft European Union herbal monograph on Mastix
- Draft European Union herbal monograph on Ricini oleum
- Draft European Union herbal monograph and draft list entry on Sideritis herba
- Draft European Union herbal monograph on Silybi marianae fructus
- Draft European Union list entry on Valerianae radix

The draft monograph together with the 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&mid=WC0b01ac058001fa1d

Other

Cancellation of assessment work

Upon recommendation by the MLWP the Committee agreed to discontinue the assessment work for

- Juniperi communis summitatis

Following a public call for scientific data in 2014 and a request for information on products on the market among National Competent Authorities, the Rapporteur considered available data on the traditional use as insufficient.

The HMPC priority list will be updated accordingly. The document can be found here:

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

Drafting Group on Quality (DG Q)

The HMPC heard a report on the DG Q meeting held on 21 May 2015.

Beside a check of the work plan implementation status, the DG had a first discussion on possible specific Q&A following the finalisation of the reflection paper on microbiological aspects (EMA/HMPC/95714/2013) and further progressed with a reflection paper on new analytical methods. A first draft for an assessors training on quality topics to be held at the EMA in December was elaborated for discussion/agreement by HMPC. Current topics experienced at national level were discussed for a harmonised view vis-à-vis applicable guidelines and Ph. Eur. requirements such as use of certificates of suitability (CEP) in applications or the need for tests for uniformity of mass for multidose containers.

The next meeting of the Q DG will be held on 10 September 2015.

Drafting Group on Organisational matters (DG ORGAM)

The HMPC heard a report on the DG ORGAM meeting held on 19 May 2015.

The drafting group had finalised a proposal as regards the suitability of the current QRD template for herbal products. After final clarifications and amendments the HMPC endorsed a 'Discussion paper on Quality Review of Documents templates for SmPC, Labelling and Patient Leaflet on Mutual-recognition and Decentralised procedures for (Traditional) Herbal Medicinal Products ((T)HMPs)' for transfer to the QRD group and further coordination as required.

The next meeting of the DG ORGAM scheduled for 8 September 2015 will be cancelled.

Report from the July 2015 Working Party on European Union Monographs and List (MLWP)

The MLWP held its 56th meeting at the European Medicines Agency on 07–09 July 2015.

Monograph revisions

The working party discussed and endorsed the revised documents on Centaurii herba after peer review for transfer to the Committee for final adoption in September 2015. The revised documents on Pelargonii radix were endorsed for peer review prior to transfer to the Committee.

The MLWP further discussed revised documents on Salviae officinalis folium, Salviae officinalis aetheroleum and Altheae radix.

Monograph finalisation

The working party discussed and endorsed the documents on Sabalis serrulatae fructus, Myrtilli fructus recens and Myrtilli fructus siccus for peer review and transfer to the Committee for possible final adoption in September 2015.

Monograph drafts

The MLWP discussed and endorsed the draft documents on Origani majoranae herba, Helichrysi flos, Polygoni avicularis herba, and Salviae fruticosae folium for transfer to the HMPC for possible release in September 2015 for public consultation.

The working party continued its assessment of Allii sativi bulbus, Cisti cretici folium, Pruni africanae cortex and had first discussions on the assessment of Cinnamomi camphorae cortex/folium and Fragariae folium.

The next meeting of the MLWP is scheduled for 29 September – 1 October 2015.

Contact for further information

Anthony Humphreys

Head of Procedure Management and Committees Support Division (ad interim)

Tel.: +44 (0)20 7418 8583

Fax: +44 (0)20 7523 7051

E-mail: hmpc.secretariat@ema.europa.eu