



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 September 2020
EMA/HMPC/512587/2020
Committee on Herbal Medicinal Products (HMPC)

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

The 95th HMPC meeting, held on 21-23 September 2020

The Chair welcomed all delegates and experts to the 95th meeting (virtual) of the Committee on Herbal Medicinal Products and announced changes to the composition including as new nominations: Alessandro Assisi (new member for Italy), Stavroula Mamoucha (new alternate for Greece) and Maria Paile Hyvarinen (new member for Finland).

The full composition of the Committee can be found here:

<https://www.ema.europa.eu/en/committees/hmpc/members>

New European Union herbal monograph

The HMPC adopted the following draft monograph for **public consultation by 15 January 2021**:

- Draft EU herbal monograph on *Menyanthes trifoliata* folium

The draft monograph together supporting documents will be published on the European Medicines Agency's website at:

https://www.ema.europa.eu/en/medicines/field_ema_web_categories%253Aname_field/Herbal?sort=search_api_aggregation_ema_medicine_title&order=asc

New European Union list entry

The HMPC adopted after review of all new data since the first assessment (monograph since 2011) and public consultation for the draft the following proposed new entry to the European Union list of herbal substances, preparations and combinations thereof:

- Draft list entry on *Millefolii herba* (by majority)

The draft list entry together with the HMPC opinion and supporting documents will be transferred to the European Commission for adoption.

Revised European Union herbal monograph

The HMPC adopted after systematic review and public consultation the **final revised documents** for:

- Revised EU herbal monograph on *Millefolii herba* (by consensus)

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The revised monograph together with the HMPC opinion and supporting documents supersede the documents of the first assessments and will be published on the European Medicines Agency's website at:

https://www.ema.europa.eu/en/medicines/field_ema_web_categories%253Aname_field/Herbal?sort=search_api_aggregation_ema_medicine_title&order=asc

European Union herbal monograph review

Upon recommendation from the Rapporteur, the HMPC decided after systematic review according to procedure EMA/HMPC/124695/2011 Rev. 2 that no revision is required because no new data of relevance were detected that could change the content of the:

- EU herbal monograph on Juniperi aetheroleum

The review report will be published on the EMA website as Addendum to the existing Assessment report at:

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

Upon recommendation from the Rapporteur, the HMPC decided after systematic review that revision is required because new data of relevance were detected that could change the content of the:

- EU herbal monograph on Juniperi pseudo-fructus

The revision of the monograph will be added to the HMPC work programme.

An Overview of assessment work - Priority list (EMA/HMPC/278067/2006) is available here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001149.jsp&mid=WC0b01ac0580033a9d

Monographs in preparation

New assessment – finalisation

The HMPC discussed comments received during public consultation and agreed on final documents for Species amarae and Species sedativae for peer review and possible final adoption at the HMPC November meeting.

New assessment – drafts

The HMPC continued its assessment of *Saccharomyces cerevisiae* and had a first discussion on a draft monograph on *Taraxaci officinalis radix*.

Monograph reviews

The Committee discussed the availability of new data and the need to revise monographs for *Agropyri repentis rhizoma*, *Carvi aetheroleum*, *Carvi fructus*, *Caryophylli floris aetheroleum*, *Chamomillae romanae flos*, *Lavandulae aetheroleum*, *Lavandulae flos* and *Solani dulcamarae stipites* for possible adoption at the HMPC November meeting.

The members also discussed systematic reviews on *Colae semen*, *Mate folium*, *Urticae folium* and *Urticae herba*.

Monograph revisions – finalisation

Members discussed the finalisation of revision on Hyperici herba (traditional use).

Monograph revisions – drafts

The HMPC continued discussions on the revision of Orthosiphonis folium and Trigonellae foenugraeci semen.

Contact for further information

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