



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 November 2022
EMA/HMPC/907971/2022
Committee on Herbal Medicinal Products (HMPC)

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

The 108th HMPC meeting, held on 21-23 November 2022

New European Union herbal monograph

The HMPC adopted the following new final monograph after public consultation:

- Final EU herbal monograph on Vaccinii macrocarpi fructus (by majority)

The final monograph together with supporting documents including the Overview of comments received 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

Revised European Union herbal monograph – final

The HMPC adopted after systematic review, revision and public consultation the following revised monograph:

- Revised EU herbal monograph on Hyperici herba (by majority)

The final revised monograph together with supporting documents including the Overview of comments received 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

Revised European Union herbal monographs / list entries – draft

The HMPC adopted after systematic review and revision the following draft revised monographs for 3 months **public consultation until 15 March 2023**:

- Revised EU herbal monograph on Rosmarini aetheroleum
- Revised EU herbal monograph on Rosmarini folium

The draft revised monographs together with 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

Moreover, the HMPC adopted after systematic review and revision the following draft list entries for 3 months **public consultation until 15 March 2023**:

- Revised EU list entry on Foeniculi amari fructus
- Revised EU list entry on Foeniculi dulcis fructus

The draft revised list entries 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 monographs' review

Upon recommendation from the Rapporteurs, the HMPC decided, after systematic review according to the procedure¹ EMA/HMPC/124695/2011 Rev. 3, that no revision is required for the following monographs because no new data were detected that could change the monographs' content:

- EU herbal monograph on Agrimoniae herba
- EU herbal monograph on Paullinae semen
- EU herbal monograph on Tiliae flos

The review reports will be published as addenda to the existing assessment reports at:

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

Assessments close to finalisation²

New monograph – draft

- Cnici benedicti herba

Monograph revision – draft

- Hippocastani cortex

Enquiries to: AskEMA (<https://www.ema.europa.eu/en/about-us/contact/send-question-european-medicines-agency>)

¹ https://www.ema.europa.eu/en/documents/scientific-guideline/procedure-review-revision-european-union-herbal-monographs-european-union-list-entries-revision-3_en.pdf

² Documents endorsed for peer review and possible adoption at the HMPC January 2023 meeting