



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 May 2023
EMA/HMPC/220353/2023
Committee on Herbal Medicinal Products (HMPC)

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

The 111th HMPC meeting, held on 10-12 May 2023

Revised European Union herbal monograph - final

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

- Revised EU herbal monograph on *Fumariae herba*

The revised monograph 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

Revised European Union herbal monograph – draft

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

- Draft revised EU herbal monograph on *Ginseng radix*

The draft revised monograph 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

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, to start the revision procedure for the following monographs because new data were identified that could change the monograph's content:

- EU herbal monograph on *Ginkgo folium*
- EU herbal monograph on *Matricariae flos*

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



The revision of the monographs and supporting documents will be added to the HMPC work programme.

The HMPC decided further after systematic review that no revision is required for the following monographs because no new data were detected that could change the monograph's content:

- EU herbal monograph on Myrtilli fructus siccus
- EU herbal monograph on Myrtilli fructus recens
- EU herbal monograph on Ricini oleum
- EU herbal monograph on Rubi idaei folium
- EU herbal monograph on Sisymbrii officinalis herba

The review reports will be published as addendum 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

Call for scientific data

The HMPC agreed by consensus to start the assessment for:

- Maydis stigma

A proposal listed available minimum data on traditional medicinal use in more than one member state supporting a EU herbal monograph establishment. The substance will be added to the HMPC priority list and a Call for data to start the assessment procedure published here:

<https://www.ema.europa.eu/en/human-regulatory/herbal-products/procedures-monograph-list-entry-establishment>

Assessments close to finalisation²

Monograph revision – draft

- Rhodiolae roseae rhizoma et radix

Monograph review

- Origani majoranae herba
- Capsici fructus

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

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