



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 July 2022
EMA/HMPC/658338/20222
Committee on Herbal Medicinal Products (HMPC)

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

The 106th HMPC meeting, held on 18-20 July 2022

Revised European Union herbal monographs

The HMPC adopted after systematic review and revision the following draft revised monographs for 3-months **public consultation until 30 November 2022**:

- Revised EU herbal monograph on Foeniculi amari fructus
- Revised EU herbal monograph on Foeniculi dulcis fructus
- Revised EU herbal monograph on Juniperi pseudo-fructus

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

The HMPC adopted after systematic review and revision the following draft public statement for 3-months **public consultation until 30 November 2022**:

- Public statement on Foeniculi amari fructus aetheroleum

HMPC agreed that due to new safety concerns an EU herbal monograph cannot be supported anymore and proposes the withdrawal of monograph EMEA/HMPC/263292/2006.

The draft public statement 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

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Upon recommendation from the Rapporteur, the HMPC decided, after systematic review according to the procedure¹ EMA/HMPC/124695/2011 Rev. 2, to start the revision procedure for the following monograph because new data were identified that could change the monograph's content:

- EU herbal monograph on Ginseng radix

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

Furthermore, the HMPC decided, 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 Camelliae sinensis non fermentatum folium
- EU herbal monograph on Curcumae xanthorrhizae rhizoma
- EU herbal monograph on Juglandis folium

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

Monographs' revision - draft

- Rosmarini aetheroleum
- Rosmarini folium

Monographs' review

- Agrimoniae herba
- Epilobii herba
- Eschscholziae herba

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-2_en.pdf

² Documents endorsed for peer review and possible adoption at the HMPC September 2022 meeting