



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

31 January 2024  
EMA/HMPC/54241/2024  
Committee on Herbal Medicinal Products (HMPC)

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

The 115<sup>th</sup> HMPC meeting, held on 29-31 January 2024

### Revised European Union herbal monographs

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

- Revised EU herbal monograph on *Foeniculi amari fructus*
- Revised EU herbal monograph on *Foeniculi dulcis fructus*

The final revised monographs together with supporting documents will be published on the European Medicines Agency's website at:

<https://www.ema.europa.eu/en/medicines>

### European Union herbal monographs' review

Upon recommendation from the Rapporteurs, the HMPC decided after systematic review according to the procedure<sup>1</sup> EMA/HMPC/124695/2011 Rev.3, to start the revision procedure for the following monographs because new data were detected that could change the monograph's content:

- EU herbal monograph on *Allii sativi bulbus*
- EU herbal monograph on *Matricariae aetheroleum*
- EU herbal monograph on *Species diureticae*

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

The HMPC decided further that, after systematic review, 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 *Silybi mariani fructus*
- EU herbal monograph on *Symphyti radix*

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<sup>1</sup> [https://www.ema.europa.eu/en/documents/scientific-guideline/procedure-review-revision-european-union-herbal-monographs-european-union-list-entries-revision-3\\_en.pdf](https://www.ema.europa.eu/en/documents/scientific-guideline/procedure-review-revision-european-union-herbal-monographs-european-union-list-entries-revision-3_en.pdf)

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The review reports will be published as addenda to the existing assessment reports on the European Medicines Agency's website at:

<https://www.ema.europa.eu/en/medicines>

## Guidance document

The HMPC adopted the following draft procedure for release for public consultation:

- Procedure for the preparation of European Union herbal monographs and European Union list entries and appointment of HMPC rapporteurs and peer-reviewers

The draft procedure EMA/HMPC/887331/2022 will be published on the European Medicines Agency's website at:

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

Interested parties are invited to provide comments by **15 May 2024**.

## Assessments close to finalisation<sup>2</sup>

### Monograph revision – final

- Rhodiolae roseae rhizoma et radix

### Monograph revision – draft

- Eucalypti aetheroleum
- Pilosellae herba cum radice

### Monograph review

- Malvae sylvestris flos
- Malvae folium

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

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<sup>2</sup> Documents endorsed for peer review and possible adoption at the HMPC March 2024 meeting.