



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

20 March 2024  
EMA/HMPC/129763/2024  
Committee on Herbal Medicinal Products (HMPC)

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

The 116<sup>th</sup> HMPC meeting, held on 18-20 March 2024

### Revised European Union herbal monographs – final

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

- Revised EU herbal monograph on *Rhodiolae roseae rhizoma et radix*

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

[https://www.ema.europa.eu/en/search?f%5B0%5D=ema\\_search\\_categories%3A85&f%5B1%5D=ema\\_search\\_content\\_type%3Aema\\_herbal&landing\\_from=73303](https://www.ema.europa.eu/en/search?f%5B0%5D=ema_search_categories%3A85&f%5B1%5D=ema_search_content_type%3Aema_herbal&landing_from=73303)

### Revised European Union herbal monographs – draft

The HMPC adopted after systematic review and revision the following draft revised monographs for 3-month **public consultation until 15 July 2024**:

- Revised EU herbal monograph on *Eucalypti aetheroleum*
- Revised EU herbal monograph on *Pilosellae herba cum radice*

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/search?f%5B0%5D=ema\\_search\\_categories%3A85&f%5B1%5D=ema\\_search\\_content\\_type%3Aema\\_herbal&landing\\_from=73303](https://www.ema.europa.eu/en/search?f%5B0%5D=ema_search_categories%3A85&f%5B1%5D=ema_search_content_type%3Aema_herbal&landing_from=73303)

### 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, 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 *Malvae sylvestris flos*

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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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- EU herbal monograph on Malvae folium

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/search?f%5B0%5D=ema\\_search\\_categories%3A85&f%5B1%5D=ema\\_search\\_content\\_type%3Aema\\_herbal&landing\\_from=73303](https://www.ema.europa.eu/en/search?f%5B0%5D=ema_search_categories%3A85&f%5B1%5D=ema_search_content_type%3Aema_herbal&landing_from=73303)

## Guidance document

The HMPC adopted the following draft revised guideline for 3-month **public consultation until 15 July 2024**:

- Guideline on good agricultural and collection practice (GACP) of starting materials of herbal origin

The draft revised guideline EMA/HMPC/246816/2005 will be published on the European Medicines Agency's website at:

<https://www.ema.europa.eu/en/good-agricultural-collection-practice-starting-materials-herbal-origin-scientific-guideline>

Moreover, the HMPC adopted the following draft revised templates for 3-month **public consultation until 15 July 2024**:

- Template for Assessment report for the development of European Union herbal monographs and European Union list entries
- Template for a European Union herbal monograph

The draft revised templates EMA/HMPC/418902/2005 and EMEA/HMPC/107436/2005 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>

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

### New assessments – draft

- Hyperici herba/Cimicifugae rhizoma
- Tribuli terrestris herba

### Monograph revision – final

- Foeniculi amari fructus aetheroleum
- Ginseng radix
- Pelargonii radix

### Monograph revision – draft

- Zingiberis rhizoma

**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 May 2024 meeting.