



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

22 November 2023  
EMA/HMPC/535681/2023  
Committee on Herbal Medicinal Products (HMPC)

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

The 114<sup>th</sup> HMPC meeting, held on 20-22 November 2023

### Revised European Union herbal monograph

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

- Revised EU herbal monograph on Hippocastani cortex

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)

### 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 monograph because new wording was adopted for the therapeutic indication that could change the monograph's content:

- EU herbal monograph on Fragariae folium

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

### Guidance documents

The HMPC adopted the revision 7 of the:

- Questions and answers on quality of herbal medicinal products/traditional herbal medicinal products

The revised document EMA/HMPC/41500/2010 will be published here:

<https://www.ema.europa.eu/en/questions-answers-quality-herbal-medicinal-products-traditional-herbal-medicinal-products-scientific>

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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 HMPC adopted the revision 1 of the:

- Questions & Answers on the EU framework for (traditional) herbal medicinal products, including those from a 'non-European' tradition

The revised document EMA/HMPC/402684/2013 will be published here:

[https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/questions-answers-european-union-framework-traditional-herbal-medicinal-products-including-those-non\\_en.pdf](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/questions-answers-european-union-framework-traditional-herbal-medicinal-products-including-those-non_en.pdf)

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

### **Monograph and List entry revision – final**

- Foeniculi amari fructus
- Foeniculi dulcis fructus

### **Monograph revision – draft**

- Urticae radix
- Zingiberis rhizoma

### **Monograph review**

- Allii sativi bulbus
- Matricariae aetheroleum
- Silybi mariani fructus
- Species diureticae
- Symphyti radix

**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 January 2024 meeting.