



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

21 September 2022  
EMA/HMPC/782037/20222  
Committee on Herbal Medicinal Products (HMPC)

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

The 107<sup>th</sup> HMPC meeting, held on 19-21 September 2022

### Revised European Union herbal monograph

The HMPC adopted after systematic review and revision the following draft revised monograph for 3 months **public consultation until 31 January 2023**:

- Revised EU herbal monograph on Fumariae herba

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](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 procedure<sup>1</sup> EMA/HMPC/124695/2011 Rev. 2, 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 Epilobii herba
- EU herbal monograph on Eschscholziae herba

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](https://www.ema.europa.eu/en/medicines/field_ema_web_categories%253Aname_field/Herbal?sort=search_api_aggregation_ema_medicine_title&order=asc)

### Guidance documents

The HMPC adopted a concept paper for the revision of the:

- Guideline on Assessment of genotoxicity of herbal substances/preparations

The concept paper on revision of guideline EMEA/HMPC/107079/2007 will be published here:

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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-2\\_en.pdf](https://www.ema.europa.eu/en/documents/scientific-guideline/procedure-review-revision-european-union-herbal-monographs-european-union-list-entries-revision-2_en.pdf)

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<https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines/multidisciplinary/herbal-medicinal-products-scientific-guidelines>

Interested parties are invited to provide comments **by 31 January 2023**.

The HMPC adopted a modified version for the:

- Procedure for the review and revision of EU herbal monographs and EU list entries

The third version of procedure EMA/HMPC/124695/2011 contains an improved review template to harmonise review reports, while main principles of the procedure are maintained. Procedure and annexed template will be published here:

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

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

### **New assessments – final**

- Vaccinii macrocarpi fructus

### **Monograph revisions – final**

- Hyperici herba

### **List entries revisions – draft**

- Foeniculi amari fructus
- Foeniculi dulcis fructus

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

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<sup>2</sup> Documents endorsed for peer review and possible adoption at the HMPC November 2022 meeting