



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 September 2023
EMA/HMPC/430913/2023
Committee on Herbal Medicinal Products (HMPC)

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

The 113th HMPC meeting, held on 18-20 September 2023

New European Union herbal monograph

The HMPC adopted the following new final monograph after public consultation:

- Final EU herbal monograph on Cnici benedicti herba (by majority)

The final 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

Revised European Union herbal monograph – draft

The HMPC adopted after systematic review and revision the following draft revised monograph for 3 months **public consultation until 15 January 2024**:

- Draft revised EU herbal monograph on Pelargonii radix

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

European Union herbal monographs' review

Upon recommendation from the Rapporteurs, the HMPC decided after systematic review according to the procedure¹ EMA/HMPC/124695/2011 Rev.3, to start the revision procedure for the following monographs because new wording was adopted for the therapeutic indication that could change the monograph's content:

- EU herbal monograph on Ononidis radix
- EU herbal monograph on Pilosellae herba cum radice

¹ 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 Polygoni avicularis herba

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

The HMPC decided further 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 Pruni africanae cortex
- EU herbal monograph on Rosae flos
- EU herbal monograph on Sideritis 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

Guidance documents

The HMPC adopted the herbal Quality Drafting Group (QDG) three-year workplan, which is proposed for integration into the Quality domain workplan.

Assessments close to finalisation²

Monograph revision – final

- Hippocastani cortex
- Rosmarini aetheroleum
- Rosmarini folium

Monograph revision – draft

- Lavandulae aetheroleum
- Urticae herba

Monograph review

- Fragariae folium

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

² Documents endorsed for peer review and possible adoption at the HMPC November 2023 meeting.