



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

25 January 2023  
EMA/HMPC/43482/2023  
Committee on Herbal Medicinal Products (HMPC)

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

The 109<sup>th</sup> HMPC meeting, held on 23-25 January 2023

### **New European Union herbal monograph – draft**

The HMPC adopted the following draft monograph for 3 months **public consultation until 15 May 2023**:

- Draft new EU herbal monograph on Cnici benedicti herba

The draft 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)

### **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 31 May 2023**:

- Draft revised EU herbal monograph on Hippocastani cortex

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)

### **Guidance documents**

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

- Guideline on declaration of herbal substances and herbal preparations

The concept paper on revision of guideline EMA/HMPC/CHMP/CVMP/287539/2005 will be published here:

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

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Interested parties are invited to provide comments for 3 months of **public consultation until 31 May 2023**.

The HMPC adopted the following Question & Answer document:

- Questions & Answers regarding Cannabis-derived medicinal products and the scope of EU herbal monographs for herbal medicinal products within the EU medicines legislation

The Q&A aim at clarifying basic regulatory requirements to obtain a marketing authorisation for medicinal products in the EU and at explaining the work of the HMPC regarding EU herbal monographs for stakeholders that may not have extensive experience with the EU pharmaceutical regulatory system in order to understand the limited scope of the upcoming Call for data for Cannabis flos. The Q&A will be published here:

<https://www.ema.europa.eu/en/human-regulatory/herbal-products/herbal-medicinal-products-questions-answers>

## **Calls for scientific data**

HMPC decided to start the following procedures in line with its work plan 2023 for which new calls for data will be published for:

*New assessments to be started in 2023*

- Cannabis flos
- Pruni cerasi stipites
- Species pectoralis (Sp. expectorantes, Sp. antitussivae)

*Periodic reviews to be started in 2023*

- Allii sativi bulbus
- Fragariae folium
- Lecithinum ex soya
- Malvae sylvestris flos
- Malvae folium
- Mastic (Mastix, Pistaciae lentisci resina)
- Soiae oleum raffinatum
- Species diureticae
- Silybi mariani fructus
- Thymi herba

Calls for data will be published in 3 waves to ease data collection and provision by Interested parties and will be found here:

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

## **HMPC Chair election**

The HMPC re-elected Emiel van Galen from the Medicines Evaluation Board (NL) as HMPC Chair for a second 3-year mandate starting 02 March 2023.

## HMPC work plan 2023

The HMPC adopted its Workplan for 2023.

The Workplan 2023 including the Annex 1 (planned assessment work towards EU herbal monographs and List entries) and Annex 2 (planned herbal specific guidance) will be published here:

<https://www.ema.europa.eu/en/committees/committee-herbal-medicinal-products-hmpc>

### Assessments close to finalisation<sup>1</sup>

#### New assessments – draft

- Cisti cretici herba

#### Monograph revision – final

- Juniperi pseudo-fructus (galbulus)

#### Monograph reviews

- Crataegi folium cum flore
- Helichrysi flos

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

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<sup>1</sup> Documents endorsed for peer review and possible adoption at the HMPC March 2023 meeting