



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

24 November 2021  
EMA/HMPC/708689/2021  
Committee on Herbal Medicinal Products (HMPC)

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

The 102<sup>nd</sup> HMPC meeting, held on 22-24 November 2021

### **New European Union herbal monograph**

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

- Final EU herbal monograph on *Taraxaci officinalis radix* (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](https://www.ema.europa.eu/en/medicines/field_ema_web_categories%253Aname_field/Herbal?sort=search_api_aggregation_ema_medicine_title&order=asc)

The HMPC adopted the following public statement after public consultation:

- Public statement on *Saccharomyces cerevisiae* CBS 5926

The public statement together with supporting documents explains the reasons why there was no majority at the HMPC to establish an EU herbal monograph.

[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**

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

- Revised EU herbal monograph on *Trigonellae foenugraeci semen*

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/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 monograph review**

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Upon recommendation from the Rapporteur, the HMPC decided after systematic review according to procedure EMA/HMPC/124695/2011 Rev. 2 to start the revision procedure for following monographs because new data were identified that could change the:

- EU herbal monograph on Urticae herba
- EU herbal monograph on Zingiberis rhizoma

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

The HMPC decided further that after systematic review no revision is required because no new data were detected that could change the content of the:

- EU herbal monograph on Cucurbitae semen
- EU herbal monograph on Grindeliae herba
- EU herbal monograph on Levistici radix
- EU herbal monograph on Lichen islandicus

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 committee adopted a concept paper for the revision of the:

- Guideline on Good Agricultural and Collection Practice (GACP) of starting materials of herbal origin

The concept paper on revision of guideline EMA/HMPC/246816/2005 will be published here:

<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 15 March 2022**.

The Committee adopted further a Q&A regarding nitrosamine impurities and herbal medicinal products. The short clarification is proposed to be added to the CMDh practical guidance for Marketing Authorisation Holders which is published here:

<https://www.hma.eu/226.html>

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

### New assessments – final

- Species digestivae

### Monograph revisions – final

- Agropyri repentis rhizoma

### Monograph revisions – draft

- Fumariae herba

### Monograph reviews

- Cichorii intybi radix

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<sup>1</sup> Documents endorsed for peer review and possible adoption at the HMPC January 2022 meeting

- Eucalypti aetheroleum
- Eucalypti folium
- Fraxini folium
- Fucus vesiculosus
- Marrubii herba
- Origani dictamni herba
- Paullinae semen

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