



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 September 2021
EMA/HMPC/537632/2021
Committee on Herbal Medicinal Products (HMPC)

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

The 101th HMPC meeting, held on 20-22 September 2021

New European Union herbal monograph

The HMPC adopted the following new draft monograph for 3-months **public consultation until 31 January 2022**:

- Draft EU herbal monograph on *Centellae asiaticae 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

Revised European Union herbal monograph

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

- Revised EU herbal monograph on *Orthosiphonis folium*

The final revised monograph together with supporting documents including the Overview of comments received during public consultation 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 monograph review

Upon recommendation from the Rapporteur, the HMPC decided after systematic review according to procedure EMA/HMPC/124695/2011 Rev. 2 that no revision is required because no new data were detected that could change the content of the:

- EU herbal monograph on *Solidaginis virgaureae herba*

The review report will be published as Addendum to the existing Assessment report at:

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

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Guidance documents

The committee adopted by consensus the final revised

- Guideline on quality of herbal medicinal products/traditional herbal medicinal products

Following adoption by CHMP and CVMP; the final revised document EMA/HMPC/201116/2005 Rev. 3 together with the Overview of comments received during public consultation will be published here:

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

The committee adopted by majority the final revised

- Guideline on Specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products

Following adoption by CHMP and CVMP, the final revised document EMA/HMPC/162241/2005 Rev. 3 together with the Overview of comments received during public consultation will be published here:

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

The committee adopted by majority the final revised

- Public statement on the use of herbal medicinal products containing estragole

Following agreement by CHMP and CMDh, the final revised document EMA/HMPC/137212/2005 Rev 1 together with the Overview of comments received during public consultation will be published here:

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

Assessments close to finalisation¹

New assessment – final

- *Saccharomyces cerevisiae* CBS 5926
- *Taraxaci officinalis radix*

Monograph revisions – final

- *Trigonellae foenugraeci semen*

Monograph revisions – draft

- *Juniperi pseudo-fructus*

Monograph reviews

- *Arnicae flos*
- *Cucurbitae semen*
- *Grindeliae herba*
- *Hippocastani cortex*
- *Levistici radix*

¹ Documents endorsed for peer review and possible adoption at the HMPC November 2021 meeting

- Lichen islandicus

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