



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

07 July 2021
EMA/HMPC/386494/2021
Committee on Herbal Medicinal Products (HMPC)

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

The 100th HMPC meeting, held on 5-7 July 2021

The Chair welcomed all delegates and experts to the 100th meeting (virtual) of the Committee on Herbal Medicinal Products.

New European Union herbal monograph

The HMPC adopted the following new draft monograph for 3-months **public consultation until 31 October 2021**:

- Draft EU herbal monograph on Species digestivae

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 and revision the following draft revised monograph for 3-months **public consultation until 31 October 2021**:

- Revised EU herbal monograph on Agropyri repentis rhizoma

The draft revised monographs 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 monograph review

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 Rosmarini aetheroleum
- EU herbal monograph on Rosmarini folium

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

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

- EU herbal monograph on *Sabalisa serrulatae fructus*

The review report will be published on the EMA website 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

Cancellation of assessment

Upon reconsideration and recommendation by the Rapporteur, the HMPC agreed to cancel the assessment for:

- *Andrographidis paniculatae folium*

because of insufficient data to establish an EU herbal monograph.

The substance will be taken from the HMPC work programme and the existing Public statement EMA/HMPC/709282/2012 remains valid.

The Overview of assessment work - Priority list (EMA/HMPC/278067/2006) will be updated accordingly and is available here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001149.jsp&mid=WC0b01ac0580033a9d

Guidance documents

The committee adopted by majority the final revised

- Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) including recommendations regarding contamination with PAs

The final revised document EMA/HMPC/893108/2011 Rev. 1 together with the Overview of comments received during public consultation will be published here:

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

Monographs in preparation

New assessment – final

Since no comments were received on the draft public statement on *Salviae mitiorrhizae radix et rhizoma* the documents were transferred for peer review and possible final adoption at the HMPC September meeting.

New assessment – drafts

The Committee concluded on the documents for *Centellae asiaticae herba* and *Cisti cretici folium* for peer review and possible adoption for release for public consultation at the HMPC September meeting.

Monograph reviews

The Committee discussed the availability of new data and the need to revise monographs for *Solidaginis virgaureae herba* and *Zingiberis rhizoma* for possible decision at the HMPC September meeting.

Members also had first discussions on the systematic review of *Cucurbitae semen* and *Hippocastani cortex*.

Monograph revisions – final

The Committee discussed comment received during public consultation and agreed on the documents for *Orthosiphonis folium* for peer review and possible final adoption at the HMPC September meeting.

Monograph revisions – drafts

The Committee endorsed draft documents for *Juniperi pseudo-fructus* for peer review and possible adoption for release for public consultation at the HMPC September meeting.

The Committee further continued the revision of *Foeniculi amari fructus*, *Foeniculi amari fructus aetheroleum*, *Foeniculi dulcis fructus* and *Lavandulae aetheroleum* and had a first discussion on the revision of *Fumariae herba*.

Upcoming meetings

The next meeting of the HMPC will be held on 20-22 September 2021.

<https://www.ema.europa.eu/en/committees/hmpc/hmpc-meetings>

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