



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

05 May 2021
EMA/HMPC/262813/2021
Committee on Herbal Medicinal Products (HMPC)

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

The 99th HMPC meeting, held on 3-5 May 2021

The Chair welcomed all delegates and experts to the 99th meeting (virtual) of the Committee on Herbal Medicinal Products including Jūratė Antanavičienė as new member and Asta Kubilienė as new alternate for Lithuania.

The Committee elected as new co-opted member with expertise in clinical pharmacology Prof. Maria da Graça Campos (PT) for a 3-year mandate starting 5 July 2021.

The full composition of the Committee can be found here:

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

New European Union herbal monographs

The HMPC adopted the following **final herbal monograph** after public consultation:

- EU herbal monograph on *Menyanthes trifoliata* folium (by consensus)

The final EU herbal monograph together with the 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

The HMPC adopted the following draft monographs for 3-months **public consultation until 31 August 2021**:

- Draft EU herbal monograph on *Taraxaci officinalis* radix
- Draft EU herbal monograph on *Vaccinii macrocarpi* fructus

The HMPC adopted further the following draft public statement for 3-months **public consultation until 31 August 2021**:

- Public statement on *Saccharomyces cerevisiae* CBS 5926

The document explains the reasons why the HMPC could not establish a monograph at present. Interested parties are invited to comment. The draft statement together with the 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 Fumariae herba
- EU herbal monograph on Plantaginis lanceolatae folium

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 Colae semen
- EU herbal monograph on Mate folium
- EU herbal monograph on Violae tricoloris herba

The review reports will be published on the EMA website 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

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

Calls for scientific data

HMPC agreed on the availability of minimum requirements and decided to start a **new assessment** procedure for:

- Tribulus terrestris herba

The substance is added to the HMPC work programme and a Call for data will be published:

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

Guidance documents

The committee agreed to extent Q&A EMA/HMPC/345132/2010 (Rev.5) with an explanation on the elaboration and use of herbal tea combination monographs. The Regulatory Q&A on herbal medicinal products are made available here:

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

Monographs in preparation

New assessment – drafts

The Committee concluded on the documents for *Species digestivae* for peer review and possible adoption for release for public consultation at the HMPC July meeting.

Members also reconsidered the assessment of *Andrographidis paniculatae folium* and continued the assessment of *Centellae asiaticae herba* and *Cisti cretici folium*.

Monograph reviews

The Committee discussed the availability of new data and the need to revise monographs for *Rosmarini aetheroleum*, *Rosmarini folium*, *Sabalis serrulatae fructus*, *Urticae folium*, *Urticae herba* for possible decision at the HMPC July meeting.

Members also discussed systematic review of *Solidaginis virgaureae herba*.

Monograph revisions – drafts

The Committee endorsed draft documents for *Agropyri repentis rhizoma* for peer review and possible adoption for release for public consultation at the HMPC July meeting.

The Committee further continued the revision of *Juniperi pseudo-fructus*.

Upcoming meetings

The next meeting of the HMPC will be held on 05-07 July 2021.

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

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