



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 January 2021
EMA/HMPC/35098/2021
Committee on Herbal Medicinal Products (HMPC)

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

The 97th HMPC meeting, held on 11-13 January 2021

The Chair welcomed all delegates and experts to the 97th meeting (virtual) of the Committee on Herbal Medicinal Products including, Sarah Kellaghan as new member for Ireland and Rahat Nazmi as new alternate for Denmark.

The full composition of the Committee can be found here:

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

New European Union herbal monograph

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

- EU herbal monograph on *Aloysiae citriodorae 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 further the following draft public statement for **3-months public consultation until 30 April 2021**:

- Public statement on *Salviae miltiorrhizae radix et rhizoma*

The document explains the reasons why the HMPC could not establish a monograph at present. Interested parties are invited to comment and provide additional data. 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

Revised European Union herbal monograph

The HMPC adopted after systematic review and revision the following **draft revised monograph for 3-months public consultation until 30 April 2021**:

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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- Revised EU herbal monograph on Orthosiphonis folium

The 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

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 because new data were identified that could change the

- EU herbal monograph on Agropyri repentis rhizoma

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

An Overview of assessment work - Priority list (EMA/HMPC/278067/2006) 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 decided to start the following procedures in line with its work plan 2021 for which new calls for data will be published for:

New assessments to be started in 2021

- Cnici benedicti herba
- Combination Hyperici herba / Cimicifugae rhizoma

Periodic reviews to be started in 2021

- Arnicae flos
- Camelliae sinensis non fermentatum folium
- Cichorii intybi radix
- Cucurbitae semen
- Curcumae xanthorrhizae rhizoma
- Eucalypti aetheroleum
- Eucalypti folium
- Fraxini folium
- Ginseng radix
- Grindeliae herba
- Hippocastani cortex
- Juglandis folium
- Levistici radix
- Lichen islandicus
- Liquiritiae radix

- Marrubii herba
- Origani dictamni herba
- Paullinae semen
- Rhodiolae roseae rhizoma et radix
- Tiliae flos
- Urticae radix

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

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

HMPC work plan 2021

The HMPC adopted its work plan 2021 including Annex 1 for monograph / list entry assessment work and Annex 2 for guideline development.

The activities outlined in the work plan for 2021 have been agreed taking into consideration the ongoing phase of EMA's business continuity due to the Covid-19 pandemic. The work plan will be published here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/herbal_search.jsp&mid=WC0b01ac058001fa1d

Monographs in preparation

New assessment – drafts

The Committee agreed on draft documents for *Species digestivae / stomachicae* and on *Vaccinii macrocarpi fructus* for peer review and possible release for public consultation at the HMPC March 2021 meeting.

The HMPC continued its assessment of *Centellae asiaticae herba* and re-instated the discussion on *Cisticrii folium*.

Monograph reviews

The Committee discussed the availability of new data and the need to revise monographs for *Cinnamomi corticis aetheroleum* and *Cinnamomi cortex* for possible decision at the HMPC March 2021 meeting.

The members also discussed systematic review of *Fumariae herba*.

Monograph revisions – drafts

The HMPC endorsed the documents on *Hyperici herba* (WEU/TU) and on *Trigonellae foenugraeci semen* for peer review and possible release for public consultation at the HMPC March 2021 meeting.

The HMPC had initial discussions on the revision of *Foeniculi amari fructus*, *Foeniculi amari fructus aetheroleum*, *Foeniculi dulcis fructus* and *Sabalidis serrulatae fructus*.

Upcoming meetings

The next meeting of the HMPC will be held on 01-03 March 2021.

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