



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 January 2020
EMA/HMPC/28633/2020
Committee on Herbal Medicinal Products (HMPC)

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

The 91th HMPC meeting, held on 13-15 January 2020

The Vice-Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 91th meeting of the Committee at the premises of the new EMA building.

The Committee noted the nomination of Michele Brum as new alternate for France and Susanne Flemisch as new alternate for Germany.

The full composition of the Committee can be found here:

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

The Committee held a vote to elect a Chair following the expiry of the three-year mandate of the previous Chair. No candidate reached a majority during this round. A new Chair election will therefore be organised at the March HMPC meeting.

Revised European Union herbal monographs and list entry

The HMPC adopted after systematic review and public consultation the following **final revised documents**:

- Revised EU herbal monograph on Hippocastani semen
- Revised EU herbal monograph and revised list entry on Menthae piperitae aetheroleum
- Revised EU herbal monograph on Menthae piperitae folium

The revised monographs together with supporting documents including the overviews 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_relevance&order=desc

The draft revised list entry will be transferred to the European Commission.

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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 of relevance were detected that could change the content of the:

- EU herbal monograph on *Arctii radix*

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

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

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 2020 for which new calls for data will be published:

New assessments to be started in 2020

- *Taraxaci radix*

Periodic reviews to be started in 2020

- *Agropyri repentis rhizoma*
- *Caryophyllii floris aetheroleum*
- *Carvi aetheroleum*
- *Carvi fructus*
- *Chamomillae romanae flos*
- *Cinnamomi cortex*
- *Cinnamomi corticis aetheroleum*

- *Colae semen*
- *Fucus vesiculosus*
- *Fumariae herba*
- *Lavandulae aetheroleum*
- *Lavandulae flos*
- *Mate folium*
- *Plantaginis lanceolatae folium*

- *Solani dulcamarae stipites*
- *Urticae herba*
- *Urticae folium*
- *Violae tricoloris herba*

- Zingiberis rhizoma

Revisions to be started in 2020

- Pelargonii 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 2020

The HMPC adopted its work plan 2020 including Annex 1 for monograph / list entry assessment work and Annex 2 for guideline development.

The activities outlined in the work plan for 2020 have been agreed taking into consideration that activities are only gradually reinstated following a phase of EMA's business continuity. The work plan will be published here:

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

EU herbal monographs in preparation

New assessment – drafts

The HMPC endorsed draft documents for Species amarae for finalisation and possible release for public consultation in March 2020.

The HMPC continued its assessment of Menyanthes trifoliata folium, Saccharomyces cerevisiae CBS 5926 and Vaccinii macrocarpi fructus and had a first discussion on Salviae milthiorrhizae radix et rhizoma.

Review of monographs for decision on revision

The HMPC discussed the need to revise the monographs on Absinthi herba, Filipendulae ulmariae flos, Juniperi aetheroleum, Juniperi pseudo-fructus, Pelargonii radix, Sabalis serrulatae fructus, and Zingiberis rhizoma after review of newly available data.

Contact for further information

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