



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

06 May 2020
EMA/HMPC/257185/2020
Committee on Herbal Medicinal Products (HMPC)

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

The 93th HMPC meeting, held on 04-06 May 2020

The Chair welcomed all delegates and experts to the 93th meeting (virtual) of the Committee and announced changes to the composition: Markéta Příhodová (new member for CZ), Marie Heroutová (new alternate for CZ) and Burt Kroes (new member for NL).

The full composition of the Committee can be found here:

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

Erika Svedlund was elected as new Vice-Chair of the Committee with a 3-year mandate that started on 05 May 2020.

New European Union herbal monographs

The HMPC adopted the following **draft documents for 3-months public consultation**:

- Draft EU herbal monograph on *Aloysiae folium*
- Draft EU herbal monograph (combination) on *Species amarae*
- Draft EU herbal monograph (combination) on *Species sedativae*

The draft 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

Revised European Union herbal monographs

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

- Revised EU herbal monograph on *Rhamni purshianae cortex* by majority
- Revised EU herbal monograph on *Rhei radix* by majority

The revised monographs together with supporting documents including the overviews of comments received during public consultation supersede the documents of the first assessments and will be published on the European Medicines Agency's website at:

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

An agency of the European Union



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

- EU herbal monograph on Filipendulae ulmariae herba
- EU herbal monograph on Filipendulae ulmariae flos

The review reports 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

Upon recommendation from the Rapporteur, the HMPC decided after specific unscheduled review according to procedure EMA/HMPC/124695/2011 Rev. 2 that the revision procedure should start for the existing

- EU herbal monograph on Pelargonii radix

The HMPC further decided after specific unscheduled review that the decision on the revision of the existing monograph on the

- EU herbal monograph on Sabalis serrulatae fructus

should be taken after systematic review of all newly available public data since the first assessment in 2015 and a **Call for data** will be published on the EMA website.

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

Other

Revised Rules of Procedure for emergency situations

HMPC adopted by consensus revised Rules of procedures (RoP) as proposed and adopted by the EMA Management Board (MB) in March. These amendments are required to enable those bodies to continue their workings in a virtual emergency setting, as well as to ensure the validity of the various output decisions that each committee will adopt during remote meetings. A change is also introduced in the quorum required for adoption of scientific opinions or recommendations in case of an emergency situation. To add flexibility to the system, the possibility is introduced to give a proxy vote to another member or to the alternate of a member who is present at the relevant meeting of the body concerned.

The revised RoP will be published here:

<https://www.ema.europa.eu/en/committees/committee-herbal-medicinal-products-hmpc>

EU herbal monographs in preparation

New assessment – finalisation

The HMPC endorsed after discussion of comments received during public consultation the documents on *Herniariae herba* for peer review and possible final adoption in July 2020.

New assessment – drafts

The HMPC continued its assessment of *Vaccinii macrocarpi fructus* and *Menyanthes trifoliata folium*.

Monograph revisions – finalisation

The committee discussed feedback from patient representatives with regard to the finalisation of the revision of documents for *Tanacetii parthenii herba*.

Contact for further information

Radhouane Cherif

Head of Committees and Quality Assurance Department

Human Medicines Division

Tel. +31 88781 7389 | Fax +31 88781 5525

E-mail: hmpc.secretariat@ema.europa.eu