



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

23 November 2020  
EMA/HMPC/632627/2020  
Committee on Herbal Medicinal Products (HMPC)

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

The 96<sup>th</sup> HMPC meeting, held on 16-18 November 2020

The Chair welcomed all delegates and experts to the 96<sup>th</sup> meeting (virtual) of the Committee on Herbal Medicinal Products including Hilda Kuin as new alternate for the Netherlands.

The Committee re-elected as co-opted members Gert Laekeman as expert in Experimental/non-clinical pharmacology and Maria Helena Pinto Ferreira as expert in General and family medicine, both for another 3-year mandate starting on 24 November 2020.

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 EU herbal monographs** after public consultation:

- EU herbal monograph (combination) on Species amarae (by majority)
- EU herbal monograph (combination) on Species sedativae (by majority)

The final EU herbal monographs together with the supporting documents including the Overview 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\\_aggregation\\_ema\\_medicine\\_title&order=asc](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 Rapporteurs, 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 Carvi aetheroleum
- EU herbal monograph on Carvi fructus
- EU herbal monograph on Caryophyllii floris aetheroleum
- EU herbal monograph on Chamomillae romanae flos
- EU herbal monograph on Lavandulae flos

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- EU herbal monograph on *Solani dulcamarae stipites*

The review reports will be published on the EMA website as Addenda to the existing Assessment reports at:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/herbal\\_search.jsp&mid=WC0b01ac058001fa1d](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/herbal_search.jsp&mid=WC0b01ac058001fa1d)

Upon recommendation from the Rapporteur, the HMPC decided after systematic review that revision is required because new data of relevance were detected that could change the content of the:

- EU herbal monograph on *Lavandulae aetheroleum*

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

## Monographs in preparation

### New assessment – finalisation

The HMPC discussed the finalisation of documents after public consultation for *Aloysiae citriodoraefolium* for peer review and possible final adoption at the HMPC January 2021 meeting.

### New assessment – drafts

The Committee agreed on draft documents for *Taraxaci radix* for peer review and possible release for public consultation at the HMPC January 2021 meeting.

The HMPC continued its assessment of *Centellae asiaticae herba*, *Saccharomyces cerevisiae*, *Salviae miltiorrhizae radix et rhizoma*, *Species digestivae/ stomachicae* and *Vaccinii macrocarpi fructus* and had a first discussion on *Andrographidis paniculatae folium*.

### Monograph reviews

The Committee discussed the availability of new data and the need to revise monographs for *Agropyri repentis rhizoma*, *Mate folium* and *Violae tricoloris herba* for possible decision at the HMPC January 2021 meeting.

The members also discussed systematic reviews of *Cinnamomi corticis aetheroleum*, *Cinnamomi cortex*, *Colae semen*, *Fumariae herba* and *Sabalis serrulatae fructus*.

### Monograph revisions – finalisation

Members discussed the finalisation of revision on *Hyperici herba*.

### Monograph revisions – drafts

The HMPC endorsed the documents on *Orthosiphonis folium* for peer review and possible release for public consultation at the HMPC January 2021 meeting.

The HMPC continued discussions on the revision of *Trigonellae foenugraeci semen*.

## Other information

### Hearing with AESGP

In a hearing with the Association of the European Self-Care Industry (AESGP) the Committee received some new information and answered questions on 3 key topics in the herbal area:

Updates were given and views exchanged with regard to HMPC guidance development concerning herbal products containing pyrrolizidine alkaloids and the alignment of EU herbal monographs with Ph. Eur. monographs as regards declaration of the active substance. AESGP also presented data and views on the pharmacokinetics and metabolism of pyrrolizidine alkaloids and preliminary model predictions of relative potency.

A hearing report will be published here:

<https://www.ema.europa.eu/en/committees/working-parties-other-groups/hmpc/interested-parties-hmpc>

### Upcoming meetings

The next meeting of the HMPC will be held on 11-15 January 2021.

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