



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

25 September 2019  
EMA/HMPC/532472/2019  
Committee on Herbal Medicinal Products (HMPC)

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

The 89<sup>th</sup> HMPC meeting, held on 23-25 September 2019

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 89<sup>th</sup> meeting of the Committee.

The Committee welcomed Sheena Kennedy as new member for Ireland, Clémence Varret as new alternate for Luxemburg and Karoline Holm Felding as new alternate for Denmark.

The full composition of the Committee can be found here:

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

### Revised European Union herbal monographs and list entries

The HMPC adopted after systematic review, revision and public consultation the following **final revised** EU herbal monographs:

- Revised EU herbal monograph on Frangulae cortex (by majority)
- Revised EU herbal monograph on Valerianae radix/Lupuli flos (by majority)

The revised monographs together with the HMPC opinion and supporting documents including the Overview of comments as 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](https://www.ema.europa.eu/en/medicines/field_ema_web_categories%253Aname_field/Herbal?sort=search_api_relevance&order=desc)

The HMPC adopted after systematic review the following **draft revised documents** for **public consultation until 15 January 2020**:

- Revised EU herbal monograph on Rhamni purshianae cortex
- Revised EU herbal monograph on Rhei radix
- Revised EU herbal monograph on Tanaceti parthenii herba
- Revised EU herbal monograph on Thymi aetheroleum

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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\\_relevance&order=desc](https://www.ema.europa.eu/en/medicines/field_ema_web_categories%253Aname_field/Herbal?sort=search_api_relevance&order=desc)

## 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 would change the content of the:

- EU herbal monograph on Hamamelidis cortex
- EU herbal monograph on Hamamelidis folium
- EU herbal monograph on Hamamelidis folium et cortex aut ramunculus destillatum

The review reports will be published on the EMA website as Addenda to the existing Assessment report 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)

## European Union herbal monograph new assessments

After a call for data and review of all available data the HMPC agreed to the recommendation of the Rapporteur to start the assessment towards monograph establishment for

- Centellae asiaticae herba

An overview on proposals for assessment and the status of HMPC assessment work is available here:

- Inventory of herbal substances for assessment – proposals for assessment (EMA/HMPC/494079/2007)
- Overview of assessment work - Priority list (EMA/HMPC/278067/2006)

[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)

## Procedural guidance

After public consultation the HMPC adopted an amendment to the following **revised procedure**:

- Procedure on management of proposals submitted by interested parties for EU List Entries or EU Herbal Monographs (EMA/HMPC/328575/2007 Rev.2)

The draft revised procedure together with the Overview of comments will be published on the European Medicines Agency's website at:

<https://www.ema.europa.eu/en/human-regulatory/herbal-products/procedures-monograph-list-entry-establishment>

## **EU herbal monographs in preparation**

### **New monographs - drafts**

The HMPC discussed the assessment and possibilities for monographs on *Calendulae herba* and *Verbenae citriodoraefolium*.

### **Review of monographs for decision on revision**

The HMPC discussed the need to revise monographs after review of newly available data on *Arctii radix*, *Orthosiphonis folium*, *Taraxaci folium*, *Taraxaci radix cum herba*, *Quercus cortex* and *Solidaginis virgaureae herba*.

### **Monograph revisions - drafts**

The HMPC discussed and agreed on draft revised documents for *Millefolii herba* for peer-review and possible adoption for release for public consultation in November 2019.

## **Contact for further information**

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