



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

25 November 2019  
EMA/HMPC/639497/2019  
Committee on Herbal Medicinal Products (HMPC)

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

The 90<sup>th</sup> HMPC meeting, held on 18-20 November 2019

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 90<sup>th</sup> meeting of the Committee.

The Committee noted the nomination of Matthew Camilleri as new alternate for Malta.

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 current chair. No candidate reached a majority during this round. A new chair election will therefore be organised at the January HMPC meeting.

### New European Union herbal monograph

The HMPC adopted the following **draft documents** for **public consultation until 15 March 2020**:

- EU herbal monograph on *Herniariae herba*

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

The Committee further decided to cancel the assessment towards monograph establishment in line with procedure EMA/HMPC/84530/2010 Rev.2 for:

- *Calendulae herba*

due to insufficient data available in the public domain for the only preparation marketed in different ways in EU member states.



## Revised European Union herbal monograph and list entry

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

- Revised EU herbal monograph and new draft list entry on Millefolii herba

The draft revised monograph and the new draft list entry 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 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 would change the content of the:

- EU herbal monograph on Quercus cortex
- EU herbal monograph on Taraxaci folium
- EU herbal monograph on Taraxaci radix cum herba

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)

Upon recommendation from the Rapporteur, the HMPC decided after systematic review according to procedure EMA/HMPC/124695/2011 Rev. 2 that revision is required because new data of relevance were detected that could change the content of the:

- EU herbal monograph on Orthosiphonis folium

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

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

- 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)

## Scientific guidance

After public consultation and discussion of comments and available data the HMPC adopted a new amended version for **public consultation until 30 April 2020** of the:

- Public statement on the use of herbal medicinal products containing estragole (EMA/HMPC/137212/2005 Rev 1)

Due to substantial changes in the draft revised public statement compared to the draft previously published, the HMPC decided to exceptionally allow a second public consultation for transparency.

The second draft revised public statement together with the Overview of comments received during the previous consultation 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**

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

The HMPC discussed the need to revise the monograph on *Arctii radix* as well as on *Sabalidis serrulatae fructus* after review of newly available data.

### **Monograph revisions - finalisation**

After public consultation the committee finalised its assessment for monograph revision on *Hippocastani semen*, *Menthae piperitae aetheroleum* and *Menthae folium*. Following peer-review, final adoption is scheduled for January 2020.

### **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 key topics in the herbal area. Updates were given and views exchanged with regard to HMPC guidance development concerning herbal products containing pyrrolizidine alkaloids, estragole and polycyclic aromatic hydrocarbons; the alignment of EU herbal monographs with Ph. Eur. monographs as regards declaration of the active substance; the publication of HMPC meeting outcomes; the increase in European procedures for herbal medicinal products including use of EU herbal monographs; and the possible impact of the Medical Device Regulation for products containing herbal ingredients. A hearing report will be published here:

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

### **Contact for further information**

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