



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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EMA/HMPC/213739/2018  
Committee on Herbal Medicinal Products (HMPC)

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

The 81<sup>st</sup> HMPC meeting, held on 26-27 March 2018

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 81<sup>st</sup> meeting of the Committee.

The Committee elected Ewa Balkowiec Iskra as new co-opted member with expertise in Clinical pharmacology for a 3-year mandate starting 04 June 2018. The new HMPC co-opted member was also appointed as new MLWP member.

### Revised European Union herbal monographs

Upon recommendation from the MLWP, the HMPC adopted after systematic review the following **final revised** EU herbal monograph:

- Revised EU herbal monograph on Cimicifugae rhizoma (by majority)

The revised monograph together with the HMPC opinion and supporting documents including the Overview of comments received during public consultation will be published on the European Medicines Agency's website 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 MLWP, the HMPC adopted after systematic review the following **final revised** EU herbal monographs:

- Revised EU herbal monograph on Agni casti fructus (by majority)
- Revised EU herbal monograph on Calendulae flos (by consensus)
- Revised EU herbal monograph on Cynarae folium (by consensus)
- Revised EU herbal monograph on Sambuci flos (by consensus)
- Revised EU herbal monograph on Verbasci flos (by consensus)

Because of only minor changes compared to the original monographs the HMPC considered that a public consultation is not necessary.

The revised monograph together with the HMPC opinion and supporting documents will be published on the European Medicines Agency's website 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)

After systematic review the following **draft revised** EU herbal monograph has been adopted for **public consultation until 15 July 2018**:

- Draft revised EU herbal monograph on Gentianae radix

Draft revised documents will be published here:

[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)

## Draft European Union herbal monographs

Upon recommendation from the MLWP the following new **draft** EU herbal monograph has been adopted for **public consultation until 15 July 2018**:

- Draft EU herbal monograph on Fragariae folium

Draft documents will be published here:

[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)

## Other

### Monograph review outcome according to procedure EMA/HMPC/124695/2011 Rev. 2

Upon recommendation from the Rapporteur and MLWP, the HMPC decided after systematic review that no revision is required because no new data of relevance were detected that would change the content of the following EU herbal monographs:

- EU herbal monograph on Avenae fructus (by consensus)
- EU herbal monograph on Avenae herba (by consensus)

The review summary and HMPC position 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](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/herbal_search.jsp&mid=WC0b01ac058001fa1d)

## Quality Drafting Group (Q DG)

The HMPC noted the report on the Q DG meeting held on 22 February 2018 (face-to-face).

The progress with drafting activities was reported with main focus on revision of the guidelines on quality and specifications.

The next meeting of the Q DG will be held on 19 April 2018.

## Organisational Matters Drafting Group (ORGAM DG)

The HMPC noted a report on the ORGAM DG meeting held on 14 March 2018.

Upon recommendation by the DG, the committee adopted Revision 4 of the Procedure for calls for scientific data for use in HMPC assessment works (EMA/HMPC/1004/2006 Rev. 4).

Minor changes had been introduced with regard to the use of unpublished data and the introduction of the modified review/revision procedure. The revised procedure will be published 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)

HMPC further noted a report by the ORGAM Chair on the progress with regard to 6 procedural topics.

The next meeting of the DG ORGAM is scheduled for 23 April 2018.

## **Report from the March 2018 meeting of the Working Party on European Union Monographs and List (MLWP)**

The MLWP held its 72<sup>st</sup> meeting at the European Medicines Agency on 27- 28 March 2018.

### **New assessments - final**

MLWP agreed after public consultation to the draft revised documents on Glycini semen for peer review and transfer to the HMPC in June 2018 for possible final adoption.

### **New monographs - drafts**

Following request from HMPC the MLWP re-discussed and agreed to the draft revised documents on Malvae folium and Malvae sylvestris flos for transfer to the HMPC in June 2018 for possible release for public consultation.

The working party continued its assessment of Species digestivae/stomachicae.

### **Monograph revisions - finalisation**

After public consultation, the working party finalised the revision of the documents on Pelargonii radix and Curcumae longae rhizoma for peer review and transfer to the HMPC in June 2018 for possible final adoption.

The MLWP continued its assessment of Menthae piperitae folium.

For the following substances the MLWP considered the draft revisions as finalised and due to the minor changes in the revised monographs no public consultation necessary: Oenotherae biennis and Echinaceae pallidae radix. Documents are transferred for peer review and to the HMPC for possible final adoption in June 2018.

### **Monograph revisions - drafts**

The MLWP continued the revision of documents for Menthae piperitae aetheroleum and Tanacetii parthenii herba.

### **Monograph systematic review**

The MLWP agreed after systematic review that no revision of the monograph is required for Polypodii rhizoma. An amended proposal for an Addendum to the existing assessment report will be transferred to the HMPC for possible adoption in June 2018.

The MLWP agreed after systematic review that a revision of the monograph is required for Hippocastani semen. A respective proposal will be transferred to the HMPC for possible adoption in June 2018.

The working party continued to discuss the need for revision of the monograph on *Trigonellae foenugraeci semen*.

### **Contact for further information**

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