



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

11 June 2018  
EMA/HMPC/388189/2018  
Committee on Herbal Medicinal Products (HMPC)

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

The 82<sup>nd</sup> HMPC meeting, held on 04-05 June 2018

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 82<sup>nd</sup> meeting of the Committee.

### Revised European Union herbal monographs

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

- Revised EU herbal monograph on *Pelargonii radix* (by majority)

The trigger and scope of the revision were new scientific data with regard to the validity and use of the Bronchitis Severity Score (BSS; see also HMPC meeting report May 2013 and January 2015).

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 *Echinaceae pallidae radix* (by consensus)
- Revised EU herbal monograph on *Oenotherae biennis oleum* (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)



## New European Union herbal monograph

Upon recommendation from the MLWP, the HMPC adopted after a second public consultation the following **final** EU herbal monograph:

- EU herbal monograph on Silybi mariani fructus (by majority)

The 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)

## Draft European Union herbal monographs

Upon recommendation from the MLWP the following new **draft** EU herbal monographs have been adopted for **public consultation until 30 September 2018**:

- Draft EU herbal monograph on Malvae folium
- Draft EU herbal monograph on Malvae flos

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

### Public statement

Upon recommendation from the MLWP, the HMPC adopted after public consultation the following **final public statement**:

- Public statement on Glycini semen (by consensus)

Following assessment and public consultation, insufficient information was identified to allow establishment of an EU herbal monograph. No comments had been received during public consultation.

The statement 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)

### 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:

- EU herbal monograph on Polypodii rhizoma.

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)

Upon recommendation from the Rapporteur and MLWP, the HMPC decided after systematic review that monograph revision is required because new data of relevance were detected that change the content of the following EU herbal monograph:

- EU herbal monograph on Hippocastani semen

The Rapporteur and MLWP were asked to start the revision of monograph and supporting documents. Once agreed by HMPC, draft revised documents will be released for public consultation.

### **Quality Drafting Group (Q DG)**

The HMPC noted the report on the Q DG meeting held on 19 April 2018.

The progress with drafting activities was reported including completion of the draft revised guidelines on quality and specifications (adopted by HMPC for further coordination) and cooperation with EDQM and also with the Quality WP such as comments on the revised Guideline on quality of water for pharmaceutical use (EMA/150605/2018) currently under finalisation.

The next meeting of the Q DG will be held on 21 June 2018.

### **Organisational Matters Drafting Group (ORGAM DG)**

The HMPC noted a report on the ORGAM DG meeting held on 23 April 2018.

The ORGAM DG Chair reported on the progress with regard to 4 procedural topics including final amendments to the 'Procedure for the systematic review of EU herbal MOs and LEs and supporting documents' after public consultation.

The next meeting of the DG ORGAM is scheduled for 18 June 2018.

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

The MLWP held its 73<sup>st</sup> meeting at the European Medicines Agency on 05- 07 June 2018.

#### **New monographs - drafts**

The MLWP continued its assessment of *Species digestivae/stomachicae* as well as *Vaccinii macrocarpi fructus*.

#### **Monograph revisions - finalisation**

After public consultation, the working party finalised the revision of the documents on *Sennae folium* and *Sennae fructus* for peer review and transfer to the HMPC in July 2018 for possible final adoption.

MLWP further discussed comments and finalisation of the revised documents on *Valerianae radix/Lupuli flos* after public consultation.

#### **Monograph revisions - drafts**

The MLWP continued the revision of documents for *Tanaceti parthenii herba* and had a first discussion on *Hippocastani semen* following HMPC decision to start the revision procedure.

## **Monograph systematic review**

The MLWP agreed after systematic review of newly available data that no monograph revision is required for *Trigonellae foenugraeci semen*, *Myrrha* and *Phaseoli fructus (sine semine)*. The Review outcome reports as basis for Addenda to the existing assessment report will be transferred to the HMPC for possible adoption in July 2018.

## **Contact for further information**

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