



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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EMA/HMPC/82378/2015  
Committee on Herbal Medicinal Products (HMPC)

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

The 62<sup>nd</sup> HMPC meeting, held on 27-28 January 2015

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 62th meeting of the Committee.

The Chair announced the nomination of Gabriela Duchajová, new HMPC member from Slovakia.

The full composition of the HMPC can be found at:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/2010/02/people\\_listing\\_000006.jsp&mid=WC0b01ac0580028e7e](http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/2010/02/people_listing_000006.jsp&mid=WC0b01ac0580028e7e)

The HMPC re-elected I. Chinou as Chair of the Monograph and List Working Party, for a new 3-year term starting 28 January 2015.

### Final European Union herbal monographs

Upon recommendation from the MLWP as a result of its November 2014 meeting, the HMPC adopted the following final European Union herbal monographs and related documents:

- European Union herbal monograph on Agrimoniae herba, by majority vote
- European Union herbal monograph on Eschscholziae herba cum flore, by consensus
- European Union herbal monograph on Ginkgo folium, by majority vote

The final monographs as well as the HMPC opinions, assessment reports, lists of references and overview of comments 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)

### Revised European Union herbal monographs

Upon recommendation from the MLWP as a result of its November 2014 meeting, the HMPC adopted the following draft revised European Union herbal monographs for 3 months public consultation until **15 May 2015**. These revisions had been triggered by new scientific data available to the HMPC (Re-evaluation of the Validity of the Bronchitis Severity Scale BSS, see meeting report May 2013

[EMA/HMPC/301544/2013](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/herbal_search.jsp&mid=WC0b01ac058001fa1d)):



- Revised European Union herbal monograph on Hederae helices folium
- Revised European Union herbal monograph on Thymi herba/Primulae radix

The draft monographs together with the 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)

## Draft European Union herbal monographs and list entries

Upon recommendation from the MLWP, the HMPC adopted the following draft European Union herbal monographs for public consultation until **15 May 2015**:

- Draft European Union List entry on Crataegi folium cum flore
- Draft European Union herbal monograph on Myrtilli fructus recens
- Draft European Union herbal monograph on Myrtilli fructus siccus

The draft monographs together with the 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)

## Other

### **Public statements**

Upon recommendation of the MLWP following public consultation without receiving further data, the HMPC adopted the following final public statement explaining why a European Union herbal monograph could not be developed:

- Public statement on Picrorhizae kurroae rhizoma

The final public statement together with a supporting list of references 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)

### **Guidance documents**

The committee adopted the following **draft revised guideline** for public consultation until **30 June 2015**:

- Guideline on the use of the CTD format in the preparation of a registration application for traditional herbal medicinal products (EMA/HMPC/71049/2007 Rev. 2)

The draft revised guideline will be published on the European Medicines Agency's website at:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document\\_listing/document\\_listing\\_000355.jsp&mid=WC0b01ac0580118a1d](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000355.jsp&mid=WC0b01ac0580118a1d)

### **Call for scientific data**

Calls for submission of scientific data with a deadline for submission on **15 May 2015** will be initiated to support the systematic review of

- Hyperici herba
- Harpagophyti radix

These calls can be found on the European Medicines Agency's website at:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document\\_listing/document\\_listing\\_000214.jsp&mid=WC0b01ac0580033a9c](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000214.jsp&mid=WC0b01ac0580033a9c)

### ***HMPC work plan 2015***

Following final discussions and adoption in December 2014, the first annual HMPC work plan is now published:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/about\\_us/general/general\\_content\\_000122.jsp&mid=WC0b01ac0580028e7d](http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000122.jsp&mid=WC0b01ac0580028e7d)

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

The HMPC heard a report on the DG Q meeting held on 10 December 2014.

The main discussion points were Revision of the Quality Q&A, finalisation of appendix 2 (mock-up) for the CTD guideline, and the reflection paper on microbiological aspects.

The Q DG work plan 2015 is published here:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/HMPC/people\\_listing\\_000049.jsp&mid=WC0b01ac0580028e9b](http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/HMPC/people_listing_000049.jsp&mid=WC0b01ac0580028e9b)

The next meeting of the Q DG will be held on 11-12 February 2015.

### **Drafting Group on Organisational matters (DG ORGAM)**

The HMPC heard a report on the DG ORGAM meeting held on 9 December 2014.

The Committee adopted some modifications as regards to list entry revision introduced in:

- Procedure for the systematic review of European Union herbal monographs and/or European Union list entries and supporting documents (EMA/HMPC/124695/2011 rev 1)

The document will be published here:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document\\_listing/document\\_listing\\_000212.jsp&mid=WC0b01ac058003380a](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000212.jsp&mid=WC0b01ac058003380a)

The drafting group had further reviewed the suitability of the QRD template used in mutual recognition and decentralised procedures regarding specifics for (traditional) herbal medicinal products.

The ORGAM work plan 2015 is published here:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/HMPC/people\\_listing\\_000048.jsp&mid=WC0b01ac0580028e9a](http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/HMPC/people_listing_000048.jsp&mid=WC0b01ac0580028e9a)

The next meeting of the DG ORGAM will be held on 10 February 2015.

### **Report from the January 2015 Working Party on European Union Monographs and List (MLWP)**

The MLWP held its 53<sup>rd</sup> meeting at the European Medicines Agency on 28–30 January 2015.

#### ***Monograph revisions***

The MLWP discussed draft revised monographs on *Menthae piperitae aetheroleum*, *Menthae piperitae folium* and *Valerianae radix*.

### ***Monograph finalisation***

The working party had a first discussion on *Capsici fructus* after public consultation.

### ***Monograph drafts***

The MLWP endorsed the draft monograph on *Epilobii herba* and agreed on draft documents for the assessment of *Uncariae tomentosae cortex* and *Balsamum peruvianum* for transmission to HMPC and possible release in March 2015 for public consultation.

The working party continued its assessment of *Silybi mariani fructus*, *Origanii majoranae herba* and *Pistacia lentiscus resinum* (mastix) and had first discussions on the assessment of *Helichrysi flos*, *Sideritis herba* and *Cisti cretici folium*.

The MLWP work plan 2015 is published here:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/HMPC/people\\_listing\\_000046.jsp&mid=WC0b01ac0580028e98](http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/HMPC/people_listing_000046.jsp&mid=WC0b01ac0580028e98)

The next meeting of the MLWP is scheduled for 10–12 March 2015.

### **Contact for further information**

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