



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

14 October 2015  
EMA/HMPC/657448/2015 *Corr.*<sup>1</sup>  
Committee on Herbal Medicinal Products (HMPC)

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

The 66<sup>th</sup> HMPC meeting, held on 28-29 September 2015

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 66<sup>th</sup> meeting of the Committee including Una Mockler now as member and Annamarie O'Sullivan as new alternate for Ireland. The renunciation of Artūras Kažemekaitis (awaiting new member nomination from Lithuania) was announced.

### Final European Union herbal monographs

Upon recommendation from the MLWP, the HMPC adopted the following final EU herbal monographs and supporting documents:

- European Union herbal monograph on *Myrtilli fructus recens*, by majority vote
- European Union herbal monograph on *Myrtilli fructus siccus*, by majority vote

The 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)

### Revised European Union herbal monographs

Upon recommendation from the MLWP the HMPC adopted the following draft revised EU herbal monograph and supporting documents for 3 months public consultation until **31 January 2016**:

- European Union herbal monograph on *Pelargonii radix*

The review 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). Although no major changes were introduced in the monograph, a public consultation was considered useful after careful new assessment of scientific data as reflected in the revised assessment report. Interested parties are given the opportunity to comment before finalisation of the revision.

---

<sup>1</sup> Correction of end of consultation date under heading 'Guidance documents'.



The revised 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

Upon recommendation from the MLWP, the HMPC adopted the following draft EU herbal monographs for public consultation until **15 January 2016**:

- Draft European Union herbal monograph on *Helichrysi flos*
- Draft European Union herbal monograph on *Polygonii avicularis herba*

The draft monograph 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)

## Guidance documents

The Committee adopted the:

- Concept paper on the revision of the "Guideline on the assessment of clinical safety and efficacy in the preparation of Community Herbal Monographs for Well-established and of Community Herbal Monographs/Entries to the Community list for Traditional Herbal Medicinal Products/Substances/Preparations" (EMA/HMPC/427510/2015)

The concept paper will be published here:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general\\_content\\_000427.jsp&mid=WC0b01ac0580034cf7](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000427.jsp&mid=WC0b01ac0580034cf7)

Interested parties are welcome to submit comments by **31 January 2016**.

The Committee further adopted the

- Revised public statement on the prioritisation for assessment of herbal substances associated with safety concerns (EMA/HMPC/682247/2013 Rev. 1)

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

## Other

### ***Prioritisation of new substances for assessment and call for scientific data***

Upon recommendation by the MLWP the Committee agreed to the assessment of

- *Vaccinium macrocarpon*, fructus
- *Malva sylvestris*, flos
- *Malva sylvestris*, folium

Calls for submission of scientific data with a deadline for submission by **31 January 2016** will be initiated to support the first assessment.

The HMPC agreed to the requests based on preliminary information from NCAs on the likelihood to establish 15/30 years long-standing safe medicinal use for a harmonised European opinion on safety and efficacy. The MLWP was asked to assign Rapporteur and Peer reviewer.

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)

### ***Cancellation of assessment work***

Upon recommendation by the MLWP the Committee agreed not to issue a call for scientific data and to discontinue the assessment work for

- Cinnamomi camphorae cortex / folium/ aetheroleum

Following a request for information on products on the market among National Competent Authorities, the Rapporteur considered available data on the traditional use as insufficient with reference to identification of combination products only, mainly with synthetic camphor, as well as difficulties to distinguish between synthetic and natural camphor.

### ***Prioritisation of substances for monograph systematic review and revision***

The HMPC confirmed the need to keep monographs as up-to-date EU standard for national procedures. In view of limited resources and the back-log with the systematic review of monographs after 5 years, the Committee agreed to a proposal by the Monograph and List Working Party to prioritise 35 substances for systematic review. The MLWP work plan 2016 will be drafted accordingly.

For possible finalisation in 2016:

- Absinthii herba
- Aloe
- Althaeae radix
- Equiseti herba
- Foeniculi amari fructus
- Foeniculi amari aetheroleum
- Foeniculi dulcis fructus
- Harpagophyti radix
- Meliloti herba
- Menthae piperitae aetheroleum
- Menthae piperitae folium
- Salicis cortex
- Salviae officinalis folium
- Salviae officinalis aetheroleum
- Sennae folium
- Sennae fructus
- Valerianae radix

For possible finalisation in 2017:

- Agni casti fructus
- Cimicifugae rhizoma
- Curcumae longae rhizoma
- Cynarae folium
- Echinaceae purpureae radix
- Echinaceae pallidae radix
- Frangulae cortex
- Hederae hellicis folium
- Hyperici herba
- Hippocastani semen
- Millefolii flos
- Millefolii herba
- Oleae folium
- Rhamni purshianae cortex
- Rhei radix
- Uvae ursi folium
- Valerianae radix/Lupuli flos
- Vitis viniferae folium

Calls for submission of new scientific data to support the systematic review, if not already published, will be initiated in waves. Interested parties are invited to submit new data relevant for the monographs with a deadline **31 January 2016** for following substances:

- *Aesculus hippocastanum*, semen
- *Arctostaphylos uva-ursi*, folium
- *Cimicifuga racemosa*, rhizoma
- *Echinacea purpurea*, radix
- *Hedera helix*, folium
- *Vitex agnus-castus*, fructus
- *Vitis vinifera*, folium

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)

The HMPC priority list and inventory will be updated accordingly. The documents can be found here:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general\\_content\\_000208.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05800240cf](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000208.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05800240cf)

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

The HMPC heard a report on the DG Q meeting held on 10 September 2015.

The DG discussed the follow-up on the reflection paper on microbiological aspects (EMA/HMPC/95714/2013) and draft Q&A in this regard. Because of detailed discussions expected during the HMPC assessors training in December finalisation of the Q&A is only expected in February 2016. The revision 3 of the Guideline on quality of herbal medicinal products/traditional herbal medicinal products was started. DG Q had further discussed the preparation of the 2015 HMPC assessors training on quality as well as status of work 2015 and a first draft of the work plan 2016.

The next meeting of the DG Q will be held on 15 October 2015.

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

The meeting of the DG ORGAM scheduled for 8 September 2015 had been cancelled.

The next meeting of the DG ORGAM is scheduled for 13 October 2015.

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

The MLWP held its 57<sup>th</sup> meeting at the European Medicines Agency on 29 September–01 October 2015.

### ***Monograph revisions***

The working party discussed and endorsed the revised documents on *Hederae heliis folium* after public consultation for peer review and transfer to the Committee for final adoption as well as the draft revised documents on *Althaeae radix* for possible public consultation in November 2015.

The MLWP further discussed revised documents on *Salviae officinalis folium*, *Salviae officinalis aetheroleum*, *Aloe*, *Harpagophyti radix*, *Sennae folium* and *Sennae fructus*.

### ***Monograph finalisation***

Upon request by the HMPC, the working party re-discussed and finalised the documents on *Sabalisa serrulatae fructus* for possible final adoption at the HMPC November 2015 meeting.

Following public consultation, the MLWP discussed and endorsed the documents on *Crataegi folium cum flore*, *Epilobii herba* and *Uncariae tomentosae cortex* for peer review and transfer to the Committee for possible final adoption in November 2015.

### ***Monograph drafts***

The MLWP discussed and endorsed the draft documents on *Balsamum peruvianum*, *Pruni africanae cortex* and *Cisti cretici folium* for transfer to the HMPC for possible release in November 2015 for public consultation.

The working party continued its assessment of *Fragariae folium* and had a first discussion on the assessment of *Saccharomyces cerevisiae/S. boulardii*.

The next meeting of the MLWP is scheduled for 24-26 November 2015.

### **Contact for further information**

Anthony Humphreys

Head of Procedure Management and Committees Support Division (ad interim)

Tel.: +44 (0)20 7418 8583

Fax: +44 (0)20 7523 7051

E-mail: [hmpc.secretariat@ema.europa.eu](mailto:hmpc.secretariat@ema.europa.eu)