



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

The 61th HMPC meeting, held on 24 November 2014

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 61th meeting of the Committee.

The Chair announced the resignation of M. Backes-Lies as member for Luxembourg.

The HMPC re-elected S. Giroto as co-opted member with expertise in paediatric medicine, for a 3-year term starting 27 January 2015.

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)

### Entry to the list of herbal substances, preparations and combinations thereof

Upon recommendation from the MLWP as a result of its September 2014 meeting, the HMPC adopted the following list entry and related documents:

- Melaleucaea alternifoliae aetheroleum, by majority vote

The list entry as well as the HMPC opinion, assessment report and list of references will be transmitted to the European Commission.

### Final European Union herbal monographs

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

- European Union herbal monograph on Lichen islandicus, by consensus
- European Union herbal monograph on Melaleucaea alternifoliae aetheroleum, 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/herbal/medicines/herbal\\_med\\_000174.jsp&mid=WC0b01ac058001fa1d](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000174.jsp&mid=WC0b01ac058001fa1d)



## Revised European Union herbal monographs

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

- European Union herbal monograph on *Betulae folium*, by majority vote
- European Union herbal monograph on *Echinaceae purpureae herba*, by majority vote

The revised monographs as well as the HMPC opinions, assessment reports and lists of references will be published on the European Medicines Agency's website at:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal\\_med\\_000174.jsp&mid=WC0b01ac058001fa1d](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000174.jsp&mid=WC0b01ac058001fa1d)

## Draft European Union herbal monographs

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

- European Union herbal monograph on *Carvi aetheroleum*
- European Union herbal monograph on *Carvi fructus*
- European Union herbal monograph on *Sabalis serrulatae fructus*

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/herbal/medicines/herbal\\_med\\_000174.jsp&mid=WC0b01ac058001fa1d](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000174.jsp&mid=WC0b01ac058001fa1d)

## Other

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

Upon recommendation of the MLWP the HMPC agreed to cancel the assessment work on *Cyani flos* and *Myrtilli folium* due to insufficient data.

### ***Guidance documents***

The committee adopted the

- Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs)

The **final** public statement will be published on the European Medicines Agency's website at:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general\\_content\\_000497.jsp&mid=WC0b01ac05804545f1](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000497.jsp&mid=WC0b01ac05804545f1)

The committee adopted the following **draft revisions** for public consultation until **31 March 2015**:

- Public statement on the use of herbal medicinal products containing estragole
- Public statement on the use of herbal medicinal products containing pulegone and menthofuran

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

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general\\_content\\_000497.jsp&mid=WC0b01ac05804545f1](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000497.jsp&mid=WC0b01ac05804545f1)

### ***Call for scientific data***

Calls for submission of scientific data with a deadline for submission on **15 March 2015** will be initiated to support the assessment of

- Cinnamomi camphorae folium/cortex
- Fragariae folium

and the systematic review of

- Altheae radix
- Centaurii herba
- Salviae officinalis folium.

The 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)

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

The HMPC heard a report on the DG Q meeting held on 12 November 2014.

Beside guidance on benzene as a potential impurity in solvents used for the manufacture of herbal preparations, the group had prepared a recommendation on the comparability on virgin and refined castor oil to support MLWP assessment work and drafted the 2015 work plan proposed to the HMPC.

The next meeting of the DG Q will be held on 10 December 2014.

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

The HMPC heard a report on the DG ORGAM meeting held on 10 November 2014.

The group had reviewed the suitability of the QRD template used in mutual recognition and decentralised procedures regarding specifics for (traditional) herbal medicinal products and had started the work on procedural details for the revision of list entries.

The Committee agreed to further procedural scrutiny on the revision procedure of List entries in order to establish a differentiation based on the magnitude of the modification to trigger a revision process.

The next meeting of the DG ORGAM will be held on 9 December 2014.

### **Report from the November 2014 Working Party on European Union Monographs and List (MLWP)**

The MLWP held its 52th meeting at the European Medicines Agency on 26-28 November 2014.

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

The MLWP re-discussed and endorsed the draft revised monographs on Lini semen, Thymi herba/Primulae radix and Hederae heliis folium. The revised monographs together with supporting documents will be finalised by the Rapporteur and transmitted, after peer-review, to the HMPC for adoption at the January 2015 meeting.

### ***Monograph finalisation***

The working party discussed and endorsed the final documents on Ginkgo folium, Agrimoniae herba, Eschscholziae herba cum flore, Picrorhizae kurroae rhizoma and Pilosellae herba cum flore, taking into account comments received by interested parties (if any). After peer review, the documents will be finalised by the Rapporteurs and transmitted to the HMPC for possible final adoption at the January 2015 meeting.

The working party had a first discussion on Matricariae aetheroleum and Matricariae flos after public consultation.

### ***Monograph drafts***

The MLWP endorsed the draft monographs on Myrtilli fructus siccus and Myrtilli fructus recens; and a draft list entry for Crataegi folium cum flore for transmission to HMPC and possible release in January 2015 for public consultation.

The working party continued its assessment of Ricini oleum and Silybi mariani fructus and had first discussions on the assessment of Balsamum peruvianum, Epilobii herba, Salviae trilobae folium, Origanum majoranae herba and Pistacia lentiscus resinum (mastix).

The next meeting of the MLWP is scheduled for 28–30 January 2015.

## **HMPC Assessors Training 2014**

An HMPC Assessors Training on the development and use of European Union herbal monographs was held at the Agency on 25 November 2014. The training covered specific challenges in establishment of monographs and on the other side experiences with monographs in national and European procedures. Examples, problems, solutions, open questions were discussed based on 8 presentations from experienced assessors.

More than 60 participants in London and 25 participants online formed a platform for an in-depth exchange between members of HMPC/MLWP and assessors at the national competent authorities. The usefulness of monographs in national and MRP/DCP procedures was unanimously underlined. Benefits but also limits of the European harmonised view on the use of a herbal substance vis-à-vis the specific assessment of individual final products were demonstrated. Views were exchanged as regards use of monographs, HMPC documents and additional data required leading to proposals to be taken into account for monograph establishment/revision. Moreover the importance of monographs for patients and health care professionals beyond their regulatory role for product registration/authorisation was emphasized by some participants and proposals discussed to better disseminate such valuable assessments to the public.

## **Contact for further information**

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