



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

16 March 2016 *Corr.*<sup>1</sup>  
EMA/HMPC/99558/2016  
Committee on Herbal Medicinal Products (HMPC)

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

The 68<sup>th</sup> HMPC meeting, held on 1-2 February 2016

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 68<sup>th</sup> meeting of the Committee.

The HMPC elected Prof. Heidi Foth as new co-opted member with expertise in toxicology for a 3-year term starting 4 April 2016. She was also appointed to replace Prof. O. Pelkonen as toxicologist in the Monograph and List Working Party (MLWP).

The HMPC elected Dr. Linda Anderson as new Chair of the Quality Drafting Group for a 3 year term starting 11 March 2016.

The Chair thanked both, O. Pelkonen and Dr. B. Kroes, the previous Q DG Chair, for their work over a decade and important contributions in their respective roles.

The current compositions of HMPC, MLWP and QDG can be found here:

[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)

[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)

[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)

### Entries to the European Union List of herbal substances

Upon recommendation from the MLWP, the HMPC adopted the following EU list entries and supporting documents for transmission to the European Commission for adoption and publication:

- EU list entry on Valerianae radix, by majority vote
- EU list entry on Sideritis herba, by majority vote

All draft list entries adopted by the HMPC can be found here (browse by outcome 'list entry'):

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<sup>1</sup> Editorial



[http://www.ema.europa.eu/ema/index.jsp?curl=/pages/medicines/landing/herbal\\_search.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001fa1d](http://www.ema.europa.eu/ema/index.jsp?curl=/pages/medicines/landing/herbal_search.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001fa1d)

All final list entries adopted and published by the European Commission can be found here:  
[http://ec.europa.eu/health/human-use/herbal-medicines/index\\_en.htm](http://ec.europa.eu/health/human-use/herbal-medicines/index_en.htm)

## Final European Union herbal monographs

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

- EU herbal monograph on Mastix, by majority vote
- EU herbal monograph on Ricini oleum, by majority vote
- EU herbal monograph on Sideritis herba, by consensus

The monographs together with the supporting documents including the overview of comments when available, 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 monograph

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

- Draft EU herbal monograph on Origani majoranae 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)

## Revised European Union herbal monographs

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

- EU herbal monograph on Equiseti herba, by majority vote
- EU herbal monograph on Valerianae aetheroleum, by majority vote
- EU herbal monograph on Valerianae radix, by majority vote

The Committee further adopted the following **draft** revised EU herbal monographs and supporting documents for 3 months public consultation until **15 May 2016**:

- EU herbal monograph on Harpagophyti radix
- EU herbal monograph on Salviae officinalis folium

The final and draft revised 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)

## Public statements

The HMPC adopted the following **draft** public statements and supporting documents for 3 months public consultation until **15 May 2016**:

- Public statement on Paeoniae radix alba
- Public statement on Paeoniae radix rubra

The reasons why EU herbal monographs cannot currently be drafted are explained and interested parties are invited to submit additional data to allow the continuation of assessment towards monograph establishment.

The draft public statements together with 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

### Call for scientific data (systematic monograph review)

According a MLWP proposal the HMPC agreed to initiate a call for new scientific data supporting the systematic review of

- Boldi folium

The call with a deadline for submission by **15 May 2016** 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)

### Public statement minor correction

The Committee agreed to minor corrections to the public statement as requested by the Rapporteur:

- Public statement on Salviae aetheroleum

Following the systematic review and update of assessment report and List of references, no new data were identified to allow the establishment of a monograph. The PS *Corr.* with minor updates will be made available 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)

## Quality Drafting Group (QDG)

The HMPC heard a report on the QDG meeting (face to face) held on 8-9 December 2015.

The DG had discussed comments received on the revised herbal CTD guideline, mainly the new Appendix 2 'mock-up module 3'. Changes were introduced in the document and the Overview of comments finalised. Beside the follow-up on the Assessors training on quality, coordination topics with the CHMP QWP and with EDQM were discussed such as changes in Ph. Eur monographs affecting HMPC monographs, a proposal for an amendment of the Ph. Eur. herbal extracts monograph for clarification of the drug extract ratio ( $DER_{\text{genuine}}$  versus  $DER_{\text{total}}$ ), and status of the Ph. Eur. 13 A expert group activities as regards essential oils.

The next meeting of the QDG (virtual) will be held on 11 February 2016.

## Organisational Matters Drafting Group (ORGAM DG)

The HMPC heard a report on the DG ORGAM meeting (virtual) held on 10 December 2015.

The DG had discussed comments received by the QRD group and further progressed with an annotated QRD template which addresses specifics for HMP/THMP.

The next meeting of the DG ORGAM is scheduled for 09 February (virtual) 2016.

## **Report from the February 2016 meeting of the Working Party on European Union Monographs and List (MLWP)**

The MLWP held its 59<sup>th</sup> meeting at the European Medicines Agency on 3–4 February 2016.

### **Monograph finalisation**

Following public consultation, the MLWP discussed and endorsed the documents on *Helichrysi flos* and *Polygoni avicularis herba* for peer review and possible transfer to the Committee for possible final adoption in April 2016.

### **Monograph drafts**

The MLWP discussed and endorsed the draft documents on *Cisti cretici folium* for transfer to the HMPC for possible release in April 2016 for public consultation.

The working party continued its assessment of *Allii sativi bulbus* and *Saccharomyces cerevisiae*.

### **Monograph revisions**

The working party discussed and endorsed the revised documents after public consultation on *Thymi herba*/ *Primulae radix* for peer review and transfer to the HMPC for final adoption at the April 2016 meeting.

The MLWP further discussed the systematic review and revision of *Aloe*, *Meliloti herba* and *Salicis cortex*.

### **Guidance documents**

The MLWP endorsed a draft Reflection paper on herbal medicinal products containing polycyclic aromatic hydrocarbons (PAH) for transfer to the HMPC for discussion and possible release in April 2016.

The working party continued its revision of the 'Guideline on assessment of clinical safety and efficacy in the preparation of monographs and list entries (EMEA/HMPC/104613/2005)' taking into account comments received on the concept paper.

The next meeting of the MLWP is scheduled for 5-7 April 2016.

## **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)