



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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EMA/HMPC/489336/2016  
Committee on Herbal Medicinal Products (HMPC)

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

The 71<sup>st</sup> HMPC meeting, held on 11-12 July 2016

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 71th meeting of the Committee. Changes in composition were announced: Slovenia new member is Samo Kreft and new alternate Barbara Razingar. Bulgaria: end of mandate for alternate Kapka Kaneva; new nomination awaited.

The composition of the HMPC 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)

### Final European Union herbal monograph

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

- EU herbal monograph on Pruni africanae cortex, by consensus

The monograph together with the 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 HMPC adopted the following **draft** EU herbal monographs for public consultation until **31 October 2016**:

- Draft EU herbal monograph on Allii sativi bulbus
- Draft EU herbal monograph on Soiae oleum raffinatum
- Draft EU herbal monograph on Lecithinum ex soya

The draft monograph together with the draft assessment report and 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)

## 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 Althaeae radix, by consensus
- EU herbal monograph on Harpagophyti radix, by consensus

The monographs together with the 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)

## Call for scientific data (systematic monograph review)

In April the HMPC had agreed to initiate the systematic review of 13 herbal substances previously not prioritised in work plans for systematic review. This is the third wave of Calls for new scientific data supporting the review of:

- Myrrha
- Oenotherae biennis oleum
- Polypodii rhizoma
- Trigonellae foenugraeci semen

The call with a deadline for submission by **15 October 2016** can be found on the European Medicines Agency's website

at: [http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general\\_content\\_001149.jsp&mid=WC0b01ac0580033a9d](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001149.jsp&mid=WC0b01ac0580033a9d)

## Scientific guidance

The HMPC adopted the following guidance documents:

- Draft revised Guideline on assessment of clinical safety and efficacy in the preparation of EU herbal monographs for well-established and of EU herbal monographs/entries to the list for traditional herbal medicinal products/substances/preparations ([EMA/HMPC/104613/2005 Rev. 1](#))

The **draft revision 1** of the guideline will be published for 3 months consultation until **30 November 2016** and will be found here:

[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)

- Concept paper on the revision of the 'Guideline on non-clinical documentation for herbal medicinal products in applications for marketing authorisation (bibliographical and mixed applications) and in applications for simplified registration' ([EMEA/HMPC/32116/2005](#))

Interested parties are invited to send comments on the planned revision of the guideline by **30 November 2016**. The **concept paper** will be published here:

[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)

- Public statement on the use of herbal medicinal products containing pulegone and menthofuran' (EMA/HMPC/138386/2005 Rev. 1)

Following public consultation and coordination with CHMP/ SWP and CMDh the HMPC adopted the modified final revision 1. After endorsement by CHMP and CMDh, **the final revision 1** of the public statement and the Overview of comments received during public consultation will be published here:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general\\_content\\_000497.jsp&mid=WC0b01ac0580033a9b](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000497.jsp&mid=WC0b01ac0580033a9b)

## **Quality Drafting Group (QDG)**

The HMPC heard a report on the QDG meeting held on 28 June 2016.

The DG finished the draft revision of the herbal quality guideline which is planned to be released for public consultation in conjunction with the revised specification guideline (expected end of 2016). The group further discussed the follow-up on extended quality Q&A, guidance on use of new analytical methods, coordination topics with EDQM, QWP and requests from NCAs.

The next meeting of the QDG will be held on 07 September 2016.

The HMPC adopted a revised mandate for the drafting group. Based on the new mandate the new composition of the group as regards active members and observers was agreed by the committee (mandate start 12/07/2016). The new mandate and composition of the drafting group will be 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)

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

The HMPC heard a report on the DG ORGAM meeting held on 30 June 2016.

The DG discussed the revision of the 'Procedure for the systematic review of EU herbal MOs and LEs and supporting documents', proposals on update of existing template for EU herbal monographs, addition to regulatory Q & A, final amendments to QRD template specifics for THMPs, and progression with items on the 2016 work plan.

The next meeting of the DG ORGAM is scheduled for 06 September 2016.

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

The MLWP held its 62<sup>th</sup> meeting at the European Medicines Agency on 12-14 July 2016.

### **New monographs - finalisation**

Following request by HMPC, the MLWP reviewed and endorsed the documents on *Silybi marianae fructus* for possible final adoption at the HMPC September meeting. The working party further discussed the progression of assessment for *Paeoniae radix alba* and *Paeoniae radix rubra* following public consultation.

## **New monograph - drafts**

The MLWP discussed and endorsed the draft documents on 'Species diureticae' for early peer review and transfer to the HMPC for possible release in September 2016 for public consultation.

The working party continued its assessment of Glycini semen and had first discussions on Calendulae herba and Piperis methystici rhizoma.

## **Monograph revisions**

Following public consultation, the working party finalised the revision of Pelargonii radix and Salviae officinalis folium for peer-review and possible final adoption at the HMPC September meeting. The MLWP further endorsed revised documents for Echinacea purpureae radix for possible adoption by the HMPC.

The MLWP continued the systematic review of Meliloti herba, Salicis cortex and Oleae folium and had first discussions on the revision of Boldi folium and Vitis viniferae folium.

## **Contact for further information**

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