



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

11 February 2014  
EMA/HMPC/67144/2014  
Committee on Herbal Medicinal Products (HMPC)

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

The 56th HMPC meeting, held on 27-28 January 2014

The HMPC re-elected Dr Emiel van Galen (The Netherlands) as Chair of the ORGAM DG for a 3-year mandate starting 27 January 2014.

### Final Community herbal monographs

Upon recommendation from the MLWP as a result of its November 2013 meeting, the HMPC adopted the following final Community herbal monographs and related documents:

- Community herbal monograph on *Curcuma xanthorrhizae rhizoma*, by consensus
- Community herbal monograph on *Rubi idaei folium*, a majority vote

The final Community herbal monographs as well as the HMPC opinion, assessment report and overview of comments received during the consultation period (if any), 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&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)

### Draft Community herbal monographs

Upon recommendation from the MLWP, the HMPC adopted the following draft Community herbal monograph for public consultation until 15 June 2014:

- Draft Community herbal monograph on *Ginkgo folium*

The monograph together with the draft 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&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)



## Final public statements

Upon recommendation from the MLWP as a result of its November 2013 meeting, the HMPC adopted the following final public statement and related documents:

- Public statement on Sambuci fructus, by consensus

The final public statement as well as the HMPC assessment report and overview of comments received during the consultation period, 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&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)

## Drafting Group on Quality (DG Q)

The HMPC heard a report on the DG Q (virtual) meeting held on 15 January 2014.

The drafting group having finalised the whole set of questions and answers on quality of essential oils, the HMPC adopted them together with the final 'Reflection paper on the quality of essential oil as active substances in herbal medicinal products /traditional herbal medicinal products' (EMA/HMPC/84789/2013). The questions and answers will be integrated in the general 'Questions & Answers on quality of HMP/THMP' (EMA/HMPC/41500/2010 Rev.3).

The HMPC adopted the draft 'Reflection paper on microbiological aspects of HMP/THMP' (EMA/HMPC/95714/2013) for release for public consultation until 15 June 2014.

The documents will be published at:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general\\_content\\_000365.jsp&mid=WC0b01ac0580029569](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000365.jsp&mid=WC0b01ac0580029569)

The next meeting of the DG Q will be held on 12-13 February 2014. The drafting group will work on the elaboration of a mock-up module 3 as second appendix to the 'Guideline on the use of the CTD format in the preparation of a registration application for THMP' (EMA/HMPC/71049/2007 Rev. 1.)

### ***HMPC observers in meetings of the Ph. Eur. expert groups 13A, 13B and TCM***

The HMPC welcomed the provision of financial means to allow participation of the HMPC observers in meetings of the three Expert Groups established at EDQM and responsible for the elaboration of pharmacopoeial monographs on herbal substances/preparations. Such observerships enable a continued coordination between the EMA and the European Pharmacopoeia in the field of herbal medicinal products.

## Drafting Group on Organisational matters (DG ORGAM)

The HMPC heard a report on the DG ORGAM meeting (virtual) held on 14 January 2014, in particular the progress concerning an improved structure for assessment report that support monographs (template clarified with greater instructions on intended content of the different sections) and the development of a Questions & Answers pointing to sources of (regulatory) guidance for traditional herbal medicinal products with herbal constituents from a 'non-European tradition'.

The HMPC adopted a revision of the 'HMPC procedure on publication of public statements when no monographs are established' (EMA/HMPC/84530/2010 Rev.2), clarifying the approach taken on the submission of new data by interested parties, after the publication of a final public statement that points to the data missing to establish a Community herbal monograph.

The document will be available at:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document\\_listing/document\\_listing\\_000212.jsp&mid=WC0b01ac058003380a#section5](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000212.jsp&mid=WC0b01ac058003380a#section5)

The next meeting (virtual) of the DG ORGAM is scheduled for 10 February 2014.

## **Report from the January 2014 Working Party on Community Monographs and Community List (MLWP)**

The MLWP held its 47<sup>th</sup> meeting at the European Medicines Agency on 28 to 30 January 2014.

### ***Revisions***

The MLWP continued its work towards the revision of the monograph and/or list entry (and supporting documents) on Echinaceae purpureae herba, Menthae piperitae aetheroleum, Eleutherococci radix, Passiflorae herba and Lupuli flos. Another round of MLWP discussion is scheduled for March for Echinaceae purpureae herba and Menthae piperitae aetheroleum; the others were transmitted for peer-review for possible adoption by the HMPC in March.

### ***Finalisation***

On request from the HMPC, the working party re-discussed the monograph on Ginseng radix as comments were raised in the plenary meeting at the time of presentation for adoption as final. The set of documents will be transmitted to the HMPC for possible final adoption at the March 2014 meeting.

The MLWP reviewed the comments received during the public consultation on the draft monographs on Eucalypti aetheroleum and Ononidis radix. After peer-review, the documents will be transmitted to the HMPC for possible final adoption at the March 2014 meeting. The draft monograph on Arnicae flos and supporting documents will be rediscussed by the MLWP in March.

### ***Drafts***

The MLWP continued its assessment of Matricariae flos & M. aetheroleum, Myrtilli fructus siccus, Pruni africanae cortex, Silybi mariani fructus, Sabalis serrulatae fructus, Agrimoniae herba, Lichen islandicus and Pilosellae herba cum flore. Rapporteurs for Crataegi folium cum flore and Eschscholziae herba cum flore received input from the MLWP on specific aspects of the scientific assessment work to be focused upon in the further development of the documents.

The next meeting of the MLWP is scheduled for 25-27 March 2014.

## **Contact for further information**

Anthony Humphreys  
Head of Scientific Committee Support Department  
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)