



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

24 July 2013  
EMA/HMPC/301544/2013  
Committee on Herbal Medicinal Products (HMPC)

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

The 53rd HMPC meeting, held on 8-9 July 2013

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 53<sup>rd</sup> meeting of the Committee and in particular the new member and alternate member from Croatia, respectively Ivan Kosalec and Darko Trumbetić.

### Final Community herbal monographs

The HMPC adopted the following final Community herbal monographs and related documents by consensus:

- 'Community herbal monograph on *Juglans regia* L., folium' (EMA/HMPC/346737/2011)
- 'Community herbal monograph on *Marrubium vulgare* L., herba' (EMA/HMPC/604271/2012)
- 'Community herbal monograph on *Origanum dictamnus* L., herba' (EMA/HMPC/200429/2012)

As no comments were received on the draft monographs during the period of public consultation, the final versions are published without any 'Overview of comments received during the public consultation'. 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)

### Draft Community herbal monographs

Upon recommendation from the MLWP, the HMPC adopted the following draft Community herbal monographs, for public consultation until 15 December 2013:

- Draft 'Community herbal monograph on *Arnica montana* L., flos' (EMA/HMPC/198793/2012)
- Draft 'Community herbal monograph on *Melaleuca alternifolia* (Maiden and Betche) Cheel and other species, aetheroleum' (EMA/HMPC/320932/2012)
- Draft 'Community herbal monograph on *Ononis spinosa* L. and *Ononis arvensis* L., radix' (EMA/HMPC/138317/2013)



## Draft Community list entries

Upon recommendation from the MLWP, the HMPC adopted the following draft Community list entry, for public consultation until 15 December 2013:

- Draft 'Community list entry on *Melaleuca alternifolia* (Maiden and Betche) Cheel, aetheroleum' (EMA/HMPC/281620/2013)

The draft monographs and list entry together with the supporting draft assessment reports and lists of references will be available on the Agency's website at:

[http://www.ema.europa.eu/ema/index.jsp?curl=/pages/medicines/landing/herbal\\_search.jsp&mid=WCOb01ac058001fa1d](http://www.ema.europa.eu/ema/index.jsp?curl=/pages/medicines/landing/herbal_search.jsp&mid=WCOb01ac058001fa1d)

## Final public statements

The HMPC adopted the following final public statements and related documents (list of references and/or assessment report). As no comments were received on the draft public statement during the period of public consultation, the final versions are published without any 'Overview of comments received during the public consultation'.

- 'Public statement on *Adhatoda vasica* Nees, folium' (EMA/HMPC/681468/2012)
- 'Public statement on *Angelica sinensis* (Oliv.) Diels, radix' (EMA/HMPC/681574/2012)
- 'Public statement on *Withania somnifera* (L.) Dunal, radix' (EMA/HMPC/681519/2012)

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=WCOb01ac058001fa1d](http://www.ema.europa.eu/ema/index.jsp?curl=/pages/medicines/landing/herbal_search.jsp&murl=menus/medicines/medicines.jsp&mid=WCOb01ac058001fa1d)

## Other

### ***News medicinal plants for assessment***

As anticipated in its 2012-2015 work programme, the HMPC held, in liaison with the MLWP, a discussion to identify new herbal substances/preparations that should be covered by a monograph, having considered the views expressed by both regulatory authorities and interested parties. The existence of a monograph can serve to enhance harmonisation at different levels, from facilitating the preparation of dossiers (with a focus on applicants' interest to obtain market access where marketing had not yet taken place) to enhancing, in an harmonised way across the different Member States, the maintenance of products already marketed in some parts of the European Union (with a focus on regulators' interests). The expected benefits from the development of new monographs were reviewed for all proposals received and the HMPC concluded on the below list of 17 herbal substances to be assessed. The HMPC identified indeed willingness for such assessment works to be integrated rapidly into the current pipeline of pending works for which a Rapporteur had already been appointed. The designation of Rapporteurs for these 17 herbal substances is expected to take place by the end of the year, after two new members have joined the MLWP, replacing members who resigned. The assessment capacity in the MLWP is dependent on the number of experts who can contribute to the multidisciplinary evaluation required to embrace all aspects of the scientific and regulatory exercise undertaken.

Balsamum peruvianum, Calendulae herba, Cinnamomi camphorae folium/cortex, Cisti cretici folium/resinum, Cyani flos, Epilobii herba, Glycine max semen, Helichrysi flos, Juniperi communis summitates, Origani majoranae herba, Paeoniae radix, Pistacia lentiscus, resinum (mastix), Polygoni avicularis herba, Ricini oleum, Saccharomyces cerevisiae/S. boulardii, Salviae trilobae folium, Sideritis herba

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

Following the evaluation of comments received during public consultation, the HMPC adopted a revised version of the public statement (EMA/HMPC/893108/2011), for an exceptional, second public consultation to allow interested parties commenting on substantial changes in the recommendations. The draft document, together with the overview of comments received during the first public consultation, will be available at following website:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general\\_content\\_000497.jsp&mid=WC0b01ac05804545f1d](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000497.jsp&mid=WC0b01ac05804545f1d)

Finalisation of the monograph on Symphyti radix is put on hold in the meantime.

### ***More transparency measures***

The HMPC endorsed the new initiatives towards more transparency in relation to the Agency's scientific committees' activities. The Agency's commitment in relation to the publication of agendas and minutes shall take effect, for the HMPC, in the autumn 2013. As of September 2013, the agendas of HMPC plenary meeting will be published on the EMA website on the day of the meeting. As for the minutes from a meeting, their publication will take place at the subsequent meeting, after they have been adopted.

Further transparency concerning the approval by the HMPC of Community herbal monographs and Community list entries will result from the release, in the HMPC opinion, of both name and nominating Member State<sup>1</sup> for the members having expressed a divergent position at the time of an opinion's adoption by a majority vote.

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

The HMPC heard a report on the DG Q (virtual) meeting held on 27 June 2013.

The drafting group continued its work towards guidance on microbiological aspects of herbal medicinal products and had first discussions on comments received for the draft 'Reflection paper on quality of essential oils as active substance in HMP/THMP' and the 'Concept paper on use of recovered/recycled solvents in the manufacture of herbal preparations for use in HMP/THMP'.

The next meeting (virtual) of the DG Q will be held on 25 July 2013. Experts of the DG Q together with the Chairs of the Pharmacopoeia European expert groups 13A, 13B and TCM will join a specific session within the MLWP meeting on 17 September 2013. They will discuss current quality topics, exchange work programmes and continue the important coordination between the European Directorate for the Quality of Medicines & HealthCare (EDQM) and the EMA in the field of herbal medicines.

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<sup>1</sup> For co-opted members, the area of expertise will be indicated instead of the Member State.

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

The HMPC heard a report on the two DG ORGAM (virtual) meetings on 26 June and 3 July when progress was achieved respectively with the revision of the template for ARs supporting Community herbal monographs and with the preparation of a Q&A intended to lay down guidance on non-European traditional medicines.

The next meeting of the DG ORGAM is scheduled for 15 October 2013.

## **Report from the July 2013 Working Party on Community Monographs and Community List (MLWP)**

The MLWP held its 44<sup>th</sup> meeting at the European Medicines Agency, 9-11 July 2013.

### ***Revisions***

The MLWP held a first discussion on the revision of the monograph on *Thymi herba*. It is expected that the new version will be released for public consultation.

### ***Finalisation***

Further work took place on the supporting documents for the public statement on *Andrographidis paniculatae folium*, which will be transmitted to the HMPC for final adoption at the September meeting.

### ***Drafts***

The working party continued its assessment of *Matricariae flos*, *Matricaria aetheroleum*, *Rosae flos*, *Silybi mariani fructus* and *Sisymbrii officinalis*.

### ***Work continues on Ginkgo folium***

The MLWP noted the position reached by the HMPC after discussing the conclusions from the toxicological report prepared and presented by Germany, Sweden and O. Pelkonen, on their joint assessment of the US NTP<sup>2</sup> report published at the end of March 2013. The HMPC concluded that at present there is no proof for an increased cancer risk identified for patients taking *Ginkgo* medicinal products at their approved posology. The MLWP will integrate, in its assessment to establish a monograph on *Ginkgo folium*, both the NTP report findings and their detailed evaluation. Besides continuation of this on-going work, the HMPC conclusions on the data reviewed will be sent to the SWP and the PRAC for information.

The next meeting of the MLWP is scheduled for 17-19 September 2013.

## **Contact for further information**

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<sup>2</sup> <http://ntp.niehs.nih.gov/>