



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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EMA/HMPC/768189/2012  
Patient Health Protection

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

The 49th HMPC meeting, held 19-20 November 2012

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts. On behalf of the Committee, he thanked M. Figuerola-Santos for her valuable input to the work of the HMPC in her capacity of the Eur. Com. representative, since her appointment in January 2010 in this role. Coordination and collaboration with DG SANCO is an important part of the dialogue taking place in the EU for harmonisation across competent authorities in the interpretation and implementation of the provisions of Directive 2004/24/EC. The Committee wished her well and looks forward to the announcement of the new Eur. Com. representative in the HMPC.

### Final Community herbal monographs

Upon recommendation from the MLWP as a result of its 26-28 September 2012 meeting, the HMPC adopted the following final Community herbal monograph and related documents by consensus:

- 'Community herbal monograph on *Pelargonium sidoides* DC and/or *Pelargonium reniforme* Curt., radix' (EMA/HMPC/560961/2010)
- 'Community herbal monograph on *Levisticum officinale* Koch, radix' (EMA/HMPC/524621/2011)
- 'Community herbal monograph on *Grindelia robusta* Nutt., *Grindelia squarrosa* Dunal, *Grindelia humilis* Hook. et Arn., *Grindelia camporum* Greene, herba' (EMA/HMPC/748220/2011)

The HMPC also adopted the following final Community herbal monograph and related documents by majority vote:

- 'Community herbal monograph on *Cucurbita pepo* L., semen' (EMA/HMPC/136024/2010)

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)



## Final public statements

Upon recommendation from the MLWP, the HMPC adopted the following final public statement:

- 'Public statement on *Viscum album* L., herba' (EMA/HMPC/57109/2011)

The final public statement, 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)

## Draft Community herbal monographs

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

- Draft 'Community herbal monograph on *Origanum dictamnus* L., herba' (EMA/HMPC/200429/2012)

## Draft public statements

Upon recommendation from the MLWP, the HMPC adopted the following draft public statements, for public consultation until 15 April 2013:

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

All draft documents will be available on the Agency's website at:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document\\_listing/document\\_listing\\_000216.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580033a9d](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000216.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580033a9d)

## Other

### **Call for submission of scientific data**

Following the start of the systematic review of adopted monographs and supporting documents, the EMA/HMPC publishes calls for the submission of scientific data in support of the two processes:

- the establishment of new monographs and
- the revision of final monographs.

Such 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)

There are currently 10 calls for submission of scientific data with a deadline for submission on 15 February 2013, one call in support of the establishment of a new monograph upon appointment of a new Rapporteur (*Lichen islandicus*) and 9 calls in support of the revision of monographs (*Aloe Frangulae cortex*, *Menthae piperitae aetheroleum*, *Menthae piperitae folium*, *Rhamni purshianae cortex*, *Rhei radix*, *Sennae folium*, *Sennae fructus* and *Thymi herba*).

Scientific contributions in response to a call for the submission of scientific data can be provided to the Agency in electronic format (e-mail or CD-ROM) or paper format (two copies by post or fax).

### ***Cancellation of assessment works***

The HMPC agreed upon recommendation of the MLWP to cancel the assessment work for Hyoscyami herba. After thorough assessment by the Rapporteur, market information and scientific data are insufficient to establish a monograph. The herbal substance has been deleted from the HMPC [priority list](#).

### ***Call for expression of interest by organisations in the field of non-European traditional medicines***

As indicated in the September 2012 meeting report concerning the assessors training organised at the Agency, the HMPC intends to consider a continued dialogue with interested parties (IP) on non-European traditional medicines. As such the Committee would like to invite organisations in the field to express their interest to become IP to the HMPC in order to establish regular contacts, in line with the HMPC rules of procedure. Requests for consideration as IP should be sent to the [hmpc.secretariat@ema.europa.eu](mailto:hmpc.secretariat@ema.europa.eu) ; they will be assessed against criteria established at the EMA for such contacts with [interested parties](#).

### ***Union reference dates and frequency of PSUR submission for herbal substances***

The HMPC adopted a list of herbal substances proposed for inclusion on the EURD List for PSUR submission, for transmission to the PRAC.

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

The HMPC heard a report on the DG Q meeting (virtual) held on 18 October 2012.

The DG Q will continue to elaborate guidance on non-pharmacopoeial reference standards for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products. It was noted that no comments had been received on the concept paper released for public consultation until 15 October 2012.

The next meeting of the DG Q will be held 13-14 December 2012 and will include a session with the Chairs of the European Pharmacopoeia's Expert Groups 13A, 13B, TCM on matters relevant to the coordination between the EMA/HMPC and EDQM.

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

The HMPC heard a report on the DG ORGAM meeting (virtual) held on 17 October 2012. The HMPC adopted the final template for Patient Leaflets with suggested wordings concerning advice on the preparation by end-users of medicinal herbal teas, together with an overview of the comments received from the QRD group and from PCWP members.

The meeting of the DG ORGAM (virtual) on 11 December 2012 was cancelled and work will resume in February 2013.

### **Report from the November 2012 Working Party on Community Monographs and Community List (MLWP)**

The MLWP held its 40th meeting at the European Medicines Agency, 20-22 November 2012.

### ***Systematic review and consequences for monographs published on the EMA website***

The HMPC discussed the orientation to be followed as regard the extent of the revision to be carried out of the scientific assessment and its conclusions found in assessment reports, especially for the

monographs adopted in the early years of establishment of the HMPC, when the working methodology was not as elaborate as it is six years later. Although the revision may not require modification of a monograph's content, the HMPC supported the view that the revision should lead to harmonised standards across all final assessment reports. Consequently, the MLWP was invited to extend the revision carried out for *Plantaginis ovatae semen*, *Plantaginis ovatae seminis tegumentum* and *Psyllii semen*. The working party further discussed the revision of the monographs on *Anisi aetheroleum* and *Anisi fructus*, which similarly will be carried out to a more extensive level.

The progress concerning the revision programme is now tracked separately in the above-mentioned HMPC priority list.

The HMPC and MLWP supported the EMA secretariat recommendation on the approach to be followed for the management of former versions of monographs and supporting documents, once revised versions (with different reference numbers though) are adopted by the Committee for publication. All former versions of monographs and supporting documents will remain accessible on the web, bearing their validity period, a watermark ('outdated') and the web address of the EMA webpage where to access the latest versions. These former versions will be accessible using for example the EMA document search function at.

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/document\\_library/landing/document\\_library\\_search.jsp&mid=](http://www.ema.europa.eu/ema/index.jsp?curl=pages/document_library/landing/document_library_search.jsp&mid=)

### ***Post-finalisation***

The MLWP adopted a revised overview of comments received during the public consultation on the draft monograph on *Liquiritiae radix*, for transmission to the HMPC for adoption in January 2013.

### ***Finalisation***

The MLWP also endorsed the monographs and supporting documents on *Solani dulcamarae stipites*, *Cichorii intybi radix*, *Eucalypti folium* and *Paullinae semen* for peer-review, prior to transmission to the HMPC for possible final adoption in January 2013. The Working Party considered that, for finalisation of the assessment of *Symphyti radix*, more discussion is required vis-à-vis the draft 'Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs)' (EMA/HMPC/893108/2011) currently under public consultation until 15 February 2013. After a second peer-review, the monograph and supporting documents will be transmitted to the HMPC for possible final adoption in March 2013.

### ***Drafts***

The MLWP further discussed the draft monograph and supporting documents on *Sambuci fructus* as a result of the peer-review agreed in September; the documents were agreed for transmission to the HMPC. The MLWP endorsed the monographs on *Juglandis folium* and *Marrubii herba* for peer-review, prior to transmission to the HMPC for possible release in January 2013 for public consultation. After a detailed assessment of available data, the publication of a draft public statement for *Adhatodae vasicae folium* was agreed; it will be adopted by the MLWP by written procedure prior to possible adoption by the HMPC in January.

The working party continued its assessment of *Rubi idaei folium*, *Eucalypti aetheroleum*, *Fucus vesiculosus*, *Ginkgo folium*, *Phaseoli fructus sine semine* and *Andrographidis paniculatae folium*, for which another round of discussion is scheduled for January. The MLWP discussed the draft assessment reports and monographs on *Arnicae flos* and *Ginseng radix*.

The next meeting of the MLWP is scheduled for 15-17 January 2013.

## Contact for further information

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