



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Patient Health Protection

## Meeting report

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# Committee on Herbal Medicinal Products (HMPC)

## Report of the 44th HMPC meeting, held 21-22 November 2011

The HMPC Chair welcomed Ms Gordana Petrovic, new observer from Serbia and Dr Eeva Sofia Leinonen, expert from Finland, who is in the process of being appointed as the new Finnish HMPC member.

### Final Community herbal monographs

Upon recommendation from the MLWP as a result of its 13-15 September 2011 meeting, the HMPC adopted the following final Community herbal monographs and related documents:

- 'Community herbal monograph on *Agropyron repens* L., rhizoma' (EMA/HMPC/563408/2010)
- 'Community herbal monograph on *Chamaemelum nobile* (L.) All., flos' (EMA/HMPC/560734/2010)
- 'Community herbal monograph on *Cola nitida* (Vent.) Schott et Endl. and *Cola acuminata* (P. Beauv.) Schott et Endl. (L.), semen' (EMA/HMPC/722367/2010)
- 'Community herbal monograph on *Olea europaea* L., folium' (EMA/HMPC/430507/2009)
- 'Community herbal monograph on *Plantago lanceolata* L., folium' (EMA/HMPC/437858/2010)

The first two monographs were adopted by consensus, whilst the latter were adopted by a majority vote.

The HMPC agreed to adopt by the end of the year the 'Community herbal monograph on *Oenothera biennis* L.; *Oenothera lamarckiana* L., oleum' (EMA/HMPC/227792/2009) by written procedure as the supporting documents were still in the process of finalisation.

Anticipating a positive outcome for this written procedure, the HMPC noted the results in terms of attaining its annual Key Performance Indicator (KPI), as the committee adopted in 2011 20 final monographs (exactly meeting the KPI) and 21 draft monographs (thus exceeding the KPI by one); this achievement is complemented by the assessment works which were conducted and led to the release of public statements when no monograph could be established (2 final, 5 draft). These results will be taken up in the Agency annual report for this year.



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**

No draft Community herbal monographs were adopted for public consultation.

## **Final Public statements**

The HMPC adopted the following final public statement and related documents:

- 'Public statement on *Syzygium aromaticum* (L.) Merrill et L.M. Perry, flos (EMA/HMPC/112102/2011)

## **Other**

### ***Appointment of Rapporteurs and calls for submission of scientific data for new assessment works***

Rapporteurs were appointed for the establishment of monographs/list entries on *Angelica sinensis* (Oliv.) Diels, radix; *Eschscholzia californica* Cham., herba cum flore; *Hieracium pilosella* L., herba cum flore and *Hyoscyamus niger* L., herba.

Following these appointments, calls for data will be published. The deadline for the submission of scientific data in response to each respective call is 15 April 2012.

These appointments have been reflected in the Rapporteurships' distribution given in the HMPC priority list (EMA/HMPC/278067/2006) published on the Agency's website at:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general\\_content\\_000208.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05800240cf](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000208.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05800240cf)

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

DG Q members and other experienced assessors were the speakers for the HMPC quality assessors training held on 14 October 2011 at the EMA. Current issues and developments in the assessment of quality dossiers were discussed using specific examples in four sessions: Combination products, Non-European traditional medicines, Stability and other critical aspects of (T)HMP assessment and Comparability of herbal preparations. The training was considered very helpful for less experienced assessors across the EU but also for exchange of information and intensive discussions towards harmonised views in all Member States on key quality topics in the herbal area.

Upon proposal from the DG Q, the HMPC adopted the revision 1 of the Questions & Answers on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/41500/2010 Rev. 1) with clarification on quality of water and an additional question on stability.

The next meeting of the DG Q is scheduled for 15 December 2011, including a meeting with the Chairs of the Ph. Eur. expert groups 13A, 13B, and 13C in order to continue the mutual information and coordination, in particular via the exchange and adjustment of work programmes.

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

The next meeting of the DG ORGAM is scheduled for 14 December 2011.

### **Other relevant information**

#### ***HMPC 2012-2015 work programme***

The HMPC fine-tuned its work programme for the period 2012-2015, which can be found on the EMA website at:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/about\\_us/general/general\\_content\\_000122.jsp&mid=menus/about\\_us/about\\_us.jsp&mid=WC0b01ac0580028e7d](http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000122.jsp&mid=menus/about_us/about_us.jsp&mid=WC0b01ac0580028e7d)

#### ***Successful use of the traditional use registration scheme in the Member States***

The HMPC heard a preliminary report on the outcome of the survey on traditional use registration (TUR) and marketing authorisation (MA) granted since the implementation of Directive 2004/24/EC until June 2011. The report published in May 2011 on TUR granted until December 2010 has been updated as regards figures on TUR and extended to cover new MA for herbal medicinal products according to Art. 10a of Directive 2001/83/EC as amended. The figures show further increase in applications received as well as TUR and MA granted by the national competent authorities. The report with updated figures (EMA/HMPC/322570/2011 Rev.1) will be found on the EMA website at:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general\\_content\\_000208.jsp&mid=WC0b01ac05800240cf](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000208.jsp&mid=WC0b01ac05800240cf)

Much effort has been put by the national contact persons, identified in coordination with the CMDh, to provide all information as sought and within set deadlines; this coordinated exercise is well appreciated and the Agency and HMPC anticipate communicating upon deeper analysis of the data. Overall a greater harmonisation on the EU market for herbal medicines is observed, yet a review of the Member States' approach to the assessment of herbal medicinal products dossiers will be undertaken, especially vis-à-vis European recommendations expressed by the HMPC in the form of Community herbal monographs.

### **Report from the November 2011 Working Party on Community Monographs and Community List (MLWP)**

The MLWP held its 35th meeting at the European Medicines Agency on 22-24 November 2011.

The Working Party made significant progress on the scientific work towards the finalisation of the assessment of *Pelargonii radix* and *Thymi herba/Primulae radix*. The MLWP adopted the monograph on *Solani dulcamarae stipites* for transmission to the HMPC for release in January 2012 for a 3-month public consultation; the working party continued its assessment of *Levistici radix*, *Matricariae aetheroleum* and *Matricariae flos*. The MLWP discussed the draft assessment report and monograph on *Cichorii intybi radix* and *Eucalypti folium*. Guidance was provided to Rapporteurs for *Grindeliae herba* and on issues raised at the beginning of the assessment works on *Guaranae semen*, *Rubi idaei folium*, *Sambuci flos* and *Uncariae tomentosae cortex*; establishment of monographs will continue.

Progress with the packages on *Echinaceae angustifoliae radix*, *Lavandulae aetheroleum*, *Lavandulae flos* and *Uvae ursi folium* at their respective step was postponed to January 2012.

The next meeting of the MLWP is scheduled for 24-26 January 2012.

Second announcement of procedural change:

#### CHANGE TO PUBLIC CONSULTATION ON HERBAL MONOGRAPHS AND LIST ENTRIES

With a view to improving the process supporting the establishment of Community herbal monographs and Community list entries, the HMPC/MLWP will apply a new approach to the public consultation on draft monographs, list entries, public statements and supporting documents. This approach shall facilitate the assessment of comments, suggestions and corresponding justifications.

Interested parties are invited to send  
comments together with a copy of the cited references.

When the reference consists of a book chapter, the copy must include  
the page of the book showing the year of publication.

**As of 2012**, comments without copies of the supporting literature will not be considered.

The template for the submission of comments by interested parties (EMA/HMPC/384286/2006 Rev. 2) was revised to reflect this new approach. The updated template can be found here:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document\\_listing/document\\_listing\\_000264.jsp&mid=WC0b01ac0580118a1d&jenabled=true](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000264.jsp&mid=WC0b01ac0580118a1d&jenabled=true)

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