



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 34th HMPC meeting, held 10-11 March 2010

The Committee welcomed representatives from Serbia, Montenegro and Kosovo under the status of observers and as part of the participation of these EU candidate countries and potential candidate countries in the Agency's activities. New representatives from the former Yugoslav Republic of Macedonia and Turkey were also welcomed. The committee was also informed about the nomination of Dr A. Lukosius and Pharm. E. Backhaus, alternate member respectively from Lithuania and Poland.

The HMPC re-elected Prof. O. Pelkonen as co-opted member with expertise in toxicology, for a 3-year term. Dr. B. Kroes was re-elected by the committee as Chair of the HMPC Quality Drafting Group upon expiry of his first Chair's mandate.

The full composition of the HMPC can be found at:

[http://www.ema.europa.eu/htms/general/contacts/HMPC/HMPC\\_members.html](http://www.ema.europa.eu/htms/general/contacts/HMPC/HMPC_members.html)

## Final Community herbal monographs and related documents

Upon recommendation from the Working Party on Community Monographs and Community List (MLWP), the HMPC adopted the following final Community herbal monographs and related documents:

- 'Community herbal monograph on *Echinacea purpurea* (L.) Moench, radix' (EMA/HMPC/142986/2009);
- 'Community herbal monograph on *Orthosiphon stamineus* Benth., folium' (EMA/HMPC/281496/2009).

The final Community herbal monographs — as well as the respective HMPC opinions, assessment reports and overview of comments received during the consultation period — will be published in due course on the European Medicines Agency's website at:

<http://www.ema.europa.eu/htms/human/hmpc/hmpcmonographs.htm>

As regards *Orthosiphon stamineus* folium, finalisation of the assessment work saw a reduction in the number of preparations covered by the monograph as it appeared that the evidence required to



demonstrate the long-standing medicinal use was incomplete for some preparations. Interested parties that commented on the draft monograph as well as a number of companies marketing products containing these preparations are being contacted with a view to gathering the missing evidence. A rapid revision of the monograph and related documents is envisaged upon receipt of relevant data.

The committee also adopted a revised 'Overview of comments received during the public consultation' for the monograph on *Curcuma longa* L., rhizoma.

## **Draft Community herbal monographs**

Upon recommendation from the MLWP, the HMPC adopted the following draft Community herbal monographs, to be released for public consultation until 15 July 2010:

- Draft 'Community herbal monograph on *Viola tricolor* L., herba cum flore' (EMA/HMPC/131734/2009);
- Draft 'Community herbal monograph on *Potentilla erecta* (L.) Raeusch., rhizoma' (EMA/HMPC/5513/2010);
- Draft 'Community herbal monograph on *Juniperus communis* L., aetheroleum' (EMA/HMPC/12402/2009).

Draft monographs will be available on the Agency's website at:

<http://www.ema.europa.eu/htms/human/hmpc/hmpcmonographs.htm>

## **Other documents**

The HMPC adopted an 'HMPC statement on environmental risk assessment of herbal medicinal products' (EMA/HMPC/121934/2010). The document will be available at:

<http://www.ema.europa.eu/htms/human/hmpc/hmpcguide.htm>

### ***Appointment of Rapporteurs***

The HMPC appointed a Rapporteur for the preparation of a Community herbal monograph/Community list entry on *Fumariae herba*, *Grindeliae herba*, *Tiliae tomentosae flos* and *Tiliae flos*.

### ***Calls for submission of scientific data***

A call for submission of scientific data has been published for the four above-mentioned herbal substances as well as for *Sabalidis serrulatae fructus* and *Silybi mariani fructus*<sup>1</sup>. Data are requested by 22 May 2010.

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

The MLWP held its 25th meeting at the European Medicines Agency on 8-10 March 2010. In addition to the work that supported the adoption of the above-mentioned documents by the HMPC, the MLWP made significant progress on the scientific work relating to the draft monographs on *Ribis nigri folium*, *Mate folium* and *Valerianae radix/Lupuli flos*.

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<sup>1</sup> Formerly listed as *Serenoae repentis fructus* and *Cardui mariae fructus*.

The MLWP discussed draft monographs on *Tanacetum parthenium* herba and *Trigonella foenugraeci* semen. Further discussion in the MLWP on the monograph on *Olea* folium could not lead to an adoption for release for public consultation by the HMPC and the assessment work was put on hold.

The MLWP discussed the possible discontinuation of the assessment work of *Terebinthina larinica* as, after exchange of information on marketed products, it appears that only one combination product and no single-ingredient-product can be found on the European market. Unless information to support a high priority level is received from interested parties until the next MLWP meeting, the working party will recommend to the HMPC in May not to continue establishing a monograph.

An updated 'Overview of status of HMPC assessment work – March 2010' (EMA/HMPC/278067/2006) will be published on the Agency's website at:

<http://www.ema.europa.eu/pdfs/human/hmpc/27806706en.pdf>

The MLWP agreed to a pilot phase for 3 meetings with a number of small groups reviewing draft monographs in parallel on Mondays of the MLWP, as part of changes to working methodology aiming at improving the output of the HMPC in terms of quality and quantity of monographs. The MLWP also discussed proposals for the revision of current quantitative Key Performance Indicators and the HMPC will review concrete proposals jointly agreed by the MLWP and the ORGAM DG prior to the May HMPC meeting.

The working party continued discussing challenges related to the data situation/assessment on the use of herbal medicines in the paediatric population, leading to the HMPC decision to strengthen its coordination with the PDCO. A statement is under preparation.

The next meeting of the MLWP is scheduled for 3-5 May 2010.

### **Organisation matters Drafting Group (ORGAM DG)**

The report to the HMPC on progress achieved during the ORGAM DG meeting on 11 February 2010 was postponed to May 2010.

The next meeting of the ORGAM DG is scheduled for 14 April 2010.

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

The HMPC heard a report on progress achieved during the Q DG meetings on 15 December 2009 and 10 February 2010.

The HMPC re-adopted the 'Guideline on declaration of herbal substances and preparations in herbal medicinal products/traditional herbal medicinal products' (EMA/HMPC/CHMP/CVMP/287539/2005 **Rev.1**)' after the revision initiated in October 2008 to integrate the declaration in package leaflet and labelling (beside 'declaration in the SPC', the original scope of the guideline). The final guideline had been adopted in November 2009, however a discussion by the Q DG in February 2010 of the comments raised by the Agency Quality Review of Documents Group concluded the finalisation of the guideline.

The HMPC adopted the final 'Reflection paper on stability testing of herbal medicinal products and traditional herbal medicinal products' (EMA/HMPC/3626/2009) together with the 'overview of comments received during the public consultation' (EMA/HMPC/5893/2010).

Documents will be available at the Agency website:

<http://www.ema.europa.eu/htms/human/humanguidelines/quality.htm>

The HMPC adopted a 'Glossary on instructions for the preparations of herbal teas' (EMA/HMPC/5829/2010) as a result of the initiative launched in September 2008 to evaluate standard tea preparation methods and agree on definitions and instructions, to support a standardisation of the terminology used in Community herbal monographs/Community list entries and related documents.

The document shall be found at:

<http://www.ema.europa.eu/htms/human/raguidelines/herbal.htm>

The HMPC adopted an update of the mandate for the Q DG (EMA/HMPC/410043/2008 Rev.1), revised to address the need for coordination with the MLWP since "At the request of the MLWP", the Q DG will "respond to questions arising during the establishment of Community herbal monographs and Community list entries, in particular related to the content of the pharmaceutical sections".

The mandate, objectives and composition of the Q DG can be found at:

<http://www.ema.europa.eu/pdfs/human/hmpc/qdg/qdgmandate.pdf>

The next meeting of the Q DG is scheduled for 15 April 2010.

## **Other matters**

The HMPC agreed on the scope of presentations by the HMPC Chair to the CMDh and to the Management Board, respectively on 17 and 18 March 2010.

Discussion in the CMDh focused on possible options to remedy the limited use of the Mutual Recognition & Decentralised procedures by companies for marketing authorisation/traditional use registration applications for HMPs/traditional HMPs, acknowledging the demanding requirements imposed by the legal framework, especially for small and medium sized companies, and recognising the current preference given to a purely national licensing and marketing of these products.

The presentation to the Management Board captured current challenges faced by the HMPC as well as those anticipated in the years ahead, noting that the committee will enter its third mandate at the end of 2010. An 'Action plan for herbal medicines 2010-2011' was agreed by the Board, which shall be published on the Agency website once endorsed by the Heads of Medicines Agencies – a discussion is scheduled for their April meeting. The document encompasses objectives and performance indicators set for 2011, a number of which being dependent on decisions to be taken this year.

## **Contact for further information**

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