



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 41st HMPC meeting, held 10 May 2011

The HMPC Chair welcomed all participants in the meeting, in the new setting whereby the HMPC meetings are now held prior to the meetings of the Working Party on Community Monographs and Community List (MLWP). With a view to maintaining the same level of transparency as before, information on the progress achieved in the MLWP on 11-13 May 2011 is included at the end of this meeting report, although it was not reported to the HMPC on 10 May 2011.

## Final Community herbal monographs

Upon recommendation adopted by the MLWP in March 2011, the HMPC adopted by consensus the following final Community herbal monographs and related documents:

- 'Community herbal monograph on *Cinnamomum verum* J. S. Presl., cortex' (EMA/HMPC/246774/2009)
- 'Community herbal monograph on *Cinnamomum verum* J. S. Presl., corticis aetheroleum' (EMA/HMPC/706229/2009)

The final Community herbal monographs as well as the HMPC opinion, 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)

## Appointment of Rapporteurs

Changes in Rapporteurships took place during the March-May 2011 period following changes in the composition of the MLWP or in the role of MLWP members; such changes concern *Allii sativi* bulbus, *Cichorii intybi* folium, *Cichorii intybi* radix, *Ginseng* radix, *Melaleucaea alternifoliae* aetheroleum, *Pruni spinosae* flos and *Pruni spinosae* summitates. They 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)

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

At the request of the respective Rapporteurs, calls for the submission of scientific data will be released for *Allii sativi bulbosus*, *Eucalypti folium* and *Eucalypti aetheroleum* with a submission sought by 15 September 2011. Information about calls for data can be found here:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document\\_listing/document\\_listing\\_000214.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580033a9c&jsenabled=true](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000214.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580033a9c&jsenabled=true)

### ***Extension of deadline for public consultation on 4 draft monographs***

Following the delayed publication of the draft assessment reports supporting draft monographs, the period of public consultation is extended until 15 August 2011 for:

- 'Community herbal monograph on *Thymus vulgaris* L. and *Thymus zygis* L., herba; *Primula veris* L. and *Primula elatior* (L.) Hill, radix' (EMA/HMPC/130042/2010)
- 'Community herbal monograph on *Lavandula angustifolia* Mill., flos' (EMA/HMPC/734125/2010)
- 'Community herbal monograph on *Lavandula angustifolia* Mill., aetheroleum' (EMA/HMPC/143181/2010)
- 'Community herbal monograph on *Olea europaea* L., folium' (EMA/HMPC/430507/2009)

The documents can be found 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)

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

The HMPC heard a report on the work carried out during the Q DG meeting held on 6 April 2011, in particular, as part of the revision of the 'Guideline on the use of the CTD format in the preparation of a registration application for traditional herbal medicinal products' (EMA/HMPC/71049/2007), progress on the preparation of 2 annexes, a Best practice guide and a Mock-up for Module 3, as anticipated in the work programme of the Q DG.

The format for Q DG recommendations on comparability of herbal preparations was discussed and the involvement of the MLWP will be sought in clarifying the content and scope of the document, taking into account practice at NCA level and during monographs' establishment by the working party.

The next meeting of the Q DG is scheduled for 16 June 2011.

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

The HMPC heard a report on the work carried out during the ORGAM DG meeting on 7 April 2011, in particular on new procedures for the systematic review of final monographs and for scientific support and advice to companies on traditional herbal medicinal products.

The HMPC adopted the third revision of the template for assessment reports supporting Community herbal monographs and Community list entries (EMA/HMPC/418902/2005 Rev.3) prepared by the ORGAM DG. The document will be published on the European Medicines Agency's website at:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document\\_listing/document\\_listing\\_000264.jsp&murl=menus/regulations/regulations.jsp&mid=WCOb01ac0580118a1d](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000264.jsp&murl=menus/regulations/regulations.jsp&mid=WCOb01ac0580118a1d)

The next meeting of the ORGAM DG is scheduled for 17 June 2011 (VITERO).

## **Other relevant information**

A progress report on the different objectives and actions foreseen in the '[Action plan for herbal medicines 2010-2011](#)' (see HMPC meeting report from May 2010) was presented to the HMPC for discussion at its meeting in July. The Committee reviewed the report on the '[Uptake of the traditional use registration scheme in EU Member States](#)' (EMA/HMPC/322570/2011).

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

The MLWP held its 32nd meeting at the European Medicines Agency on 11-13 May 2011.

The MLWP finalised the assessment of Millefolii flos, Millefolii herba, Bursae pastoris herba, Filipendulae ulmariae flos, Filipendulae ulmariae herba and Myrrha, for transmission to the HMPC for adoption at their July meeting. The working party made significant progress on the scientific work towards the finalisation of assessment of Cynarae folium and Plantaginis lanceolatae folium. Comments received on the public statement on Chelidonii herba were also discussed.

The MLWP concluded the scientific work on Zingiberis rhizoma, Symphyti radix, Liquiritae radix, Fraxini folium and Rhodiolae roseae rhizoma; draft monographs are expected to be adopted by the HMPC in July for release for a 3-month public consultation. Progress was achieved for the draft monograph on Cucurbitae semen with adoption by the working party anticipated for July. The MLWP discussed draft assessment reports on Citri bergami aetheroleum, Hippocastani cortex, Juglandis folium, Tiliae flos, Tiliae tomentosae flos and Allii cepae bulbus, which will lead to the release of either a monograph or a public statement.

Upon agreement by the HMPC, the MLWP met representatives from the Association of the European Self-Medication Industry (AESGP) on 11 May 2011, in order to discuss a number of general issues related to Community herbal monographs/Community list entries and related documents adopted by the HMPC. Once adopted, the report from the hearing will be published on the EMA website at:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/about\\_us/document\\_listing/document\\_listing\\_000223.jsp&murl=menus/about\\_us/about\\_us.jsp&mid=WCOb01ac058003529f&jsenabled=true](http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000223.jsp&murl=menus/about_us/about_us.jsp&mid=WCOb01ac058003529f&jsenabled=true)

The next meeting of the MLWP is scheduled for 12-14 July 2011.

## **Contact for further information**

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