



London, 5 February 2009
Doc. Ref. EMEA/HMPC/44177/2009

COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

Meeting report, 14-15 January 2009

The HMPC held its 27th meeting at the EMEA on 14-15 January 2009. The HMPC welcomed Mr Cathal Gallagher new alternate member from Ireland and Mrs Evelin Saar new alternate member from Estonia.

The Committee elected Dr. Silvia Giroto as co-opted member with expertise in paediatric medicine in the HMPC.

The updated composition of the Committee can be found at:

http://www.emea.europa.eu/htms/general/contacts/HMPC/HMPC_members.html

The HMPC elected Prof. Ioanna Chinou as Chair of the Working Party on Community Monographs and Community List (MLWP) upon expiry of the mandate of the previous Chair, Dr H. Pittner. The Committee expressed warm appreciation for Dr Pittner's outstanding work in establishing/setting up and leading the working party. Elections for the MLWP Vice-chair will take place in March 2009.

The HMPC appointed Dr S. Giroto and Dr B. Huber as members of the MLWP. The composition of the MLWP can be found at:

http://www.emea.europa.eu/htms/general/contacts/HMPC/HMPC_MLWP.html

Upon recommendation from the MLWP, the HMPC adopted the following Community herbal monographs and related documents:

Final Community herbal monographs

- 'Community herbal monograph on *Peumus boldus* Molina, folium (EMEA/HMPC/591648/2007)
- 'Community herbal monograph on *Salix* sp, cortex (EMEA/HMPC/295338/2007)

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

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

The HMPC adopted the following draft Community herbal monographs, released for public consultation until 15 May 2009:

- Draft 'Community herbal monograph on *Salvia officinalis* L., folium (EMEA/HMPC/331653/2008)
- Draft 'Community herbal monograph on *Juniperus communis* L., pseudo-fructus (EMEA/HMPC/441929/2008)
- Draft 'Community herbal monograph on *Taraxacum officinale* Weber ex Wigg., radix cum herba (EMEA/HMPC/212895/2008)
- Draft 'Community herbal monograph on *Taraxacum officinale* Weber ex Wigg., folium (EMEA/HMPC/579636/2008)

The draft Community herbal monographs, together with a draft list of references used during the assessment will be published in due course on the EMEA website at:

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

The HMPC discussed a draft monograph on *Urticae radix*, but could not find an agreement to publish a positive assessment. The draft will be reconsidered by the MLWP that will prepare a public statement on the issues discussed.

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

The MLWP held its 18th meeting at the EMEA on 13-14 January 2009.

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 draft Community herbal monographs and assessment reports on *Althaeae radix* and *Centaurii herba*. The MLWP also discussed draft monographs on *Cimicifugae rhizoma*, *Urticae radix*, *Gentianae radix* and *Mate folium* and the preparation of monographs on *Echinaceae angustifoliae radix* and *Echinaceae purpureae radix*.

An updated 'Overview of status of HMPC assessment work – January 2009 (EMEA/HMPC/278067/2006)' will be published on the EMEA website at:

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

The MLWP appointed a Rapporteur for the preparation of a Community herbal monograph on *Lavandulae flos* and on *Lavandulae aetheroleum*, considering the proposal submitted by an interested party for *Lavandulae aetheroleum* together with supporting scientific literature.

The next meeting of the MLWP is scheduled for 9-11 March 2009.

Quality Drafting Group (Q DG)

A meeting of the Q DG was held on 11 December 2008.

The HMPC adopted the following document for release for public consultation until 15 May 2009:

- Draft 'Reflection paper on stability of herbal medicinal products and traditional herbal medicinal products' (EMEA/HMPC/3626/2009).

This reflection paper aims to generate discussion on establishing criteria to give detailed guidance on the application of existing stability guidance to herbal preparations and herbal medicinal products. It is considered of primary importance that interested parties provide examples and comments covering the range of possible stability scenarios which are specific for herbal preparations and herbal medicinal products.

The reflection paper will be available on the EMEA website at:

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

The period of public consultation on the draft 'Reflection paper on level of purification of extracts to be considered as herbal preparations' (EMEA/HMPC/186645/2008) has been extended to 15 April 2009. <http://www.emea.europa.eu/pdfs/human/hmpc/18664508en.pdf>

In order to strengthen cooperation with the European Directorate for the Quality of Medicines, the HMPC appointed I. Chinou and H. Neef respectively as HMPC observer to the Ph. Eur. group of experts in Phytochemistry 13A and 13B. The Committee also agreed to the participation, on an annual basis in a meeting of the Q DG, of the chairs of the above-mentioned groups of experts as well as the chair of the group in charge of the elaboration of Eur. Ph. monographs on herbs used for Traditional Chinese Medicine.

The next meeting of the Q DG is scheduled for 11 February 2009.

Other relevant information

The HMPC agreed on a new policy for the organisation of hearings with interested parties. The committee favours the organisation of focused hearings with individual association upon receipt of specific issues/questions with a view to leading to constructive dialogues with interested parties that contribute actively to the work of the HMPC.

The HMPC was informed about the WHO congress on traditional medicine held on 7-9 November 2008 in Beijing, China, which the HMPC Chair attended. Further information can be found on the WHO website. <http://www.who.int/medicines/areas/traditional/en/index.html>

For further information, please contact:

Tony Humphreys
Head of Regulatory Affairs and Organisational Support Sector
Tel.: (44-20) 7418 8583
Fax: (44-20) 7523 7051
hmpc.secretariat@emea.europa.eu