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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

**Meeting report, 16-17 September 2009**

The HMPC held its 31st meeting at the EMEA on 16-17 September 2009.

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

- Draft 'Community herbal monograph on *Cimicifuga racemosa* (L.) Nutt., rhizoma'  
(EMEA/HMPC/600717/2007)
- Draft 'Community herbal monograph on *Vitex agnus castus* L., fructus'  
(EMEA/HMPC/144006/2009)

The draft Community herbal monographs, together with a draft list of references used during the assessment will be published in due course. The HMPC decided to release during the consultation period the preliminary draft assessment report which supports these draft monographs, on an exceptional basis, considering the complexity of the assessment.

They will be available on the EMEA website at:

<http://www.emea.europa.eu/htms/human/hmhc/hmhcmonographs.htm>

The assessment of *Centella asiatica* (L.) Urban, herba did not result in a draft Community herbal monograph because all data examined by the HMPC/MLWP concerning specific products known to be on the European market do not refer to a herbal preparation. The HMPC adopted a draft public statement (EMEA/HMPC/579663/2009), which will be released for public consultation until 15 January 2010; the committee looks forward to receiving additional data if available to allow the preparation of a monograph.

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

The MLWP held its 22<sup>th</sup> meeting at the EMEA on 14-16 July 2009. The preparation of the Community herbal monographs and related documents on Hamamelidis cortex, Hamamelidis folium, Hamamelidis folium et cortex aut ramunculus destillatum, Juniperi pseudo-fructus, Salviae folium, Taraxaci folium and Taraxaci radix cum herba was finalised at the meeting. The texts will be transmitted to the HMPC for adoption in November.

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 Hyperici herba and Curcumae longae rhizoma.

The MLWP discussed the monograph on Gentianae radix together with the respective comments received during the public consultation period; further discussion is scheduled at the November 2009 meeting. The MLWP also discussed draft monographs on Vitis viniferae folium, Arctii folium and Uvae ursi folium and the preparation of monographs on Visci albi herba and Chelidonii herba.

The MLWP appointed Rapporteurs for the preparation of Community herbal monographs/Community list entries on Juniperi aetheroleum and Rhodiolae roseae rhizoma.

The MLWP discussed the proposal for a draft Community herbal monograph on Leonuri cardiaca herba submitted by an interested party in accordance with the 'Procedure on management of proposals submitted by interested parties for Community list entries or Community herbal monographs' (EMEA/HMPC/328575/2007). A Rapporteur is going to be appointed.

With a view to initiating assessment work on several herbal substances, calls for the submission of scientific data have been published. They can be found at:

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

An updated 'Overview of status of HMPC assessment work – September 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 work programme for 2010 was adopted and will be published on the EMEA website at:

[http://www.emea.europa.eu/htms/general/contacts/HMPC/HMPC\\_MLWP.html](http://www.emea.europa.eu/htms/general/contacts/HMPC/HMPC_MLWP.html)

The HMPC endorsed the draft programme of an Assessors Training on Clinical Safety and Efficacy assessment for herbal medicinal products scheduled for 23 November 2009. The programme includes presentations by renowned speakers to bring their expertise in various fields including evidence-based medicine, Health Technology Assessment beyond RCTs and systematic reviews.

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

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

There was no meeting of the Q DG since June 2009.

The HMPC was provided with a brief overview of the comments received during the public consultation on the draft 'Reflection paper on stability testing of herbal medicinal products and traditional herbal medicinal products' (EMEA/HMPC/3626/2009). The committee also noted that comments had been received on the draft 'Guideline on selection of test materials for genotoxicity testing for traditional herbal medicinal products/herbal medicinal products' (EMEA/HMPC/67644/2009).

The Q DG will further progress these documents during its next meeting on 14 October 2009.

### **Other relevant information**

The HMPC heard various presentations during which suggestions and comments were raised addressing the committee's expectations in the field of herbal medicinal products where relevant. The presentations were on:

- the legal proposals on pharmacovigilance with a representative from the Pharmaceuticals Unit bringing clarification on the proposals and their adoption by co-decision procedure at European Parliament and Council levels
- the preparation of the European Medicine Agency Road Map to 2015
- the Joint Heads of Medicines Agencies / European Medicines Agency Training Project Team 'Draft Strategy for Regulatory and Scientific Training within the European Regulatory Network' (EMEA/460027/2009).

Finally, the HMPC met representatives from ESCOP to celebrate the launch of the ESCOP monographs Second Edition 2009 supplement. A report from the meeting can be found at:

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

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