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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

Meeting report, 15-16 July 2009

The HMPC held its 30th meeting at the EMEA on 15-16 July 2009.

The HMPC welcomed Mrs. E. Mendes as a new alternate member from Portugal.

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

- 'Community herbal monograph on *Echinacea pallida* Nutt., radix' (EMEA/HMPC/332350/2008)
- 'Community herbal monograph on *Artemisia absinthium* L., herba' (EMEA/HMPC/234463/2008)
- 'Community herbal monograph on *Aesculus hippocastanum* L., semen' (EMEA/HMPC/225319/2008)

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 in due course on the EMEA website at:

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

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

- Draft 'Community herbal monograph on *Ilex paraguariensis* St. Hil., folium' (EMEA/HMPC/580539/2008)
- Draft 'Community herbal monograph on *Echinacea purpurea* (L.) Moench., radix' (EMEA/HMPC/577784/2008)
- Draft 'Community herbal monograph on *Ribes nigrum* L., folium' (EMEA/HMPC/142986/2009)
- Draft 'Community herbal monograph on *Rosmarinus officinalis* L., folium' (EMEA/HMPC/13633/2009)
- Draft 'Community herbal monograph on *Rosmarinus officinalis* L., aetherolum' (EMEA/HMPC/235453/2009)
- Draft 'Community herbal monograph on *Orthosiphon stamineus* Benth., folium' (EMEA/HMPC/281496/2009)

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/hmhc/hmhcmonographs.htm>

The assessment of *Urtica dioica* L.; *Urtica urens* L., radix did not result in a draft Community monograph because not all requirements for the acceptance of the well-established use and the traditional use were considered to be fulfilled. The HMPC adopted a public statement (EMEA/HMPC/4440359/2009), which will be released for public consultation until 15 December 2009 together with the list of references and the supporting draft assessment report in order to facilitate comments and the provision of additional data if available.

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

The MLWP held its 21th meeting at the EMEA on 13-15 July 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 the draft Community herbal monograph and assessment report on Hamamelidis cortex, Hamamelidis folium, Hamamelidis folium et cortex aut ramunculus destillatum, Juniperis communis L., Salviae folium, Taraxaci folium, and Taraxaci radix cum herba.

The MLWP discussed the monographs on Hyperici herba and Curcumae longae rhizoma together with the respective comments received during the public consultation period; further discussion is scheduled at the September 2009 meeting. The MLWP also discussed draft monographs on Cimicifugae rhizoma, Agni casti fructus, Vitis viniferae folium and the preparation of monographs on Centellae asiaticae herba, Visci albi herba, and Chelidonii herba.

The MLWP appointed Rapporteurs for the preparation of Community herbal monographs/Community list entries on Chamomillae romanae flos, Colae semen, Fraxini folium, Myrtilli folium, and Pelargonii radix. Rhodiola rosea was added to the HMPC priority list.

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

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

The next meeting of the MLWP is scheduled for 14-15 September 2009.

Quality Drafting Group (Q DG)

A meeting of the Q DG was held on 18 June 2009.

The Q DG discussed comments received from public consultation for the reflection paper on level of purification to be considered as herbal preparations (EMEA/HMPC/186645/2008). The Q DG prepared a Q&A document on acceptable limits of the active substance in the specification of the finished product for addition to a general quality Q&A document for publication at:

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

The Q DG discussed also announced changes in Ph. Eur. monographs as published in Pharmeuropa and recent developments within the ISO ICH M5 framework for a harmonised standard terminology of herbal products for a global database to manage pharmacovigilance reports worldwide.

The next meeting of the Q DG is scheduled for 14 October 2009.

Other relevant information

The HMPC initiated a dialogue with the European Food Safety Agency (EFSA) with support of European Commission DG Enterprise and Industry and DG SANCO on possible coordination at the borderline between herbal medicinal products and food supplements in the clinical data evaluation for the efficacy assessment of (Traditional) Herbal Medicinal Products by HMPC and the substantiation of health claims for 'Botanicals' by the EFSA-NDA panel.

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