



29 January 2010
EMA/HMPC/29724/2010
Patient Health Protection

Meeting report

Committee on Herbal Medicinal Products (HMPC)

Report of the 33rd HMPC meeting, held 14 January 2010

The Committee welcomed Ms María-Angeles Figuerola-Santos, the new representative from the European Commission in the HMPC, and Dr W. Dymowski, the new HMPC member from Poland.

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 *Urtica dioica* L., *Urtica urens* L., folium' (EMA/HMPC/508015/2007);
- 'Community herbal monograph on *Thymus vulgaris* L. and *Thymus zygis* Loefl. Ex L., aetheroleum' (EMA/HMPC/131901/2009).

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>

Draft Community herbal monographs and list entries

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

- Draft 'Community list entry on *Thymus vulgaris* L. and *Thymus zygis* Loefl. Ex L., aetheroleum' (EMA/HMPC/255527/2009);
- Draft 'Community list entry on *Vitis vinifera* L., folium' (EMA/HMPC/5816/2010);
- Draft 'Community herbal monograph on *Quercus robur* L., cortex' (EMA/HMPC/3203/2009);
- Draft 'Community herbal monograph on *Arctium lappa* L., radix' (EMA/HMPC/246763/2009);



- Draft 'Community herbal monograph on *Hedera helix* L., folium' (EMA/HMPC/289430/2009). The HMPC decided to release during the consultation period the preliminary draft assessment report supporting the draft 'Community herbal monograph on *Hedera helix* L., folium'. This represents an exceptional case justified by the complexity of the assessment and the advanced stage of preparation of the assessment report.

The HMPC also adopted a revision of the draft 'Community herbal monograph on *Vitis vinifera* L., folium' (EMA/HMPC/16635/2009 Rev.1). The monograph remains under public consultation until 15 April 2010; interested parties are invited to pay particular attention to this new version (changes affecting sections 2, 4.2, 4.4, 4.8 and 5.3).

Draft monographs and list entries will be available on the Agency's website respectively at:

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

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

Other documents

The HMPC adopted the 'Reflection paper on ethanol content in herbal medicinal products and traditional herbal medicinal products used in children' (EMA/HMPC/85114/2008), finalised after coordination with the CHMP and PDCO. The document, together with the overview of comments received during public consultation (EMA/HMPC/427952/2009), 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 *Allii cepae bulbosus*.

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

The MLWP held its 24th meeting at the European Medicines Agency on 11-13 January 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 monograph on *Echinaceae purpureae radix*.

The MLWP finalised the draft monograph on *Violae tricoloris herba cum flore* for transmission to the HMPC in March, and discussed draft monographs on *Juniperi aetheroleum* and *Tormentillae rhizoma*. Progress in the MLWP with the monograph on *Oleae folium* could not lead to an adoption for release for public consultation, after a split vote by the HMPC on the proposed traditional medicinal use; the MLWP will therefore further attempt to establish this monograph.

The MLWP decided to put the assessment work of *Urticae radix* on hold until the outcome of a class-review for plants used in BPH (e.g. *Serenoae repentis fructus*, *Curcubitae semen*).

The working party experienced difficulties in gathering evidence for 30 years of use for powdered herbal substances included in the French *Avis aux fabricants*, affecting several monographs under finalisation by the Committee after public consultation. Reference is made to the *Avis* first published in 1985, and the MLWP is looking into the availability in the public domain of earlier versions of the document known to have been subject to consultation with industry.

The MLWP had preliminary discussions on possible scenarios to improve its working methodology, and agreed on an early appointment of peer-reviewers; 29 peer-reviewers were consequently appointed. The working party also started a discussion on current challenges related to the data situation/assessment on the use of herbal medicines in the paediatric population.

An updated 'Overview of status of HMPC assessment work – January 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 next meeting of the MLWP is scheduled for 8-10 March 2010.

Quality Drafting Group (Q DG)

The report to the HMPC on progress achieved during the Q DG meeting of 15 December 2009 was postponed to March 2010.

The next meeting of the Q DG is scheduled for 10 February 2010.

Other matters

The HMPC was informed of the herbal medicines related discussion points by the Management Board in recent meetings, and further discussion will take place to assess the need for coordinated actions within the European regulatory network ahead of the deadline (30 April 2011) for the Member States to apply the provisions of Directive 2004/24/EC for traditional herbal medicinal products already on the market on the entry into force of the Directive.

http://www.ema.europa.eu/htms/general/manage/MB/MB_documents.html

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