



London, 6 February 2007
Doc. Ref. EMEA/HMPC/45867/2007

COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

Meeting report, 11 January 2007

The Committee on Herbal Medicinal Products met for the 15th time at the EMEA on 11 January 2007.

The Chair introduced new members and alternate members to the Committee including the representatives from Bulgaria and Romania who became formally members of the HMPC following the accession of these two new Countries to the the EU on 1 January 2007. He welcomed:

- Caroline Attard, from Malta; Cora Nestor, from Ireland; Peter Potůček, from Slovakia as new members;
- Sinead Harrington, from Ireland, Elena Mustakerova, from Bulgaria as new alternate members;
- Ivan Kosalec, from Croatia as new alternate observer.

In addition, he welcomed Anne Deltour as new European Commission representative.

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

The 6th meeting of the permanent HMPC Working Party on Community Monographs and Community List (MLWP) was held on 9-10 January 2007.

The HMPC adopted the 'MLWP Work programme for 2007' (EMEA/HMPC/152126/2006), which is now available on the EMEA website at:

<http://www.emea.europa.eu/pdfs/human/hmpc/mlwp/15212606en.pdf>

The MLWP made significant progress on the scientific work related to draft Community herbal monographs and assessment reports for Echinaceae purpureae herba, Passiflorae herba, Primulae radix, Betulae folium, Menthae piperitae aetheroleum, Urticae herba, Lupuli flos and Rhamni purshianae cortex. Further discussions are scheduled to take place during the March 2007 MLWP meeting in accordance with the 'Overview of status of HMPC assessment work January 2007 (EMEA/HMPC/278067/2006)', which can be found on the EMEA website at:

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

The next meeting of MLWP is scheduled for 5-7 March 2007.

Report from the Organisational Matters Drafting Group

During the meeting on 5 December 2006, the Organisational Matters Drafting Group agreed on the following document further to the end of the consultation period:

- 'Assessment report template for the development of Community herbal monographs and for inclusion of herbal substance(s), preparation(s) or combinations thereof in the Community list' (EMEA/HMPC/418902/2005)

Subsequently the document was submitted to and adopted by the HMPC. The revised version of the assessment report template takes into account the experience gained so far by Rapporteurs in using the template.

No comments were received from the general public during the consultation period. The final document can be found on the EMEA website at:

<http://www.emea.europa.eu/pdfs/human/hmpc/41890205en.pdf>

The HMPC also endorsed a revised versions of the following documents, underpinning the preparation of Community herbal monographs and Community list entries:

- Revised 'Procedure for the preparation of Community monographs for traditional herbal medicinal products' (EMEA/HMPC/182320/2005 Rev. 2)
- Revised 'Procedure for the preparation of Community monographs for herbal medicinal products with well-established medicinal use' (EMEA/HMPC/182352/2005 Rev. 2)
- Revised 'Template for a Community herbal monograph' (EMEA/HMPC/107436/2005 Rev. 2)

These documents have been revised to take account of current practice in the MLWP in the preparation of draft monographs as well as to bring consistency with other HMPC templates and guidelines. The revised procedures and templates can be found on the EMEA website at:

<http://www.emea.europa.eu/htms/general/direct/legislation/legislationherbal.htm>

The HMPC adopted also a new 'Template for a Community list entry' (EMEA/HMPC/439705/2006), which can be found at the same location.

Report from the Quality Drafting Group

A meeting of the Quality Drafting Group was held on 6 December 2006.

The Quality Drafting Group presented a revised version of the 'Guideline on quality of combination herbal medicinal products/traditional herbal medicinal products' (EMEA/HMPC/214869/2006). The HMPC made further comments on the draft guideline which will be taken into account by the Drafting Group when further elaborating the guideline at its next meeting.

Burt Kroes (NL) was elected by the HMPC as new Chairperson of the Quality Drafting Group following the resignation of Dairine Dempsey (IE).

Other relevant information

The HMPC agreed on a revised version of the Draft 'reflection paper on the risk associated with furocoumarins contained in preparations of *Angelica archangelica* L.' (EMEA/HMPC/317913/2006), which includes comments received from the Safety Working Party (SWP) (for background information see [HMPC meeting report October 2006](#)).

The document is now available on the EMEA website at:

<http://www.emea.europa.eu/pdfs/human/hmpc/31791306en.pdf>

In the context of the proposal launched by the European Commission for a future revision of the Variations Regulations, the HMPC participated to the first round of comments collected by the EMEA on the Commission position paper 'Better regulation of pharmaceuticals: towards a simpler, clearer and more flexible framework on Variations'. The HMPC will provide specific additional comments later in the process of the Regulations revision.

The HMPC also discussed future initiatives to strengthen the cooperation with other European Agencies and in particular with the European Food Safety Authority and its Scientific Committee (EFSA SC) with a view to opening a dialogue on areas of common interest.

Upon request from some interested parties to the HMPC, the Committee agreed to meet representatives from interested parties during its March 2007 meeting, with a view to specifically listening to their feedback and questions on the establishment of Community herbal monographs.

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