



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 October 2014
EMA/HMPC/620221/2014
Committee on Herbal Medicinal Products (HMPC)

HMPC meeting report on European Union herbal monographs, guidelines and other activities

The 60th HMPC meeting, held on 29 - 30 September 2014

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 60th meeting of the Committee and reminded on the 10th anniversary of the Committee's first meeting in September 2004 and the achievements and developments over the last 10 years.

The Chair announced as new members A. Cunney (IE) and as new alternates U. Mockler (IE), K. Kaneva (BG), and Z. Karampourmpouni (GR) and as new EDQM observer U. Rose.

The HMPC re-elected G. Calapai as co-opted member with expertise in clinical pharmacology, H. Pinto-Ferreira as co-opted member with expertise in general and family medicine, and G. Laekeman as co-opted member with expertise in experimental/non-clinical pharmacology, all for a 3-year term starting 24 November 2014.

The full composition of the HMPC can be found at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/2010/02/people_listing_000006.jsp&mid=WC0b01ac0580028e7e

Final European Union herbal monograph

Upon recommendation from the MLWP as a result of its July 2014 meeting, the HMPC adopted the following final European Union herbal monograph and related documents:

- European Union herbal monograph on *Sisymbrii officinalis herba*, by consensus

The final monograph as well as the HMPC opinion, assessment report and list of references will be published on the European Medicines Agency's website at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000174.jsp&mid=WC0b01ac058001fa1d



Draft European Union herbal monograph

Upon recommendation from the MLWP, the HMPC adopted the following draft European Union herbal monograph for public consultation until **15 January 2014**:

- European Union herbal monograph on *Crataegi herba cum flore*

The draft monograph together with the draft supporting documents will be published on the European Medicines Agency's website at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000061.jsp&mid=WC0b01ac058001fa1d

Other

Guidance documents

Based on newly available data and considering recommendations from the Safety Working Party the Committee decided to revise the Public statement on the use of herbal medicinal products containing estragole (EMA/HMPC/137212/2005) and the Public statement on the use of herbal medicinal products containing pulegone and menthofuran (EMA/HMPC/138386/2005). Adoption of draft revisions for public consultation are expected in November. The HMPC further confirmed the need to review available data on herbal medicinal products containing polycyclic aromatic hydrocarbons (PAH). In order to trigger the submission of data and a dialogue with interested parties first a reflection paper will be developed for release beginning 2015.

Drafting Group on Quality (DG Q)

The HMPC heard a report on the DG Q meeting held on 10 September 2014.

The HMPC agreed to newly proposed amendments to the Questions & answers on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/41500/2010) to be implemented by the drafting group at their next meeting and had a first discussion on future needs for new and revised guidance on quality of herbal medicinal products and a draft work plan for 2015.

The next meeting of the DG Q will be held on 12 November 2014.

Drafting Group on Organisational matters (DG ORGAM)

The HMPC heard a report on the DG ORGAM meeting held on 9 September 2014.

The Committee adopted following revised templates:

- Template for a European Union herbal monograph (EMA/HMPC/107436/2005 Rev. 7)
- Template for a European Union list entry (EMA/HMPC/439705/2006 Rev. 5)

The revised templates will be published here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000212.jsp&mid=WC0b01ac058003380a

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000213.jsp&mid=WC0b01ac0580033a9b

With reference to the Treaty on European Union and the Treaty on the functioning of the European Union (2012/C 326/01) the HMPC agreed to use in future the terms 'European Union herbal monographs' (or abbreviated EU herbal monographs) and 'Entry to the European Union List of herbal

substances and preparations thereof' replacing 'Community' within the old terms introduced by Directive 2004/24/EC amending, as regards traditional herbal medicinal products, Directive 2001/83/EC and used so far. Such change will be introduced prospectively in herbal monographs, list entries, supporting documents and guidelines.

The Committee agreed to further procedural scrutiny on the revision of list entries vis-à-vis the revision of monographs in liaison with the European Commission and had a first discussion on the needs for new and updated regulatory /procedural guidance to be reflected in the work plan 2015.

The next meeting of the DG ORGAM will be held on 10 November 2014.

Report from the September/October 2014 Working Party on European Union Monographs and European Union List (MLWP)

The MLWP held its 51th meeting at the European Medicines Agency on 30 September to 02 October 2014.

Monograph revisions

The MLWP re-discussed and endorsed the draft revised monographs on Echinaceae purpureae herba and Betulae herba. The revised monographs together with supporting documents will be finalised by the Rapporteur and transmitted, after peer-review, to the HMPC for adoption at the November 2014 meeting.

The MLWP continued its work towards the revision of the monographs on Lini semen, Menthae piperitae folium, Menthae piperitae aetheroleum, Thymi herba/Primulae radix, Pelargonii radix and Hederae helicis folium.

Monograph finalisation

The working party discussed and endorsed the monographs on Melaleucaae alternifoliae aetheroleum and Lichen islandicus taking into account comments received by interested parties. The documents will be finalised by the Rapporteurs and transmitted after peer review, to the HMPC for possible final adoption at the November 2014 meeting.

The working party had a first discussion on Ginkgo folium after public consultation.

Monograph drafts

The MLWP endorsed for early peer-review and transmission to HMPC and possible release in November 2014 for public consultation: the draft monograph on Sabalis serrulatae fructus, the draft monographs on Carvi aetheroleum and Carvi fructus (after re-discussion due to newly available data) and a draft list entry for Crataegi folium cum flore (upon request by HMPC to the MLWP).

The working party continued its assessment of Myrtilli fructus siccus and Myrtilli fructus recens following early peer review as well as Uncariae tomentosae cortex and Uncariae tomentosae radice cortex.

The working party had first discussions on the assessment of Myrtilli folium, Ricini oleum, Cyani flos, Helichrysi flos and Sideritis herba.

Other guidance documents

The MLWP discussed comments from interested parties and endorsed the PS on the Use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) for transmission to the HMPC and possible final adoption in November 2014.

The next meeting of the MLWP is scheduled for 26–28 November 2014.

Contact for further information

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