



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 November 2013
EMA/HMPC/702025/2013
Committee on Herbal Medicinal Products (HMPC)

HMPC meeting report on Community herbal monographs, guidelines and other activities

The 55th HMPC meeting, held on 11-12 November 2013

The Committee re-elected Prof. Dr Werner Knöss as Chair and elected Dr Marisa Delbò as the new vice-Chair, both with a 3-year mandate that started on 11 November 2013.

The HMPC noted new nominations, with Dr Markéta Příhodová as new alternate member for Czech Republic, Pharm An Lê as new member for France, Dr Rita Németh as new member alternate for Hungary, Dr Anna Maria Serrilli as new alternate member for Italy and Pharm Dr Martina Hudecová as new member for Slovakia. 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 Community herbal monographs

Upon recommendation from the MLWP as a result of its September 2013 meeting, the HMPC adopted the following final Community herbal monograph and related documents:

- Community herbal monograph on *Camelliae sinensis non fermentatum folium*, by a majority vote
- Community herbal monograph on *Phaseoli fructus sine semine*, by consensus

Revised Community herbal monographs

As a result of the 5-year systematic review, the HMPC adopted the following revised final Community herbal monograph and related documents by consensus:

- Community herbal monograph on *Anisi aetheroleum*
- Community herbal monograph on *Anisi fructus*
- Community herbal monograph on *Thymi herba*

Given the minor changes to the monographs, a public consultation was not considered necessary after careful assessment of new scientific data. The new and revised final Community herbal monographs as well as the HMPC opinion, assessment report and overview of comments received during the consultation period (if any), will be published on the European Medicines Agency's website at:



http://www.ema.europa.eu/ema/index.jsp?curl=/pages/medicines/landing/herbal_search.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001fa1d

Draft Community herbal monographs

Upon recommendation from the MLWP, the HMPC adopted the following draft Community herbal monograph for public consultation until 15 April 2014:

- Draft Community herbal monograph on *Sisymbrii officinalis herba*

The 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/landing/herbal_search.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001fa1d

Other

Revision of the guideline on the use of the CTD format in the preparation of a registration application for traditional herbal medicinal products

The HMPC adopted the 'Concept paper on the revision of the guideline on the use of the CTD format in the preparation of a registration application for traditional herbal medicinal products'

(EMA/HMPC/71049/2007 Rev. 1) for 3 months public consultation. The concept paper will be published here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000355.jsp&mid=WC0b01ac0580118a1d

Following the last revision focused on quality aspects (module 3), the concept paper explains the intention to revise guideline EMA/HMPC/71049/2007 Rev. 1 regarding modules 2, 4 and 5 in order to provide further clarity to applicants for the requirements in the clinical and non-clinical sections of dossiers for the registration of traditional herbal medicinal products.

Drafting Group on Quality (DG Q)

The HMPC heard a report on the DG Q (virtual) meeting held on 16 and 17 October 2013.

The drafting group had finalised the first part of Q&A on quality of essential oils. The second set of Q&A and the final reflection paper are anticipated to be ready for adoption in January 2014. Further discussions took place towards finalisation of guidance on microbiological aspects of herbal medicinal products and on Q&A regarding benzene as a potential impurity in solvents used in manufacture of herbal preparations. Furthermore work has started regarding the elaboration of a mock-up module 3 as second appendix to the guideline EMA/HMPC/71049/2007 Rev. 1.

The HMPC adopted the 'Reflection paper on the use of recovered/recycled solvents in the manufacture of herbal preparations for use in herbal medicinal products / traditional herbal medicinal products' (EMA/HMPC/453258/2013). The document will be published at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000365.jsp&mid=WC0b01ac0580029569

The next meeting (virtual) of the DG Q will be held on 15 January 2014.

Nomination of the HMPC observers Ph. Eur. expert groups 13A, 13B and TCM

The HMPC re-nominated Prof. I. Chinou as observer in expert group 'Phytochemistry 13A', Pharm. H. Neef as observer in expert group 'Phytochemistry 13B' and confirmed Prof. R. Länger's nomination as observer in expert group 'Traditional Chinese Medicine' (TCM). These observerships for a 3-year term as of January 2014 will complement the EDQM observership in the HMPC and in the DG Q. These mutual, direct interactions via the participation of observers form the basis for a continued coordination between the EMA and the European Pharmacopoeia in the field of herbal medicinal products.

Drafting Group on Organisational matters (DG ORGAM)

The HMPC heard a report on the DG ORGAM meeting (virtual) held on 15 October 2013, in particular the progress concerning the template for assessment reports on the establishment of monographs and the development of a Questions & Answers on non-European traditional medicines.

The next meeting (virtual) of the DG ORGAM is scheduled for 14 January 2014.

Report from the November 2013 Working Party on Community Monographs and Community List (MLWP)

The MLWP held its 46th meeting at the European Medicines Agency on 12 to 14 November 2013, welcoming Prof. C. Cavaleiro (Portugal) and Dr C. Purdel (Romania) as new members.

Revisions

The MLWP further progressed the revision of the monographs and supporting documents on Echinaceae purpureae herba and Menthae piperitae aetheroleum as well as that for Eleutherococci radix Passiflorae herba and Lupuli flos.

Finalisation

The working party finalised its assessment on Curcumae xanthorrhizae rhizoma, Ginseng radix, Rubi idaei folium and Sambuci fructus, taking into account comments received during public consultation (if any). After peer-review, the documents will be transmitted to the HMPC for possible final adoption at the January 2014 meeting.

Drafts

The MLWP further worked on Ginkgo folium at the request of HMPC. The working party continued its assessment of Matricariae flos & M. aetheroleum, Myrtilli fructus siccus, Pruni africanae cortex, Silybi mariani fructus and Sabalis serrulatae fructus. First presentation/discussion took place for Agrimoniae herba, Capsici fructus, Carvi aetheroleum & C. fructus, Crataegi folium cum flore & C. fructus, Eschscholziae herba cum flore, Lichen islandicus and Pilosellae herba cum flore.

The next meeting of the MLWP is scheduled for 28-30 January 2014.

Contact for further information

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