

7 October 2013
EMA/HMPC/587804/2013
Committee on Herbal Medicinal Products (HMPC)

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

The 54th HMPC meeting, held on 16-17 September 2013

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 54th meeting of the Committee and in particular Tina Engraff, the new European Commission representative (DG SANCO Unit D-6) at the HMPC.

Draft Community herbal monographs

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

- Draft 'Community herbal monograph on *Rosa gallica* L., *Rosa centifolia* L., *Rosa damascena* Mill., flos' (EMA/HMPC/137299/2013)

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

Final public statements

The HMPC adopted the following final public statement and related documents (list of references and assessment report):

- 'Public statement on *Andrographis paniculata* Nees, folium' (EMA/HMPC/709282/2012)

As no comments were received on the draft public statement during public consultation, the final version is published without any 'Overview of comments'. 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_000173.jsp&mid=WC0b01ac058001fa1d

Other

New interested parties to the HMPC

The HMPC accepted candidatures from two organisations to be added to the List of interested parties to the HMPC: the scientific organisation 'Good practice in Traditional Chinese Medicine Research Association (GP-TCM RA)' and the industry organisation 'European Confederation of Pharmaceutical Entrepreneurs (Eucope)'. The list will be updated and can be found at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000223.jsp&mid=WC0b01ac058003529f

Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs)

Due to coordination with the Safety Working Party (SWP), the publication of the revised draft public statement has been postponed and is expected after the next SWP meeting in October. The document will be available here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000497.jsp&mid=WC0b01ac05804545f1d

Drafting Group on Quality (DG Q)

The HMPC heard a report on the DG Q (virtual) meeting held on 25 July 2013.

The drafting group had progressed with the development of Q&A on quality of essential oils and on benzene as a potential impurity in solvents used in manufacture of herbal preparations.

The HMPC adopted the DG Q work programme 2014, pending final specification of meeting dates according to available budget. The work programme will be published at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/HMPC/people_listing_000049.jsp&mid=WC0b01ac0580028e9b

The next meeting (virtual) of the DG Q will be held on 16 and 17 October 2013.

Annual meeting with Chairs of the Ph. Eur. Expert groups 13A, 13B and TCM

Experts of the DG Q together with the Chairs of the European Pharmacopoeia expert groups 13A, 13B and TCM and members of the supporting EDQM secretariat held a specific session within the MLWP meeting on 17 September 2013.

Beside mutual information on ongoing and finalised work in 2013 and the work programmes for 2014, the participants discussed current topics in the field of herbal quality standards requiring communication between EDQM and EMA such as the finalisation of the revision of Ph. Eur. monograph on extracts, possibilities for consideration of fresh plant material in the monograph on herbal drugs, analytical and regulatory aspects of pyrrolizidine alkaloids as well as quality requirements for essential oils.

The importance of continued coordination was emphasised as monographs and methods established by EDQM and regulatory -in particular safety- aspects addressed by HMPC guidance and monographs form the backbone of harmonised quality and safety criteria for the marketing of herbal medicinal products in Europe.

Drafting Group on Organisational matters (DG ORGAM)

The HMPC adopted the DG ORGAM work programme 2014, pending final specification of meeting dates according to available budget. The work programme will be published at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/HMPC/people_listing_000048.jsp&mid=WC0b01ac0580028e9a

The next meeting (virtual) of the DG ORGAM is scheduled for 15 October 2013.

Working Party on Community Monographs and Community List (MLWP)

Following nominations from Member States and on advice by the Chairs of HMPC and MLWP, the HMPC appointed Prof. C. Cavaleiro (PT) and Dr C. Purdel (RO) as new members of the MLWP in replacement of the last two members who had resigned. The composition of and other information on the MLWP can be found here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/HMPC/people_listing_000046.jsp&mid=WC0b01ac0580028e98

The HMPC adopted the MLWP work programme 2014, pending final adjustments to the progress reached at the November meeting. The work programme will be published at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/HMPC/people_listing_000046.jsp&mid=WC0b01ac0580028e98

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

The MLWP held its 45th meeting at the European Medicines Agency, 17-19 September 2013.

Revisions

The MLWP finalised its work on the revision of monographs and supporting documents for *Anisi fructus* & *Anisi aetheroleum* and for *Thymi herba* for transmission to the HMPC in November, respectively for final adoption and for release for public consultation. First discussion took place as regards possible revision of documents for *Thymi herba*/ *Primulae radix*, *Hederae helices folium*, *Pelargonii radix*, *Echinaceae purpureae herba* and *Menthae piperitae aetheroleum*.

Finalisation

The working party finalised its assessment on *Camelliae sinensis non fermentata folia* and *Phaseoli fructus (sine semine)* taking into account comments received during public consultation (if any). After peer-review, the documents will be transmitted to the HMPC for final adoption at the November meeting.

Further work took place on the assessment of *Sambuci fructus* after receiving comments on the draft public statement.

Drafts

The MLWP endorsed the monographs on *Ginkgo folium*, *Sisymbrii officinalis herba* for early peer-review and transmission to the HMPC for possible release in November 2013 for public consultation.

The working party continued its assessment of *Matricariae flos*, *Matricariae aetheroleum* and *Sabalis serrulatae fructus*. Furthermore Rapporteurs questions towards the assessment of *Myrtilli fructus siccus* and *Pruni africanae cortex* were discussed.

The next meeting of the MLWP is scheduled for 12-14 November 2013.

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