18 September 2017
EMA/HMPC/637548/2017 **FINAL**
Committee on Herbal Medicinal Products (HMPC)

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

The 78th HMPC meeting, held on 18-19 September 2017

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 78th meeting of the Committee.

Revised European Union herbal monograph

Upon recommendation from the MLWP, the HMPC adopted after systematic review the following **final revised** EU herbal monograph:

- Revised EU herbal monograph on Ribis nigri folium

The revised monograph together with the supporting documents (no comments were received during public consultation) 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&mid=WC0b01ac058001fa1d

Guidelines

Upon recommendation from the MLWP, the HMPC adopted the following **final revised** guideline:

- Assessment of clinical safety and efficacy in the preparation of EU herbal monographs for well-established and of EU herbal monographs/entries to the EU list for traditional herbal medicinal products/substances/preparations (EMA/HMPC/104613/2005 Rev. 1)

The revised guideline together with the overview of comments received during public consultation will be published here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000828.jsp&mid=WC0b01ac0580033a9b

Other

Call for proposals of substances for HMPC assessment

In line with the Committee work plan to identify gaps in herbal substances used by EU citizen but without harmonised standards so far, the HMPC enquires all Interested parties and National Competent Authorities to submit proposals for substances to be assessed by the HMPC. Proposals can include

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substances/preparations used as single active substance in herbal medicinal products but also specific combinations. The HMPC invites also to consider substances of non-European traditions. Interested parties should limit proposals to maximum 6 specific single substances or 6 specific combinations and provide for each a short justification on EU market relevance and availability of supporting data to prove 15/30 years of safe medicinal use with a specified therapeutic indication, strength and posology[1].

Proposals should be provided by **15 November 2017** to following email address: hmpc.secretariat@ema.europa.eu

The list of substances previously proposed for European assessment can be found here:

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500017723.pdf

The list of substances added to the work programme of the Committee and the current status of work can be found here:

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500017724.pdf

Interested parties to the HMPC

Upon request the HMPC accepted EUROCAM (European Complementary and Alternative Medicine Stakeholder Group) as new Interested Party to the HMPC. The list of Interested Parties will be updated accordingly. More information about interaction between HMPC and Interested Parties can be found here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000223.jsp&mid=WC0b01ac05807fa576

Quality Drafting Group (Q DG)

The HMPC noted a report on the Q DG meeting held on 07 September 2017.

Upon recommendation by Q DG, the committee adopted the following concept paper:

- Concept paper on the development of a Reflection Paper on new analytical methods/technologies in the quality control of herbal medicinal products (EMA/HMPC/541422/2017)

Interested parties are invited to send relevant information in order to allow the development of a Reflection paper. Comments/information should be sent by **30 April 2018**. The Concept paper will be published here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000497.jsp&mid=WC0b01ac0580033a9b

The HMPC further noted a report on topics under discussion including revision of the herbal specification guideline, considerations on the concept of markers after consultation of quality assessors across the network, the follow-up on the reflection paper on Polycyclic Aromatic Hydrocarbons (PAH), the preparation of an HMPC assessors training in December and the current status and limitations of WHO guidelines in the herbal area.

The next meeting of the Q DG will be held on 19 October 2017.

[1] Please refer also to specific guidance in this regards as published on the EMA website under 'Proposing substances for assessment': http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001149.jsp&mid=WC0b01ac0580033a9d

Organisational Matters Drafting Group (ORGAM DG)

The HMPC noted a report on the ORGAM DG meeting held on 05 September 2017.

Upon recommendation by the drafting group, the committee adopted the following draft revised procedure for public consultation until **31 January 2017**:

- Procedure for the review and revision of European Union herbal monographs and European Union list entries (EMA/HMPC/124695/2011 Rev. 2)

The revised procedure will be published here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001149.jsp&mid=WC0b01ac0580033a9d

Aim is to streamline the process EU herbal monographs are kept up-to-date as a workable standard for applicants and National Competent Authorities taking into account available resources at the HMPC and MLWP. The scope of the procedure has been widened from the periodic review/revision to unscheduled reviews/ revisions in line with a previous Reflection paper (EMA/HMPC/326440/2007). As a main principle, the revision of monographs and supporting documents will only be started if during the review of newly available data relevant new information has been identified that potentially change the content of a monograph.

The committee further heard a report on other discussions held at the drafting group either linked to the new procedure (template adaptations and best practice guidance) or regarding the addition of new substances to the HMPC work programme (template, criteria for prioritisation, call for proposals).

The next meeting of the DG ORGAM is scheduled for 17 October 2017.

Report from the September 2017 meeting of the Working Party on European Union Monographs and List (MLWP)

The MLWP held its 69th meeting at the European Medicines Agency on 19 - 21 September 2017.

New assessments - finalisation

The working party finalised the assessment of Piperis methystici rhizoma and supporting documents including the Overview of comments received during public consultation for peer review and possible final adoption by the HMPC in November 2017.

New assessments - drafts

The working party continued its assessment of Fragariae folium, Malvae folium, Malvae sylvestris flos, Species sedativae and Species digestivae / stomachicae.

Monograph review and revisions - finalisation

After public consultation, the working party finalised the revision of the documents on Meliloti herba, for peer review and transfer to the HMPC in November 2017 for possible final adoption.

MLWP had first discussions of comments received on the revised monograph on Uvae ursi folium.

Monograph review and revisions - drafts

The working party agreed to the revision of the documents on Valerianae radix/Lupuli flos and Curcumae longae rhizoma for peer review and transfer to the HMPC in November 2017 for possible release for public consultation.

The MLWP continued the systematic review of Cynarae folium, Hyperici herba, Rusci aculeati rhizoma and Calendulae flos and had first discussions on the review of Agni casti fructus, Gentianae radix and Oenotherae oleum.

Contact for further information

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