



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 November 2017
EMA/HMPC/784341/2017
Committee on Herbal Medicinal Products (HMPC)

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

The 79th HMPC meeting, held on 20-21 November 2017

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 79th meeting of the Committee.

The committee elected as co-opted members Maria Helena Pinto Ferreira (General and family medicine), Gert Laekeman (Experimental/non-clinical pharmacology) and Silvia Giroto (Paediatric medicine) for a renewed 3-year mandate.

Revised European Union herbal monographs

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

- Revised EU herbal monograph on *Hederae helices folium* (by majority vote)

After review of newly available data, no major changes have been introduced in the monograph and therefore a public consultation was not considered necessary.

- Revised EU herbal monograph on *Meliloti herba* (by consensus)

No comments have been received during public consultation.

The revised monographs together with the HMPC opinion and 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&mid=WC0b01ac058001fa1d

After systematic review the following **draft revised** EU herbal monographs have been adopted for **public consultation until 15 March 2018**:

- Draft revised EU herbal monograph on *Curcumae longae rhizoma*
- Draft revised EU herbal monograph on *Valerianae radix/Lupuli flos*

Draft revised documents will be published here:

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



Other

Public statement

Upon recommendation from the MLWP, the HMPC adopted after public consultation the following **final public statement** by consensus:

- Public statement on Piperis methystici rhizoma

The HMPC explains in the statement and underlying assessment report why not all requirements for monograph establishment were considered fulfilled in particular with regard to Article 16a(1)(e) and Article 10a of Directive 2001/83/EC.

The final public statement together with the HMPC opinion and supporting documents including the Overview of comments 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

Reflection paper on Polycyclic Aromatic Hydrocarbons in herbal medicinal products/traditional herbal medicinal products

Upon recommendation from the MLWP and the Quality Drafting Group, the HMPC adopted the Overview of comments received on the Reflection paper EMA/HMPC/300551/2015 during public consultation. HMPC welcomed the stepwise approach proposed by Interested parties and the willingness to contribute to the collection and sharing of data. At present, the data available on levels of contamination found in herbal medicinal products is limited and is not yet sufficient to serve as a basis for specific guidance or standard controls. However, taking into account the existing regulations in the food sector, the HMPC will reflect on appropriate consideration of potential contamination during the ongoing revision of herbal quality guidelines. Some exchange with stakeholders and assessors on experiences with substances at risk and possible future actions is expected during the assessors training in December 2017. The Overview of Comments will be published here:

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

Quality Drafting Group (Q DG)

The HMPC noted a report on the Q DG meeting held on 19 October 2017.

The progress with drafting activities was reported as well as other topics discussed including revision of the herbal specification guideline, the follow-up on the reflection paper on Polycyclic Aromatic Hydrocarbons (see above) and the preparation of the HMPC assessors training in December. The DG discussed further coordination topics with EDQM and QWP, quality-related requests from NCAs as well as the status of the work plan 2017 and the draft work plan 2018.

The next meetings of the Q DG will be held on 08 December 2017 (TC) and 14/15 December 2017 (face to face).

Organisational Matters Drafting Group (ORGAM DG)

The HMPC noted a report on the ORGAM DG meeting held on 17 October 2017.

Upon recommendation by the drafting group, the committee adopted one Q&A clarifying the difference between EU herbal monograph and individual product SmPCs. It will be added to summarised regulatory Q&As on herbal medicinal products:

- Regulatory Q&A on herbal medicinal products (EMA/HMPC/345132/2010 Rev. 4)

The revised Q&A will be published here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000152.jsp&mid=WC0b01ac0580033a9c

The committee further adopted a revised template for the HMPC opinion on EU list entries. Modifications were introduced to clarify the nature of an opinion on a change to an existing list entry or also a proposed withdrawal of a list entry in case new safety data make such a revision necessary.

The next meeting of the DG ORGAM is scheduled for 05 December 2017.

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

The MLWP held its 70th meeting at the European Medicines Agency on 21 - 23 November 2017.

New assessments - drafts

The working party continued its assessment of *Fragariae folium*, *Malvae folium*, *Malvae sylvestris flos*, *Species sedativae*, *Species digestivae / stomachicae*, *Vaccinii macrocarpi fructus* and had first discussions on *Species amarae*.

Monograph revisions - finalisation

After public consultation, the working party finalised the revision of the documents on *Uvae ursi folium*, for peer review and transfer to the HMPC in January 2018 for possible final adoption.

Upon request by HMPC the MLWP re-discussed the revision of the monograph on *Pelargonii radix* and general questions linked to the clinical assessment.

Monograph revisions - drafts

MLWP agreed to the draft revised documents on *Hyperici herba* (TU) and *Rusci aculeati rhizoma* for peer review and transfer to the HMPC in January 2018 for possible release for public consultation.

The MLWP continued the revision of *Agni casti fructus*, *Calendulae flos*, *Cynarae folium*, *Echinaceae pallidae radix*, *Gentianae radix*, *Sambuci flos*, *Verbasci flos*, *Thymi aetheroleum*, *Oenotherae oleum*, and *Tanaceti parthenii herba*.

Monograph systematic review

The working party agreed that after a call for data and systematic review no revision of the monograph on *Polypodii rhizoma* is necessary; i.e. published HMPC opinion, monograph and supporting documents will not be changed. An addendum to the existing assessment report to show the absence of relevant new data for the monograph was agreed for peer review and transfer to the HMPC in March 2018.

The MLWP had first discussions on the need for revisions of documents for Avenae herba and Avenae fructus.

Contact for further information

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