



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

The 77th HMPC meeting, held on 17-18 July 2017

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 77th meeting of the Committee.

Final European Union herbal monograph

Upon recommendation from the MLWP, the HMPC adopted by majority the following **final** EU herbal monograph and supporting documents:

- EU herbal monograph on *Allii sativii* bulbus

The final monograph together with the supporting documents including the Overview of comments 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

Revised European Union herbal monographs

Upon recommendation from the MLWP, the HMPC adopted after systematic review the following **draft revised** EU herbal monographs and supporting documents for 3 months **public consultation until 30 November 2017**:

- Revised EU herbal monograph on *Cimicifugae* rhizoma
- Revised EU herbal monograph on *Sennae folium*
- Revised EU herbal monograph on *Sennae fructus*

The revised monographs together with the 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



Guidelines

Upon recommendation from the MLWP, the HMPC adopted the following **draft revised** guideline for 3 months **public consultation until 30 November 2017**:

- Guideline on Non-clinical documentation for Herbal Medicinal Products in applications for Marketing Authorisation and in applications for Simplified Registration (EMA/HMPC/32116/2005 Rev. 1)

The draft revised guideline will be published here:

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

Quality Drafting Group (Q DG)

The HMPC noted a report on the Q DG meeting held on 28 June 2017.

The Q DG Chair highlighted items discussed and announced that the DG is finalising the review of the specification guideline. As regards future guidance on the use of new analytical methods it was agreed to publish first a concept paper. Members agreed also on main topics of an assessors training on contaminants in herbal medicinal products to be held in December at the EMA and discussed coordination topics with Quality WP, EDQM and WHO.

Upon recommendation from Q DG the HMPC adopted the following guideline by the Quality Working Party:

- Guideline on manufacture of the finished dosage form (EMA/CHMP/QWP/245074/2015)

The guideline is not mainly focused on HMP but also applicable to HMP and will be published here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000731.jsp&mid=WC0b01ac0580028e8b

The next meeting of the Q DG will be held on 07 September 2017.

Organisational Matters Drafting Group (ORGAM DG)

The HMPC noted a report on the ORGAM DG meeting held on 27 June 2017.

The Chair summarised discussions and conclusions on (1) the revision procedure including subsequent changes in the procedure for call for data, (2) the development of a Q&A on the scope of EU herbal monographs, and (3) procedure and documents for proposing/ prioritising herbal substances for HMPC assessment.

Remaining questions on principles of the review/revision procedure were presented to the committee and directions given before regulatory and legal clarification. The release for public consultation of the revised procedure is anticipated for September.

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

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

The MLWP held its 68th meeting at the European Medicines Agency on 18 - 20 July 2017.

New monographs - finalisation

No comments have been received during public consultation on the Public statement and supporting documents for *Glycini semen*. The draft document will therefore be transferred for peer review and possible final adoption by the HMPC in November 2017.

New monographs - drafts

The working party had first discussions on the assessment of herbal tea combinations (*Species digestivae/ stomachicae* and *Species sedativae*) following the call for data.

Monograph review and revisions - finalisation

Following Rapporteur request at HMPC, the MLWP re-discussed the revised documents for *Pelargonii radix* for peer review and transfer to the HMPC in September 2017 for possible final adoption.

After public consultation, the working party finalised the revision of the documents on *Ribis nigri folium* for peer review and transfer to the HMPC in September 2017 for possible final adoption.

MLWP decided to keep documents for *Menthae folium* (after public consultation) on hold until the assessment report for *Menthae piperitae aetheroleum* is completed.

Monograph review and revisions - drafts

Upon request by HMPC, the working party re-discussed the documents on *Menthae piperitae aetheroleum*.

The MLWP continued the systematic review of *Valerianae radix/Lupuli flos*, *Cynari folium*, *Curcumae longae rhizome*, *Thymi aetheroleum*, and *Rusci aculeati rhizoma* and had a first discussion on the review of *Calendulae flos*.

Contact for further information

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