



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 March 2015
EMA/HMPC/180661/2015
Committee on Herbal Medicinal Products (HMPC)

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

The 63rd HMPC meeting, held on 09-10 March 2015

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 63rd meeting of the Committee.

Revised European Union herbal monographs

Upon recommendation from the MLWP as a result of the systematic review of all newly available data, the HMPC adopted the following final revised EU herbal monograph:

- Revised European Union herbal monograph on Lini semen

The monograph 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

Draft European Union herbal monographs

Upon recommendation from the MLWP, the HMPC adopted the following draft EU herbal monograph for public consultation until **30 June 2015**:

- Draft European Union herbal monograph on Epilobii herba

The draft monograph 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

Public statements

Upon recommendation of the MLWP, the HMPC adopted the following draft public statement for public consultation **until 30 June 2015** explaining why a EU herbal monograph could not be developed so far:

- Public statement on Uncariae tomentosae cortex



The draft public statement together with 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

The committee adopted an appendix to the following **draft revised guideline** for public consultation until **30 June 2015**:

- 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. 2) - Appendix 2: Mock up dossier for the Module 3 Quality: Chemical, Pharmaceutical and Biological Information for Herbal Substances, Herbal Preparations and Traditional Herbal Medicinal Products

The draft revised guideline together with draft appendix 2 (mock-up) will be published on the European Medicines Agency's website at:

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

Drafting Group on Quality (DG Q)

The HMPC heard a report on the DG Q meeting held on 11-12 February 2015.

During the face to face meeting the group finalised draft appendix 2 (mock-up) for the CTD guideline (see above), discussed comments received on the draft reflection paper on microbiological aspects as well as coordination topics with QWP and EDQM. A first evaluation was performed on the need to update and revise the main herbal quality guidelines in line with the DG Q work plan. Upon request by the HMPC and recommended changes by the drafting group, the HMPC adopted the amended:

- Questions & answers on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/41500/2010 Rev.5)

Revision 5 pertains to updates in Q&A 1 on microbiological quality and a newly added Q&A 10 under 'testing' with respect to benzene impurities. The revised Q&A document will be published here:

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

The next meeting of the Q DG will be held on 26 March 2015.

Drafting Group on Organisational matters (DG ORGAM)

The HMPC heard a report on the DG ORGAM meeting held on 10 February 2014.

The drafting group had further reviewed the suitability of the QRD template (SmPC, labelling and package leaflet) used in mutual recognition and decentralised procedures regarding specifics for (traditional) herbal medicinal products. A proposal for discussion with the QRD group as regards to these specific products is currently under preparation. Furthermore some aspects of the Procedure for the systematic review of EU herbal monographs - currently under revision at MLWP- were discussed.

The next meeting of the DG ORGAM will be held on 24 March 2015.

Report from the March 2015 Working Party on European Union Monographs and List (MLWP)

The MLWP held its 54th meeting at the European Medicines Agency on 10–12 March 2015.

Monograph revisions

The MLWP discussed draft revised monographs on *Menthae piperitae aetheroleum*, *Menthae piperitae folium*, *Valerianae radix* and had a first discussion on the revision of *Salviae folium*.

Monograph finalisation

The working party discussed and endorsed the documents on *Capsici fructus* and *Symphyti radix* for transfer to the Committee for final adoption in May 2015. A first discussion took place on comments received during public consultation for the draft monograph on *Crataegi folium cum flore*.

Monograph drafts

The MLWP endorsed the draft monograph on *Ricini oleum* for peer review and final decision by the HMPC for possible release in May 2015 for public consultation.

The working party continued its assessment of *Origanum majoranae herba*, *Pistacia lentiscus resinum* (mastic), *Sideritis herba* and *Cistus creticus folium* and had first discussions on the assessment of *Polygonum avicularis herba*, *Juniperi communis summitates* and *Paeoniae radix*.

The next meeting of the MLWP is scheduled for 5–7 May 2015.

Contact for further information

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