



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/HMPC/633878/2016
Committee on Herbal Medicinal Products (HMPC)

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

The 72nd HMPC meeting, held on 19-20 September 2016

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 72nd meeting of the Committee. Changes in composition were announced: Expiry of mandate for the Estonian member and alternate and resignation of A. O' Sullivan as alternate for Ireland.

The composition of the HMPC can be found here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/2010/02/people_listing_000006.jsp&mid=WC0b01ac0580028e7e

Final European Union herbal monograph

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

- EU herbal monograph on *Origanum majoranae herba*, by majority vote

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 **31 January 2017**:

- Draft EU herbal monograph on *Species diureticae*

The draft monograph is the outcome of a pilot project to establish monographs on common tea combinations with a selection of a few herbal substances within certain ranges out of several herbal substances traditionally used in combination products with a similar indication.

- Second Draft EU herbal monograph on *Silybi mariani fructus*



The committee decided to exceptionally publish a second draft monograph following major changes in comparison to the first draft including the indication. Interested parties are given the chance to comment on these changes. The draft overview of comments will also be published to have a transparent feedback on comments raised earlier avoiding the need for repetition.

The draft monographs together with the draft assessment report and list of references 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 monograph

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

- EU herbal monograph on *Salviae officinalis folium*, by majority vote

The monographs 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

Regulatory guidance

The HMPC adopted the following documents:

- Amendment of the Regulatory Q&A on herbal medicinal products (EMA/HMPC/345132/2010) with four Q&A on the traditional use evidence

The **revision 3** of the document 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

- Patient Leaflet template concerning advice on the preparations of herbal teas as (traditional) herbal medicinal products by end-users' (EMA/HMPC/30603/2012 Rev.1)

The document has previously been adopted for consideration by NCAs but was now found useful to be published to be available also for consideration by Interested parties:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001159.jsp&mid=WC0b01ac058003380a

Quality Drafting Group (Q DG)

The HMPC heard a report on the QDG meeting held on 07 September 2016.

The group amended the revision of the quality guideline which after final check will be shared with HMPC in November. Release for public consultation was agreed to be kept in conjunction with the revised herbal specification guideline which has now been started. In this context the herbal quality Q&A are currently reviewed for new additions but also reductions when possible to include some questions in the revised guidelines. Furthermore work plan and coordination with EDQM were addressed.

The next meeting of the QDG will be held on 05 October 2016.

Organisational Matters Drafting Group (ORGAM DG)

The HMPC heard a report on the DG ORGAM meeting held on 06 September 2016.

The DG had discussed the revision of the 'Procedure for the systematic review of EU herbal MOs and LEs and supporting documents', proposals on update of existing template for EU herbal monographs, draft work plan 2017, new mandate, membership and future structure for ORGAM DG. HMPC agreed to a streamlined 3 step approach for the review and revision of monographs and asked the DG to draft procedural documents accordingly.

The next meeting of the DG ORGAM is scheduled for 06 October 2016.

Other

HMPC assessors training 3-4 November 2016

The HMPC adopted the agenda for training on specific aspects of risk assessment as well as experiences with European assessment of (Traditional) Herbal Medicinal Products using EU herbal monographs. The objective is to contribute to the EU-wide harmonisation when using available general standards vis-à-vis product particular requirements and recent developments. Regulatory assessors and coordinators as well as safety and efficacy assessors of herbal medicinal products are invited to discuss current challenges in two sessions comprising 13 presentations.

Report from the September 2016 meeting of the Working Party on European Union Monographs and List (MLWP)

The MLWP held its 63rd meeting at the European Medicines Agency on 20-22 September 2016.

New monographs - finalisation

The working party continued the assessment for *Paeoniae radix alba* and *Paeoniae radix rubra* following comments received on the draft public statements.

New monograph - drafts

The MLWP discussed and endorsed the draft documents on *Piperis methystici rhizoma* for early peer review and transfer to the HMPC for possible release in November 2016 for public consultation.

The working party continued its assessment of *Cisti cretici folium*, *Fragariae folium* and *Glycini semen*.

Monograph revisions

The MLWP discussed and endorsed revised documents for *Aloe*, *Boldi folium*, *Echinacea purpureae radix*, *Meliloti herba*, *Menthae piperitae aetheroleum*, *Menthae piperitae folium*, *Salicis cortex* and *Vitis viniferae folium* for peer review and possible transfer to the HMPC in November 2016.

The MLWP continued the systematic review of *Sennae folium*, *Sennae fructus* and *Oleae folium* and had first discussions on the revision of *Sambuci flos* and *Verbasci flos*.

Contact for further information

Anabela Marçal

Head of Committees and Inspections Department

Inspections, Human Medicines Pharmacovigilance & Committees Division

Tel. +44 (0)20 3660 8449 | Fax +44 (0)20 3660 5525

E-mail: hmpc.secretariat@ema.europa.eu