



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 75th HMPC meeting, held on 27-28 March 2017

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 75th meeting of the Committee.

Changes to the committee's composition were announced: end of mandate for Dace Kalke (member Latvia) and Nadia Grigoras (member Romania); start of mandate for Carmen Purdel (member Romania), Raluca Iavorszky (alternate Romania), Iliana Ionkova (alternate Bulgaria); Evita Skukauska (member Latvia), Wim Huygh (alternate Belgium) and Alessandro Assisi (member Italy).

The full composition of the committee 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 newly established **final** EU herbal monograph and supporting documents:

- EU herbal monograph on 'Species diureticae', 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

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 **15 July 2017**:

- Draft revised EU herbal monograph on Meliloti herba
- Draft revised EU herbal monograph on Uvae ursi folium



The draft 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

Quality Drafting Group (Q DG)

The HMPC noted a report on the Q DG meeting held on 23/24 February 2017.

The HMPC adopted a proposal for establishment of Ph. Eur. monographs for substances assessed by HMPC without a Ph. Eur. quality standard so far. The proposal will be submitted to EDQM.

The drafting group had continued the detailed review of the herbal specification guideline.

Q DG had also compiled comments on a draft WHO guideline on Good Herbal Processing Practice which had been shared with HMPC and EMA manufacturing and quality compliance before submission to WHO. Finally, other coordination activities with EDQM and QWP had been discussed as well as the finalisation of a draft reflection paper on new analytical methods.

The next meeting of the Q DG will be held on 20 April 2017.

Organisational Matters Drafting Group (ORGAM DG)

The HMPC adopted a new mandate for the ORGAM DG which will be published here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/HMPC/people_listing_000048.jsp&mid=WC0b01ac0580028e9a

The Committee elected G. Laekeman (BE) as the new ORGAM DG Chair with a 3-year mandate that started on 28 March 2017.

The HMPC further appointed 3 members as ORGAM DG members that had expressed an interest in continued membership.

Due to resources the HMPC decided to reduce the ORGAM DG work plan 2017. Revision 1 of the work plan will be published here

http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/HMPC/people_listing_000048.jsp&mid=WC0b01ac0580028e9a

The next meeting of the DG ORGAM was scheduled for 5 April 2017.

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

The MLWP held its 66th meeting at the European Medicines Agency on 28-30 March 2017.

New monographs - finalisation

Following comments received after public consultation, the MLWP discussed and endorsed the final documents for *Silybi mariani fructus* for peer review and transfer to HMPC for possible final adoption in May 2017. The working party had a first discussion on the comments received on the assessment of *Piperis methystici rhizoma*.

New monographs - drafts

The MLWP discussed and endorsed the documents for *Fragariae folium* for peer review and possible transfer to the HMPC in May 2017 for release for public consultation.

The working party continued its assessment of *Malvae folium* and *Malvae silvestris flos*.

Monograph review and revisions

The MLWP re-discussed and endorsed the revised documents for *Pelargonii radix* (after public consultation and HMPC request) for peer review and transfer to the HMPC in May 2017 for possible final adoption.

The MLWP further discussed and endorsed the revised documents for *Absinthii herba* (without public consultation), *Echinaceae purpureae radix* and *Vitis viniferae folium* (after public consultation) for peer review and possible transfer to the HMPC in May 2017 for final adoption.

The MLWP continued the systematic review of *Menthae piperitae aetheroleum*, *Sambuci flos*, *Verbasci flos*, *Frangulae cortex*, *Rhamni purshianae cortex*, *Rhei radix*, *Cimicifugae rhizome*, *Cynarae folium* and *Valerianae radix/Lupuli flos* and had first discussions on the need for revision of monographs on *Curcumae longae rhizoma* and *Rusci aculeati rhizoma*.

Hearing with AESGP

The MLWP welcomed representatives of the Association of the European Self-Medication Industry (AESGP) for a two hours exchange on topics related to the monograph and guidance establishment as well as linked items regarding herbal medicinal products regulation in the EU such as national and European procedures. A report on the hearing will be published here:

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

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