



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 73rd HMPC meeting, held on 21-22 November 2016

The Committee elected Marisa Delbò as the new Chair with a 3-year mandate that started on 21 November 2016.

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 73rd meeting of the Committee. Changes in composition were announced: Rachel Cox, new alternate for Ireland; Jacqueline Viguet Poupelloz, expiry of mandate as alternate for France.

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

The Committee elected Burt H. Kroes as the new vice-Chair of the Monograph and List Working Party (MLWP), for a 3-year mandate starting 21 November 2016.

Revised European Union herbal monographs

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

- EU herbal monograph on Aloe, by consensus
- EU herbal monograph on Boldi folium, by consensus

No relevant new data were detected that would lead to major changes of the monographs; therefore a public consultation was not considered necessary.

The Committee further adopted the following **draft** revised EU herbal monographs and supporting documents for 3 months public consultation until **15 March 2017**:

- Draft EU herbal monograph on Echinaceae purpureae radix
- Draft EU herbal monograph on Vitis viniferae folium

The final and 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

Public statement

Upon recommendation from the MLWP, the HMPC adopted the following **draft** public statement and supporting documents for 3 months public consultation **until 15 March 2017**:

- Draft public statement on *Piperis methystici* rhizoma

The document explains the reasons why the HMPC is of the opinion that a European Union herbal monograph on *Piper methysticum* G. Forst., rhizoma cannot be established at present.

The draft public statement together with the draft assessment report and draft 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

Quality Drafting Group (Q DG)

The HMPC noted a report on the QDG meeting held on 05 October 2016.

The group further amended the revision of the herbal quality guideline and discussed projects for 2017 mostly dedicated to the revision of guidelines, quality Q&A and coordination with EDQM.

The HMPC adopted the Q DG work plan 2017 which will be published here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/HMPC/people_listing_000049.jsp&mid=WC0b01ac0580028e9b

The next meeting of the Q DG will be held on 07 December 2016.

Organisational Matters Drafting Group (ORGAM DG)

The HMPC noted a report on the DG ORGAM meeting held on 06 October 2016.

The DG had further discussed a new 'Procedure for the review and revision of EU herbal monographs and List entries'.

The HMPC adopted the ORGAM DG work plan 2017 which 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 is scheduled for 14 December 2016.

Other

HMPC assessors training 3-4 November 2016

The HMPC assessors training titled 'Experiences with European Assessment of (Traditional) Herbal Medicinal Products and specific aspects of risk assessment' was attended by 13 speakers and 60 further participants either at the EMA premises in London or online. On the first day, the regulatory background and national experiences with DCP/MRP procedures vis-à-vis the interpretation of 'serious risks to public health' and availability/content of EU herbal monographs were

discussed. On the second day, general and specific benefit-risk topics included presentations on drug induced liver injuries, pharmacovigilance provisions for herbal medicinal products, the use in pregnancy and lactation, and the assessment approach to minor indications suitable for self-medication. The Chair and participants considered the training and discussions as very useful for the daily practice at national competent authorities. Moreover it was a valuable feedback for the future work of the HMPC and its subgroups to further facilitate the registration and authorisation of herbal medicinal products in the EU via harmonised standards.

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

The MLWP held its 64th meeting at the European Medicines Agency on 22-24 November 2016.

New monographs - finalisation

Following comments received after public consultation, the MLWP discussed and endorsed the final documents on *Paeoniae radix alba*, *Paeoniae radix rubra*, *Lecithinum ex soya* and *Soiae oleum raffinatum* for peer review and transfer to the HMPC for possible final adoption in January 2017.

New monographs - drafts

The MLWP discussed and endorsed the draft documents on *Glycini semen* for early peer review and transfer to the HMPC for possible release in January 2017 for public consultation.

The working party continued its assessment of *Fragariae folium* and had first discussion on *Malvae folium* and *Malvae sylvestris flos*.

Monograph review and revisions

The MLWP discussed and endorsed documents for *Ribis nigri folium* and *Polypodii rhizoma* for peer review and possible transfer to the HMPC in January 2017.

Upon request by the HMPC the MLWP members re-discussed, amended and finalised the revised documents of *Pelargonii radix*, *Meliloti herba* and *Salicis cortex* for peer review and possible transfer to the HMPC in January 2017.

The MLWP continued the systematic review of *Oleae folium*, *Sambuci flos*, *Verbasci flos* and had first discussions on the need for revision of *Absinthi herba*, *Echinaceae pallidae radix*, *Frangulae cortex*, *Hippocastani semen*, *Rhamni purshianae cortex*, *Rhei radix* and *Uvae ursi folium*.

Contact for further information

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