



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 November 2018

EMA/HMPC/204861/2018

Committee on Herbal Medicinal Products (HMPC)

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

The 85th HMPC meeting, held on 19-20 November 2018

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 85th meeting of the Committee and announced changes to the composition: Una Mockler took over the role as new alternate for Ireland; Elizabeth Griffiths became new alternate for UK; Wim Huygh ended his membership as alternate for Belgium. The full composition of the committee can be found here:

<https://www.ema.europa.eu/en/committees/hmpc/members>

New European Union herbal monographs

Upon recommendation from the MLWP, the HMPC adopted after public consultation the following **final** EU herbal monographs:

- EU herbal monograph on *Fragariae folium* (by majority)
- EU herbal monograph on *Malvae folium* (by consensus)
- EU herbal monograph on *Malvae sylvestris flos* (by consensus)

The monographs together with the HMPC opinion and supporting documents including the Overview of comments as received during public consultation will be published on the European Medicines Agency's website at:

https://www.ema.europa.eu/en/medicines/field_ema_web_categories%253Aname_field/Herbal?sort=search_api_relevance&order=desc

Revised European Union herbal monographs

Upon recommendation from the MLWP, the HMPC adopted after systematic review, revision and public consultation the following **final revised** EU herbal monographs:

- Revised EU herbal monograph on *Gentianae radix* (by consensus)
- Revised EU herbal monograph on *Rusci aculeati rhizoma* (by consensus)

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The revised monographs together with the HMPC opinion and supporting documents including the Overview of comments as received during public consultation will be published on the European Medicines Agency's website at:

https://www.ema.europa.eu/en/medicines/field_ema_web_categories%253Aname_field/Herbal?sort=search_api_relevance&order=desc

European Union herbal monograph review

Upon recommendation from the Rapporteur, the HMPC decided after systematic review according to procedure EMA/HMPC/124695/2011 Rev. 2 that no revision is required because no new data of relevance were detected that would change the content of the:

- EU herbal monograph on Echinaceae angustifoliae radix

The review report will be published on the EMA website as Addendum to the existing Assessment report at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/herbal_search.jsp&mid=WC0b01ac058001fa1d

An overview on proposals for assessment and the status of HMPC assessment work is available here:

- Inventory of herbal substances for assessment – proposals for assessment (EMA/HMPC/494079/2007)
- Overview of assessment work (Priority list) (EMA/HMPC/278067/2006)

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001149.jsp&mid=WC0b01ac0580033a9d

Scientific/Regulatory Guidance

Upon recommendation from the Quality DG the HMPC adopted an amendment to the:

- Questions & answers on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/41500/2010 Rev.6)

For revision 6 one Q&A was added regarding the evaluation of (traditional) herbal medicinal products with respect to content of elemental impurities, since herbal products are not in the scope of the recently updated ICH guideline Q3D.

The updated document will be published on the European Medicines Agency's website at:

<https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines/multidisciplinary/multidisciplinary-herbal-medicinal-products#Quality>

Upon recommendation from the ORGAM DG and MLWP the HMPC adopted the following **draft revised procedure**:

- Procedure on management of proposals submitted by interested parties for EU List Entries or EU Herbal Monographs (EMA/HMPC/328575/2007 Rev.2)

for public consultation until **30 June 2019**.

Interested parties are invited to send comments on the procedure which was streamlined including a new template in order to facilitate proposals to the Committee and improve stakeholder interaction.

The draft revised procedure will be published on the European Medicines Agency's website at:

<https://www.ema.europa.eu/en/human-regulatory/herbal-products/procedures-monograph-list-entry-establishment>

HMPC meeting dates 2019

HMPC noted that because of the Agency's relocation no meetings of the Working Party on European Union Monographs and List (MLWP), the HMPC Quality Drafting Group (Q DG) and the HMPC Organisational Matters Drafting Group (ORGAM DG) will take place during phase 3 of the Agency's Business Continuity Plan (BCP). Development of guidelines is temporarily suspended with few exceptions (guidance on estragole, pyrrolizidine alkaloids). Temporary suspensions and scaling back of activities is currently scheduled to last until 30 June 2019. EMA will review this in April 2019, once it has moved to its temporary building in Amsterdam. More information can be found here:

<https://www.ema.europa.eu/en/about-us/united-kingdoms-withdrawal-european-union-brexit>

https://www.ema.europa.eu/documents/other/ema-brexit-preparedness-business-continuity-plan-phase-3-implementation-plan_en.pdf

HMPC meeting dates 2019 have been reviewed and extended as follows:

- 14-16 January (2.5 days)
- 13-15 May (2.5 days)
- 8-10 July (2.5 days)
- 23-26 September (1 day HMPC, 2 days MLWP)
- 18-20 November (2.5 days)

The meeting 4-7 of March 2019 has been cancelled because of the Agency's move to Amsterdam.

Contact for further information

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