16 January 2019
EMA/HMPC/26549/2019
Committee on Herbal Medicinal Products (HMPC)

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

The 86th HMPC meeting, held on 14-16 January 2019

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 86th meeting of the Committee.

Revised European Union herbal monograph

The HMPC adopted after systematic review the following **draft revised EU herbal monograph** for **public consultation until 15 May 2019**:

- Revised EU herbal monograph on Frangulae cortex

The monograph together with supporting documents 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 Rapporteurs, 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 Bursae pastoris herba
- EU herbal monograph on Leonuri cardiacae herba
- EU herbal monograph on Millefolii flos
- EU herbal monograph on Phaseoli fructus (sine semine)
- EU herbal monograph on Tormentillae rhizoma

The review reports will be published on the EMA website as addenda to the existing assessment reports of the respective monographs at:

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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Scientific/regulatory guidance

Update to Public statement on Contamination of herbal medicinal products/traditional herbal medicinal products with pyrrolizidine alkaloids (EMA/HMPC/328782/2016)

Since the HMPC Public Statement from May 2016, new information on the risks of pyrrolizidine alkaloids in honey, tea, herbal infusions (herbs) and food supplements was published by the European Food Safety Authority (EFSA)[1]. Furthermore, the European Directorate for Quality of Medicines (EDQM) has established a Working Party to develop a general Ph. Eur. method for testing pyrrolizidine alkaloids (PAs); this work is ongoing[2].

Due to ongoing European discussions and efforts for harmonization to characterise the risk of exposure of PAs to human health, the HMPC has agreed by consensus to extend the transitional period for products with levels up to 1.0 µg PAs/day for a further 2 years.

Whilst difficulties for manufacturers of herbal medicinal products to implement measures to reduce PA contamination are acknowledged, manufacturers should continue to take appropriate actions including implementation of enhanced GACP to ensure daily intake does not exceed 1.0 µg PAs/day.

As part of the HMPC work plan, the public statements on pyrrolizidine alkaloids (PAs) (EMA/HMPC/328782/2016 and EMA/HMPC/893108/2011) will be revised to provide direction/guidance for industry and NCAs.

Calls for data will be published on the EMA website at:

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

Interested parties are invited to provide available new information **by 31 July 2019**.

Work Plan 2019

The HMPC members discussed and adopted their work plan for 2019. The final work plan will be published on the EMA website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000264.jsp&mid=WC0b01ac0580028e7c

Call for data

The HMPC confirmed with work plan adoption to start the review procedure for several substances in order to decide whether new relevant data are available which requires the revision of existing EU herbal monographs. Calls for new data since publication of the previous monograph will be published for:

- Arctii radix
- Juniperi aetheroleum

[1] EFSA Risks for human health related to the presence of pyrrolizidine alkaloids in honey, tea, herbal infusions and food supplements. EFSA Journal 2017, 15(7): 4908. Available at: https://www.efsa.europa.eu/en/efsajournal/pub/4908. Accessed 12/2018

[2] EDQM. Outcome of the 157th Session of the European Pharmacopeia Commission. 2017. Available at: https://www.edqm.eu/sites/default/files/edqm_press_release_pheur_comm_157th_session_march_2017.pdf. Accessed 12/2018

- Juniperi pseudo-fructus
- Orthosiphonis folium
- Rosmarini aetheroleum
- Rosmarini folium
- Taraxaci folium
- Taraxaci radix cum herba

Calls will be published at the EMA website here:

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

and an overview will be made available here:

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

EU herbal monographs in preparation

New monographs - drafts

The HMPC continued the assessment of Menyanthes trifoliata folium and Species digestivae/stomachicae.

Monograph revisions - finalisation

After public consultation, the committee finalised the revision of documents on Menthae piperitae folium and Valerianae radix/Lupuli flos for peer review prior to possible final adoption.

Monograph revisions - drafts

The HMPC agreed to draft revised documents to be transmitted for peer-review prior to possible adoption for release for public consultation in May 2019 for Hippocastani semen, Menthae piperitae aetheroleum, Tanaceti parthenii herba and Rhamni purshianae cortex.

The committee continued the revision of documents for Thymi aetheroleum.

Monograph systematic review

The committee discussed the reviewed documents and available new data for Hamamelidis cortex, Hamamelidis folium, Hamamelidis folium et cortex aut ramunculus destillatum prior to decision on the need for monograph revision anticipated in May 2019.

An overview of HMPC assessment work is provided by document EMA/HMPC/278067/2006, which will be updated according to status after the HMPC January meeting:

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

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