25 September 2018
EMA/HMPC/677632/2018
Committee on Herbal Medicinal Products (HMPC)

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

The 84th HMPC meeting, held on 24-25 September 2018

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 84th meeting of the Committee and announced a change to the composition: Rachel Cox retired as alternate for Ireland. The full composition of the committee can be found here:

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

The HMPC welcomed also the participation of 2 experts from the Indian ministry of AYUSH (Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy) at the Committee and the Monograph and List Working Party (MLWP) September meeting.

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 Curcumae longae rhizoma (by consensus)
- Revised EU herbal monograph on Sennae folium (by consensus)
- Revised EU herbal monograph on Sennae fructus (by consensus)

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

Regulatory/Scientific Guidance

Upon recommendation from the MLWP and coordination with the Safety Working Party and CMDh, the HMPC adopted after public consultation the following **final revised guideline**:

- Guideline on non-clinical documentation in applications for marketing authorisation/registration of well-established and traditional herbal medicinal products (EMEA/HMPC/32116/2005 Rev.1)

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The guideline together with the Overview of comments received during public consultation 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 Drafting Group (Q DG)

The HMPC noted the report on the Q DG meeting held on 06 September 2018.

The progress with drafting activities was reported including items in coordination with the European Commission, EDQM and also with the Quality WP such as herbal-specific comments on a planned Q&A 'How to use a CEP'.

In relation to the ICH-Q3D guideline for elemental impurities (herbal products outside the scope) an interim clarification for addition to the herbal quality Q&A document EMA/HMPC/41500/2010 on the Agency website was agreed as well as consideration for herbal quality and specification guidelines currently under revision.

HMPC noted that because of the Agency's move no Q DG meetings will take place during BCP phase 3 and development of guidelines is temporarily suspended. 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.

Organisational Matters Drafting Group (ORGAM DG)

The HMPC noted a report on the ORGAM DG meeting held on 04 September 2018.

The ORGAM DG Chair reported on the progress with regard to three procedural topics including a revision of the 'Procedure on management of proposals submitted by interested parties' (EMA/HMPC/328575/2007).

Upon proposal by ORGAM DG, the HMPC adopted the revised:

- Template for information exchange for the preparation of the assessment report supporting the establishment of European Union monographs and European Union list entries (EMA/HMPC/137093/2006 rev.2)

The revised template will be published here:

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

HMPC noted the intention by ORGAM DG to develop a specific template for combinations in the future.

HMPC noted that because of the Agency's move no ORGAM DG meetings will take place during BCP phase 3 and development of guidance is temporarily suspended. 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..

Report from the September 2018 meeting of the Working Party on European Union Monographs and List (MLWP)

The MLWP held its 74th meeting at the European Medicines Agency on 25-27 September 2018.

New monographs - finalisation

After public consultation, the working party finalised the assessment of Fragariae folium, Malvae flos and Malvae folium for peer review and transfer to the HMPC in November 2018 for possible final adoption.

New monographs - drafts

The MLWP continued its assessment of Vaccinii macrocarpi fructus and had first discussions on Herniariae herba, Menyanthes folium and Verbenae citriodorae folium.

Monograph revisions - finalisation

After public consultation, the working party finalised the revision of the documents on Gentianae radix and Rusci aculeatae rhizoma for peer review and transfer to the HMPC in November 2018 for possible final adoption.

MLWP further discussed finalisation of the revised documents on Valerianae radix/Lupuli flos and had a first discussion on Hyperici herba after public consultation.

Monograph revisions - drafts

The MLWP continued the revision of documents for Tanaceti parthenii herba and on Hippocastani semen.

Monograph systematic review

The MLWP agreed after systematic review of newly available data that monograph revision is required for Millefolii herba and Echinaceae angustifoliae radix. The Review outcome reports will be transferred to the HMPC for possible adoption in November 2018.

The MLWP agreed after systematic review of newly available data that **no** monograph revision is required for Millefolii flos, Phaseoli fructus (sine semine), Bursae pastoris herba, Leonuri cardiacae herba and Tormentillae rhizoma. The Review outcome reports as basis for addenda to the existing assessment report will be transferred to the HMPC for possible adoption in January 2019.

The working party did not yet come to a conclusion on the rapporteurs' proposal after review for Hamamelidis cortex, Hamamelidis folium, Hamamelidis folium et cortex aut ramunculus destillatum, Solidaginis virgaureae herba and Quercus cortex - requiring a second discussion.

Following public calls for data and review of available information for substances with previously insufficient data for monograph establishment (public statements) the working party concluded that currently no new data are available to propose the re-assessment of Adhatodae vasicae folium, Andrographidis paniculatae folium and Withaniae somniferae radix. The working party did not yet come to a conclusion after data review for Centellae asiaticae herba - requiring a second discussion.

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. A report on the hearing will be published here:

https://www.ema.europa.eu/en/committees/working-parties-other-groups/hmpc/interested-parties-hmpc

MLWP noted that because of the Agency's move no MLWP meetings will take place during BCP phase 3 and development of guidance with few exceptions is temporarily suspended. 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.

Contact for further information

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