



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 January 2018
EMA/HMPC/74171/2018 Corr.¹
Committee on Herbal Medicinal Products (HMPC)

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

The 80th HMPC meeting, held on 29-30 January 2018

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 80th meeting of the Committee.

The committee welcomed Erika Svedlund as new member from Sweden and Katarzyna Tomaszewska as new Polish alternate.

Revised European Union herbal monographs

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

- Revised EU herbal monograph on *Uvae ursi folium* (by consensus)

The revised monograph together with the HMPC opinion and supporting documents including the Overview of comments received during public consultation 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

After systematic review the following **draft revised** EU herbal monographs have been adopted for **public consultation until 31 May 2018**:

- Draft revised EU herbal monograph on *Rusci aculeati rhizoma*
- Draft revised EU herbal monograph (TU) on *Hyperici herba*

Draft revised documents will be published here:

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

¹ Corrections regarding membership and addition of more detailed information regarding calls for data.



Other

Call for data

Upon validation and suggestion by the MLWP (following a call for proposals for HMPC assessment in September 2017), the HMPC put the following new herbal substance on their work programme to start the assessment work towards establishment of EU herbal monographs:

- Herniariae herba
- Verbenae citriodoraefolium (Aloysiae folium, Lippiae citriodoraefolium)
- Menyanthidis trifoliataefolium
- Salviae miltiorrhizae radix et rhizoma

The HMPC confirmed 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:

- Echinaceae angustifoliae radix
- Filipendulae ulmariae flos
- Filipendulae ulmariae herba
- Hamamelidis cortex
- Hamamelidis folium
- Hamamelidis folium et cortex aut ramunculus destillatum
- Leonuri cardiacaeherba
- Mate folium
- Phaseoli fructus (sine semine)
- Quercus cortex
- Solidaginis virgaureaeherba
- Tormentillae rhizoma

In addition, the HMPC decided to review the availability of new data for the following substances previously assessed by the HMPC not leading to an EU herbal monograph:

- Adhatoda vasica folium
- Andrographidis paniculataefolium
- Angelicae sinensis radix
- Centellae asiaticae herba
- Withaniae somniferae radix

Calls for data will be published at the EMA website in three waves until end of April under the above mentioned substances (consultation) 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

Work Plan 2018

The HMPC discussed and adopted their work plan for 2018. 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

Quality Drafting Group (Q DG)

The HMPC noted the reports on the Q DG meetings held on 07 December (TC) and 14-15 December (face-to-face) 2017.

The progress with drafting activities was reported as well as other topics discussed including the revision of the guideline on specifications.

Upon recommendation by the drafting group, the committee adopted the Quality DG Work Plan 2018.

The Work Plan 2018 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 22 February 2018.

Organisational Matters Drafting Group (ORGAM DG)

The HMPC noted a report on the ORGAM DG meeting held on 05 December 2017.

Upon recommendation by the drafting group, the committee adopted the ORGAM DG Work Plan 2018.

The Work Plan 2018 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 20 February 2018.

Working Party on European Union Monographs and List (MLWP)

The HMPC noted a report on the MLWP meeting held on 21-23 November 2017.

Upon recommendation by the working party, the committee adopted the MLWP work plan 2018.

The HMPC adopted a revised mandate, objectives and rules of procedure. The revision clarifies that the mandate of the chair and vice-chair can be renewed once. This change has been performed to bring the MLWP mandate in line with other EMA working parties' mandates.

The work plan 2018 and the revised mandate/RoP will be published here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/HMPC/people_listing_000046.jsp&mid=Wc0b01ac0580028e98

The HMPC elected Dr. Ioanna B. Chinou as MLWP chair for another 3-year mandate starting 30 January 2018.

The HMPC appointed Erika Svedlund and Barbara Tóth as new members to the MLWP.

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

The MLWP held its 71st meeting at the European Medicines Agency on 30 January – 01 February 2018.

New monographs - drafts

MLWP agreed to the draft revised documents on *Fragariae folium*, *Malvae folium*, and *Malvae sylvestris flos* for peer review and transfer to the HMPC in March 2018 for possible release for public consultation.

The working party continued its assessment of *Vaccinii macrocarpi fructus*, *Species sedativae* and *Species amarae*.

Monograph revisions - finalisation

After public consultation, the working party finalised the revision of the documents on *Cimicifugae rhizoma* for peer review and transfer to the HMPC in March 2018 for possible final adoption.

The MLWP re-discussed the revision of the monograph on *Pelargonii radix* and general questions linked to the clinical assessment.

For the following substances the MLWP considered the draft revisions as finalised and due to the minor changes in the revised monographs no public consultation necessary: *Agni casti fructus*, *Calendulae flos*, *Cynarae folium*, *Menthae piperitae aetheroleum*, *Sambuci flos* and *Verbasci flos*. Documents are transferred for peer review and to the HMPC for possible final adoption in March 2018.

Monograph revisions - drafts

MLWP agreed to the draft revised documents on *Gentianae radix* for peer review and transfer to the HMPC in March 2018 for possible release for public consultation.

The MLWP continued the revision of *Oenothera biennis*.

Monograph systematic review

The MLWP agreed after systematic review that no revision of the monograph is required for *Polypodii rhizome*, *Avenae herba* and *Avenae fructus*. Respective proposals for an addendum to the existing assessment report will be transferred to the HMPC for possible adoption in March 2018.

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