



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 74th HMPC meeting, held on 30-31 January 2017

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 74th meeting of the Committee.

The Committee elected Emiel van Galen (NL) as the new Vice-Chair with a 3-year mandate that started on 30 January 2017.

Final European Union herbal monographs

Upon recommendation from the MLWP, the HMPC adopted the following newly established **final** EU herbal monographs and supporting documents:

- EU herbal monograph on Lecithinum ex soya, by majority vote
- EU herbal monograph on Soiae oleum raffinatum, by majority vote

The 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

Revised European Union herbal monographs

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

- EU herbal monograph on Oleae folium, by majority vote
- EU herbal monograph on Salicis cortex, by majority vote

Only minor changes were introduced in 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 **31 May 2017**:

- Draft EU herbal monograph on Menthae piperitae folium
- Draft EU herbal monograph on Ribis nigri 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 statements

Upon recommendation from the MLWP, the HMPC adopted the following **final** public statements and supporting documents:

- Final public statement on Paeoniae radix, alba
- Final public statement on Paeoniae radix, rubra

No relevant new data and comments were received during public consultation that would allow the establishment of EU herbal monographs. Final public statements and supporting documents will be published here:

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

The HMPC further adopted the following **draft** public statement for 3 months public consultation **until 31 May 2017**:

- Draft public statement on Glycini semen

The document explains the reasons why the HMPC is of the opinion that a European Union herbal monograph on Glycini semen 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 and interested parties are welcome to submit new data:

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

Other

Call for scientific data

According a MLWP proposal the HMPC agreed to start assessment work and initiate a call for new scientific data supporting the assessment of

- Herbal tea combinations traditionally used for loss of appetite
- Herbal tea combinations traditionally used for digestive disorders
- Herbal tea combinations traditionally used for nervous tensions and to aid sleep

The call with a deadline for submission **by 31 May 2017** can be found on the European Medicines Agency's website

at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000214.jsp&mid=WC0b01ac0580033a9c

HMPC work plan

The HMPC adopted its work plan 2017 which will be published here:

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

Annexed to the HMPC work plan the adopted MLWP work plan provides more details on assessment work scheduled for 2017 and will also be published here:

Quality Drafting Group (Q DG)

The HMPC noted a report on the Q DG meeting held on 07 December 2016.

The drafting group started the review of the herbal specification guideline in line with the quality guideline revision as well as of the reflection paper on markers. Furthermore coordination topics with EDQM (pyrrolizidine alkaloids, assay requirements), documents under development at MLWP (peppermint oil monograph) and at the Quality WP as well as questions from NCAs with potential for Q&A development were discussed.

The next meeting of the Q DG will be held on 23/24 February 2017.

Organisational Matters Drafting Group (ORGAM DG)

The HMPC noted a report on the DG ORGAM meeting held on 14 December 2016.

The DG had further progressed with a new 'Procedure for the review and revision of EU herbal monographs and List entries' for agreement by MLWP and HMPC.

The next meeting of the DG ORGAM (scheduled 21 February 2016) will be postponed until clarification of chairmanship, membership and mandate at the HMPC March meeting.

Report from the February 2017 meeting of the Working Party on European Union Monographs and List (MLWP)

The MLWP held its 65th meeting at the European Medicines Agency on 01-02 February 2017.

New monographs - finalisation

Following comments received after public consultation, the MLWP discussed and endorsed the final documents on *Allii sativi bulbosus* and 'Species diureticae' for peer review and transfer to the HMPC for possible final adoption in March 2017.

New monographs - drafts

The working party continued its assessment of *Fragariae folium* and had a first discussion on the possibility to establish a monograph for *Vaccinii macrocarpi fructus*.

Monograph review and revisions

The MLWP discussed and endorsed the revised documents for *Meliloti herba*, *Sennae folium*, *Sennae fructus* and *Uvae ursi folium* for peer review and possible transfer to the HMPC in March 2017 for release for public consultation.

The MLWP continued the systematic review of *Sambuci flos*, *Verbasci flos*, *Frangulae cortex*, *Rhamni purshianae cortex*, *Rhei radix* and had first discussions on the need for revision of monographs on *Hyperici herba*, *Cimicifugae rhizome*, *Cynarae folium*, *Tanacetii parthenii herba*, *Thymi aetheroleum*, and *Valerianae radix/Lupuli flos*.

Upon request by the HMPC the MLWP members re-discussed the revised documents of *Menthae piperitae aetheroleum* for final discussion and conclusion at the working party in March 2017.

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