



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 November 2015
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Committee on Herbal Medicinal Products (HMPC)

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

The 67th HMPC meeting, held on 23-24 November 2015

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 67th meeting of the Committee including Rugile Pilviniene as new member for Lithuania and Cristina Martinez Garcia as new alternate for Spain.

The current composition of the HMPC can be found here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/2010/02/people_listing_000006.jsp&mid=WC0b01ac0580028e7e

Final European Union herbal monographs

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

- EU herbal monograph on Epilobii herba, by consensus
- EU herbal monograph on Sabalis serrulatae fructus, 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 the following **final** revised EU herbal monographs and supporting documents:

- EU herbal monograph on Centaurii herba, by consensus
- EU herbal monograph on Hederae helices folium, by majority vote

The Committee further adopted the following **draft** revised EU herbal monograph and supporting documents for 3 months public consultation until **15 March 2016**:

- EU herbal monograph on Althaeae radix



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

Draft European Union herbal monograph

Upon recommendation from the MLWP, the HMPC adopted the following **draft** EU herbal monograph for public consultation until **15 March 2016**:

- Draft EU herbal monograph on Pruni africanae cortex

The draft monograph 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 statement and supporting documents:

- Public statement on Uncariaea tomentosea cortex, by consensus

No comments or new data had been received during public consultation. Therefore the HMPC considered available data as still insufficient to establish an EU herbal monograph.

The HMPC adopted further the following **draft** public statements and supporting documents for 3 months public consultation until **15 March 2016**:

- Public statement on Balsamum peruvianum
- Public statement on Salviae fruticosae folium

The reasons why EU herbal monographs cannot currently be drafted are explained and interested parties are invited to submit additional data to allow the continuation of assessment towards monograph establishment.

The final and draft public statements together with 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

Other

Call for scientific data (first assessment)

Upon recommendation by the MLWP the Committee agreed to the assessment of

- herbal tea combinations traditionally used in the therapeutic area 'urinary tract disorders' ('*Species diureticae*')

The call supports a MLWP pilot project agreed by the HMPC with the intention of developing EU herbal monographs on herbal tea combinations that are used in comparable indications with variable combination partners.

Call for scientific data (systematic monograph review)

According to the decision at the HMPC September meeting a second wave of calls for data supporting the systematic review is launched for:

- *Achillea millefolium* L., flos
- *Achillea millefolium* L., herba
- *Cynara scolymus* L., folium
- *Echinacea pallida* (Nutt.) Nutt., radix
- *Olea europaea* L., folium
- *Valeriana officinalis* L., radix/ *Humulus lupulus* L., flos

All Calls for submission of scientific data with a deadline for submission by **15 March 2016** 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

Monograph minor corrections

The Committee agreed to minor corrections to two finalised monographs as requested by the Rapporteurs:

- EU herbal monograph on *Vitis viniferae folium* (correction ATC code)
- EU herbal monograph on *Echinaceae purpureae herba* (correction single dose)

The corrected monographs 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

HMPC work plan 2016

The Committee discussed and adopted the work plan 2016 including the annexed work plans for its subgroups (Monograph and List Working Party, Drafting Groups on Quality and Organisational Matters).

The work plan will be made available on the European Medicines Agency's website at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000122.jsp&mid=WC0b01ac0580028e7d

Concerns on health claims for food supplements containing hydroxyanthracene laxatives

The HMPC noted ongoing discussion at the European Commission (working group on health claims) regarding an Art. 13(5) of Regulation (EC) No 1924/2006 health claim for food supplements containing hydroxyanthracene laxatives. HMPC participants were concerned about potential usage of such products in the food area because of risks to public health. It was agreed to communicate these serious concerns at Member State level and also via the Eur. Com. representative at the HMPC.

HMPC assessors training 7-8 December 2015

The HMPC under lead of its quality drafting group will give a training for assessors from national competent authorities on the assessment of the CTD module 3 for herbal medicinal products. The aim is to achieve harmonisation between assessors regarding the chemical-pharmaceutical quality

documentation in order to streamline discussions in MRP and DCP procedures. The training agenda was adopted by the HMPC and includes three sessions: I) current Ph. Eur. related topics (reference substances and certificates of suitability for herbal products), II) specific herbal assessment challenges (skip testing impurities, GMP/GACP/import provisions for herbal starting materials, assay requirements), III) Appendix 2 of the Guideline on the CTD for HMP/THMP - the mock-up module 3.

Visit of observers from the Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)

Dr Manoj Nesari from the Indian Ministry of AYUSH and Prof. V.K. Joshi, chair of the Ayurvedic (Indian traditional medicine) Pharmacopoeia of India Committee, visited the EMA from 23 to 26 November 2015. They observed the HMPC meeting and the MLWP meeting. This visit aimed at increasing EU-Indian mutual understanding on matters related to Indian traditional medicine and to provide the visitors with an insight of the HMPC's work, in particular of the kind of data required by the HMPC for its assessment work and of how HMPC herbal monographs are discussed and developed. This visit is a practical follow-up to the EU-India Joint WG on Pharmaceuticals, Biotechnology and Medical devices, which took place earlier this year.

Drafting Group on Quality (DG Q)

The HMPC heard a report on the DG Q meeting (virtual) held on 15 October 2015.

The DG had finalised the draft work plan 2016 and progressed with the preparation of the HMPC assessors training in December and a draft reflection paper on the use of new analytical methods in herbal quality documentation. Primary discussions were held on Revision 3 of the 'Guideline on quality of HMP/THMP', implications for individual applications of using certificates of suitability (CEPs) for herbal active substances, and comments received on the revised herbal CTD guideline including the new Appendix 2 'mock-up module 3'.

The next meeting of the DG Q (face to face) will be held on 8-9 December 2015.

Drafting Group on Organisational matters (DG ORGAM)

The HMPC heard a report on the DG ORGAM meeting (virtual) held on 13 October 2015.

The DG had discussed comments received on the revised CTD guideline for THMP (pre-clinical and clinical part) and reviewed the 2016 work plan.

The next meeting of the DG ORGAM is scheduled for 10 December 2015.

Report from the November 2015 meeting of the Working Party on European Union Monographs and List (MLWP)

The MLWP held its 58th meeting at the European Medicines Agency on 24–26 November 2015.

Monograph revisions

The working party discussed and endorsed the revised documents after public consultation on *Equiseti herba*, *Valerianae radix* and *Valerianae aetheroleum* for peer review and transfer to the HMPC for final adoption.

MLWP further agreed to draft revised documents on *Salviae officinalis folium*, *Salviae officinalis aetheroleum* and *Harpagophyti radix* for possible release for public consultation at the HMPC 2016 February meeting.

The MLWP further discussed the systematic review and revision of *Aloe* and *Meliloti herba*.

Monograph finalisation

Upon request by the Rapporteur and Peer reviewer, the working party re-discussed and finalised the documents after public consultation on *Crataegi folium cum flore* for possible final adoption at the HMPC February 2016 meeting.

Following public consultation, the MLWP discussed and endorsed the documents on *Mastix*, *Ricini oleum*, *Sideritis herba*, and *Silybi mariani fructus* for peer review and transfer to the Committee for possible final adoption in February 2016.

Monograph drafts

The MLWP discussed and endorsed the draft documents on *Paeoniae radix (rubra and alba)*, *Cisticri folium* and *Origanum majoranae herba* for transfer to the HMPC for possible release in February 2016 for public consultation.

The working party continued its assessment of *Fragariae folium*, *Saccharomyces cerevisiae* and *Glycine max*.

The next meeting of the MLWP is scheduled for 2-4 February 2016.

Contact for further information

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