



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/HMPC/315739/2015 Rev. 1
Committee on Herbal Medicinal Products (HMPC)

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

The 64th HMPC meeting, held on 04-05 May 2015

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 64th meeting of the Committee and announced Marcel Bruch as new member for Luxembourg.

Final European Union herbal monographs

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

- European Union herbal monograph on Capsici fructus, by majority vote
- European Union herbal monograph on Pilosellae herba cum radice, by majority vote
- European Union herbal monograph on Symphyti radix, by consensus

The monographs together with the 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

Guidance documents

Upon recommendation by the Drafting Group on Quality after review of comments during public consultation the Committee adopted the

- Reflection paper on microbiological aspects of herbal medicinal products and traditional herbal medicinal products (EMA/HMPC/95714/2013)

The final reflection paper together with the Overview of comments will be published on the European Medicines Agency's website at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000365.jsp&mid=WC0b01ac0580029569



Other

Prioritisation of substances for assessment

Upon request by the MLWP during the revision of the monograph for Valerianae radix, the Committee agreed to split the monograph according to standard practice and continue with revised monographs for 'radix' and 'aetheroleum'.

Following the outcome of a legal case in a Member State, the HMPC was asked to prioritise the assessment of Piperis methystici rhizoma. The HMPC agreed to the request as it recognised the need to establish a harmonised European opinion on safety and efficacy. The MLWP was asked to assign Rapporteur and Peer reviewer.

The HMPC inventory and priority list will be updated accordingly. Both documents can be found here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000208.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05800240cf

Call for scientific data

Calls for submission of scientific data with a deadline for submission by **31 August 2015** will be initiated to support the first assessment of

- Piperis methystici rhizoma

and the revision of

- Salicis cortex

Calls 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

Drafting Group on Quality (DG Q)

The HMPC heard a report on the DG Q meeting held on 26 March 2015.

During the meeting the group finalised the reflection paper on microbiological aspects of HMP/THMP (see above) and suggested to further develop specific guidance as Q&A on microbiological aspects to be included in document EMEA/HMPC/41500/2010. The DG further reviewed the need to update and revise the main herbal quality guidelines and had a first discussion on a Reflection paper on the use of new analytical methods in line with the DG Q work plan.

The HMPC adopted for public consultation until **31 August 2015**:

- Concept paper on Revision 3 of the 'Guideline on quality of herbal medicinal products/traditional herbal medicinal products'
- Concept paper on Revision 3 of the 'Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and HMP/THMPs''

After coordination with QWP/CHMP and CVMP the concept papers will be published here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000365.jsp&mid=WC0b01ac0580029569

No need for a formal revision was currently detected for the 'Guideline on the quality of combination herbal medicinal products/ traditional herbal medicinal products'.

The next meeting of the Q DG will be held on 21 May 2015.

Drafting Group on Organisational matters (DG ORGAM)

The HMPC heard a report on the DG ORGAM meeting held on 24 March 2015.

The drafting group reviewed in detail the suitability of the standard QRD template (SmPC, labelling and package leaflet) used in mutual recognition and decentralised procedures regarding specifics for (traditional) herbal medicinal products. A proposal for discussion with the QRD group as regards to these specific products is currently under preparation and expected to be presented to the HMPC in July.

The next meeting of the DG ORGAM will be held on 19 May 2015.

Report from the March 2015 Working Party on European Union Monographs and List (MLWP)

The MLWP held its 55th meeting at the European Medicines Agency on 05–07 May 2015.

Monograph revisions

The working party discussed and endorsed the revised documents on Centaurii herba for transfer to the Committee for final adoption in July 2015 and the revised documents on Valerianae radix, Valerianae aetheroleum and Equiseti herba for transfer to the Committee for adoption in July 2015 for public consultation.

The MLWP further discussed draft revised monographs on Salviae officinalis folium, while the revision of Menthae piperitae aetheroleum and Menthae piperitae folium is currently on hold awaiting the outcome of the coordinated assessment as regards the Public statement on the use of herbal medicinal products containing pulegone/menthofuran.

Monograph finalisation

The working party discussed and endorsed the documents on Matricariae flos, Matricariae aetheroleum, Carvi fructus and Carvi aetheroleum for transfer to the Committee for final adoption in July 2015.

A first discussion took place on comments received during public consultation for the draft monograph on Sabalis serrulatae fructus.

Monograph drafts

Upon request by the HMPC, the MLWP re-discussed and endorsed the draft monograph on Ricini oleum for transfer to the HMPC for possible release in July 2015 for public consultation.

The MLWP finalised the assessment of Silybi marianae fructus, Pistaciae lentiscus resinum (mastix), and Sideritis herba for transfer of documents and final decision by the HMPC for possible release in July 2015 for public consultation.

The working party continued its assessment of Balsamum peruvianum, Origani majoranae herba, Cisti cretici folium, Helichrysi flos, and Polygoni avicularis herba, and had first discussions on the assessment of Salviae fruticosae folium.

The next meeting of the MLWP is scheduled for 7–9 July 2015.

Hearing with association representing the self-medication industry

The MLWP held a hearing with representatives from AESGP on 05 May. AESGP shared with the working party experiences in 2014 of companies using EU herbal monographs for applications at national level. Several topics related to the establishment of monographs/ list entries were discussed including the status of first assessment for important herbal substances, the timelines for monograph revision, and the possibility for development of a list entry following publication of genotoxicity data by companies. Furthermore scope and procedural aspects of guidelines and guidance documents currently under development and of major interest for the herbal industry were clarified: the revision of the guideline on 'Excipients in the label and package leaflet' as regards ethanol, the planned establishment of standards for herbal combinations including herbal teas, the relevance of the mock-up Module 3 as Appendix to the Guideline on the use of the CTD format currently under consultation, the procedural steps for guidance development (other than monographs/ list entries) and the reflection paper on microbiological aspects for herbal medicinal products.

A more detailed report on the matters raised at the hearing will be available at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000223.jsp&mid=WC0b01ac058003529f

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