



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 July 2018
EMA/HMPC/510266/2018
Committee on Herbal Medicinal Products (HMPC)

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

The 83rd HMPC meeting, held on 23-24 July 2018

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 83rd meeting of the Committee and announced changes to the composition: Sue Harris retired as alternate member for the UK, Ligia Elena Dutu new alternate member for Romania.

Monograph review

Upon recommendation from the Rapporteur and MLWP, the HMPC decided after systematic review according to procedure EMA/HMPC/124695/2011 Rev. 2 that no revision is required because no new data of relevance were detected that would change the content of the:

- EU herbal monograph on Myrrha (*Commiphora molmol*)

The review report will be published on the EMA website as Addendum to the existing Assessment report at:

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

Upon recommendation from the Rapporteur and MLWP, the HMPC decided after systematic review that new data of relevance were detected that may change the content of the:

- EU herbal monograph on *Trigonellae foenugraeci semen*

The Rapporteur and MLWP were asked to start the revision of monograph and supporting documents. Once agreed by the HMPC, draft revised documents will be released for public consultation and announced in the meeting report.

For general information on the status of HMPC assessment work please check at following documents available here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001149.jsp&mid=WC0b01ac0580033a9d

- Inventory of herbal substances for assessment – proposals for assessment (EMA/HMPC/494079/2007)
- Overview of assessment work (Priority list) (EMA/HMPC/278067/2006)



- HMPC monographs: Overview of recommendations for the uses of herbal medicinal products in the paediatric population (EMA/HMPC/228356/2012)

Quality Drafting Group (Q DG)

The HMPC noted the report on the Q DG meeting held on 21 June 2018.

The progress with drafting activities was reported.

The next meeting of the Q DG will be held on 06 September 2018.

The HMPC agreed to extend the deadline for comments to **30 November 2018** for the

- Concept paper on the development of a reflection paper on new analytical methods/technologies in the quality control of herbal medicinal products (EMA/HMPC/541422/2017)

The HMPC invites again to submit data in view of scientific/technological developments and emerging trends. Cooperation is sought first via examples and comments on methods/technologies used in quality control of herbal substances/preparations. Based on the information provided the HMPC aims to explore novel opportunities via a reflection paper to stimulate and further foster the discussion and dialogue on the subject. The Concept paper is published here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/md_herbal_med_products/general_content_001886.jsp&mid=WC0b01ac0580033a9b

HMPC, QWP, CHMP and CVMP adopted at their latest meetings draft revision 3 of following two guidelines for public consultation until **30 November 2018**:

- Quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/201116/2005 Rev. 3)
- Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/162241/2005 Rev. 3)

The draft revised guidelines will be available here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000724.jsp&mid=WC0b01ac0580033a9b

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000725.jsp&mid=WC0b01ac0580033a9b

Organisational Matters Drafting Group (ORGAM DG)

The HMPC noted a report on the ORGAM DG meeting held on 18 June 2018.

The ORGAM DG Chair reported on the status of development and revision of procedural guidance and templates.

The next meeting of the DG ORGAM is scheduled for 04 September 2018.

The HMPC adopted after public consultation Revision 2 of the:

- Procedure for the review and revision of European Union herbal monographs and list entries (EMA/HMPC/124695/2011 Rev. 2)

The modified procedure including an annexed template of a Review outcome report and the Overview of comments received during public consultation will be published here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001149.jsp&mid=WC0b01ac0580033a9d

The procedure established a 3-step sequence in order to update documents if required. After the call for new data and review, an informed decision on the need is taken before the actual revision of monograph and supporting documents is started. If no new relevant data are identified, no revision is initiated and an Addendum to the existing Assessment report will be published. If relevant data are detected, the revision of monograph and supporting documents according to latest templates will be initiated followed by public consultation, final adoption and superseding of previous documents by the new opinion.

Contact for further information

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